

Research Article

Utilization Patterns and Safety Profile of Immunosuppressive Regimen among Kidney Transplant Recipients: A Descriptive Pharmacoepidemiological Study from a Tertiary Hospital in Indonesia

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Abstract

Kidney transplantation is the preferred therapy for end-stage kidney disease (ESKD), but long-term success is greatly influenced by the selection and safety of immunosuppressants. Local data on prescribing patterns and the incidence of drug side effects in Indonesia are still limited. Therefore, this study aims to evaluate induction therapy patterns, immunosuppressant maintenance, and the incidence of drug-related side effects among kidney transplant recipients at a tertiary hospital in Yogyakarta, Indonesia. Materials and methods: This was a retrospective cohort study of recipients aged ≥ 18 years who underwent outpatient follow-up



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between January 2017 and July 2024. Complete medical records were analyzed descriptively, with variables including recipient and donor characteristics, induction and maintenance immunosuppressive regimens, and adverse drug reactions such as infections and non-infections during the 12 months post-transplantation. A total of 57 among the 87 recipients met the inclusion criteria, comprising 70.2% male, 56.1% aged 18-39 years, 98.2% with a history of dialysis, 77.2% with hypertension, and all living donors. Basiliximab induction was administered to all recipients (100%) in combination with triple therapy of tacrolimus, mycophenolate sodium (MPS) or mycophenolate mofetil (MMF) and steroids. Maintenance therapy was predominantly tacrolimus, MPS, steroids 43/57 (75.4%), and tacrolimus, MMF, steroids 14/57 (24.6%). The most common adverse drug events were urinary tract infections (31.6%), followed by cytomegalovirus (CMV, 5.3%) and herpes zoster (3.5%). Non-infectious events included diarrhea (7%), tremor (3.5%), dyslipidemia (3.5%), and new-onset diabetes after transplantation (NODAT) (3.5%). Basiliximab induction and tacrolimus-mycophenolate-steroid maintenance therapy were the predominant immunosuppressive regimens and were associated with an acceptable first-year safety profile. Close monitoring for opportunistic infections, optimization of tacrolimus levels, and structured pharmacovigilance are required to maintain graft function.

Keywords

Adverse drug reactions; immunosuppressants; kidney transplantation; maintenance therapy; prescribing patterns

1. Introduction

End-stage kidney disease (ESKD) is a global health problem with an increasing incidence. Estimation shows that around 5 million people worldwide will require renal replacement therapy due to ESKD by 2023 [1]. Kidney transplants have been performed in more than 110 countries, with 12 new kidney recipients per 100,000 population. In Indonesia, 629 kidney transplants have been successfully performed in 12 transplant centers [2-4]. Kidney transplantation not only reduces the risk of complications but also improves the quality of life of recipients [5-7]. This signifies that many patients with ESKD require renal replacement therapy to survive.

The success of kidney transplantation is highly dependent on the administration of post-operative immunosuppressive therapy to prevent rejection of the donor organ. This immunosuppressive therapy needs to be taken for life by nearly all kidney transplant recipients [8]. A standard immunosuppressive regimen generally consists of a combination of three types of drugs (e.g., calcineurin inhibitors, corticosteroids, and antiproliferatives) that suppress the immune response [8, 9]. Post-transplant immunosuppressant management aims to improve clinical outcomes and minimize side effects [10-12]. In other words, immunosuppressive therapy is an essential component for ensuring graft survival and the long-term success of kidney transplantation.

Chronic use of immunosuppressants is not without significant side effects, as long-term suppression of the immune system makes transplant recipients susceptible to opportunistic infections and malignancies [13]. Various immunosuppressive drugs can cause metabolic and organ

complications. For example, long-term use of corticosteroids contributes to hypertension, hyperglycemia, dyslipidemia, osteoporosis, fluid retention, and weight gain. Calcineurin inhibitors (cyclosporine, tacrolimus) and mTOR inhibitors trigger dyslipidemia and have nephrotoxic effects [14]. Tacrolimus consumption is known to be associated with an increased risk of new-onset diabetes after transplantation (NODAT), and both classes of calcineurin inhibitors (tacrolimus and cyclosporine) can cause complications such as hyperkalemia, hypomagnesemia, and an increased risk of chronic kidney disease due to chronic graft nephropathy [14]. The long-term risks of immunosuppressive therapy include increased cardiovascular morbidity in transplant recipients triggered by a combination of factors such as hypertension, diabetes, and post-transplant dyslipidemia [13, 14]. Infectious complications are the leading cause of morbidity in the first year after transplantation, with nearly 80% of kidney transplant recipients reported to experience an episode of infection during the first year. Urinary tract infections are the most common infectious complication, with reported first-year incidence ranging from approximately 7% to 80%. In addition, cytomegalovirus infection remains a clinically significant opportunistic infection following transplantation [15-17]. Close monitoring and comprehensive management are required to balance the benefits of preventing rejection with minimizing the adverse effects of long-term immunosuppression.

Despite these clinical challenges, evidence describing real-world immunosuppressive prescribing patterns and associated adverse drug reactions in Indonesia remains fragmented and limited. Existing studies are often restricted by small sample sizes, focus primarily on clinical outcomes rather than pharmacoepidemiological patterns, or lack systematic evaluation of adverse drug reactions [18-20]. Moreover, data from high-volume tertiary referral transplant centers, where case complexity and treatment variability are typically greater, are still scarce. In particular, no comprehensive pharmacoepidemiological assessment integrating drug utilization patterns and adverse event profiles has been clearly documented in a major referral setting such as a tertiary hospital in Indonesia. This evidence gap is critical, as local prescribing patterns, patient characteristics, and healthcare system factors may substantially differ from those reported in international studies, thereby limiting the applicability of external evidence to the Indonesian context. Addressing this gap is essential for developing context-specific strategies to optimize immunosuppressive therapy and improve patient safety. To the best of our knowledge, there are no studies that specifically describe the induction and maintenance immunosuppressive regimens along with the profile of Adverse drug reactions in the first year post-transplantation at a Tertiary Hospital in Yogyakarta, Indonesia, one of the referral centers for transplantation in Indonesia. The results are expected to provide empirical data to develop strategies for the effective and safe administration of immunosuppressants in the kidney transplant recipient population in Indonesia.

2. Materials and Methods

2.1 Study Design, Setting, and Participants

This study was conducted after obtaining approval from the Ethics Committee of the Faculty of Medicine, Universitas Gadjah Mada, with number KE/FK/1055/EC/2025, and the Department of Education and Research of Dr. Sardjito General Hospital, Yogyakarta, with number DP.04.03./D.XI.2/21392/2025. A total of 87 kidney transplant recipients were initially identified. Patients were eligible if they were ≥ 18 years old, received kidney transplantation from living donors,

were on maintenance immunosuppressive therapy, attended routine follow-up at the Integrated Kidney Unit, and had complete medical records. At our center, tacrolimus is routinely used as the primary regimen for post-transplant immunosuppression; therefore, this criterion reflects the standard clinical practice rather than a study-specific selection. Patients who underwent multi-organ transplantation or had undergone transplantation more than twice were excluded. Patients who experienced post-transplant mortality were excluded due to incomplete treatment exposure and monitoring data, which precluded consistent evaluation of immunosuppressive prescribing patterns. Recipients were followed during the early post-transplant period, with an observation window ranging from 1 to 12 months after transplantation, depending on data availability and completeness of follow-up records. This period was selected to capture early immunosuppressive use patterns and the occurrence of adverse drug reactions, which are more frequently observed during the initial post-transplant phase.

A retrospective cohort study was conducted on recipients from January 2017 to July 2024 at the Integrated Kidney Unit of Tertiary Hospital in Yogyakarta, Indonesia. Data collected from medical records included demographic characteristics, donor profiles, clinical parameters, immunosuppressive regimens (induction and maintenance), and documented adverse drug reactions. Although tacrolimus trough levels and kidney function tests were routinely monitored as part of clinical care, only data relevant to the study objectives were included in the present analysis. Adverse drug reactions were defined as documented undesirable infectious and non-infectious clinical events recorded in the medical records during the first 1-12 months post-transplantation, as assessed by the treating clinicians and considered related to maintenance immunosuppressive therapy in the recipients. Immunosuppressive therapy was administered according to institutional protocols, with possible adjustments based on individual clinical conditions.

2.1.1 Induction Regimen

The standard induction regimen generally consisted of basiliximab 20 mg IV administered intravenously before and after 4 days of transplantation, in combination with methylprednisolone 125 mg IV. However, administration may vary depending on clinical considerations and the physician's discretion. All transplantations in this study involved living donors.

2.1.2 Maintenance Regimen

Recipients engaged in kidney transplantation were given the following maintenance therapy.

Main regimen:

- Tacrolimus capsules 1-7 mg twice daily (BD) + MMF capsules 500 mg twice daily (BD) + methylprednisolone tablets 4-8 mg twice daily (BD).
- Tacrolimus capsules 1-7 mg twice daily (BD) + MPS capsules 180-360 mg twice daily (BD) + Methylprednisolone tablets 4-8 mg twice daily (BD).

Dose adjustments were made based on clinical response, tolerability, and physician judgment.

2.2 Statistical Analysis

The data obtained were analyzed using univariate descriptive analysis to examine distribution and frequency (percentage). Furthermore, the data were statistically evaluated using IBM SPSS Version 26.0.

3. Results

Of the 87 kidney transplant recipients identified during the study period, 30 were excluded due to incomplete data, and follow-up control at the doctor's office. Ciptomangunkusumo General Hospital or Prof. dr. I.G.N.G. Ngoerah General Hospital, second transplant, death after transplant, and age <18 years (Figure 1). The analyzed recipients were predominantly male (70.2%) and aged 18-39 years (56.1%), with a generally non-obese nutritional status (BMI < 30 kg/m²: 86%). Nearly all had a history of dialysis (98.2%), comorbid hypertension (77.2%), followed by a combination of diabetes mellitus and hypertension (22.8%). The majority were married (68.4%), highly educated (54.4%), employed (64.9%), covered by non-government-subsidized national health insurance (87.7%), and had a history of transfusion (56.1%). Donors showed a good clinical profile, including slightly more males (56.4%), relatively balanced age distribution (18-39 years: 50.9%; 40-64 years: 49.1%), BMI < 30 kg/m² in 86%, and a majority without comorbidities (82.5%; hypertension 14%; combination of diabetes mellitus-hypertension 3.5%). Generally, the analyzed population reflected recipients of productive age with the primary comorbidity of hypertension, as well as donors with good clinical conditions suitable for transplantation (Table 1).

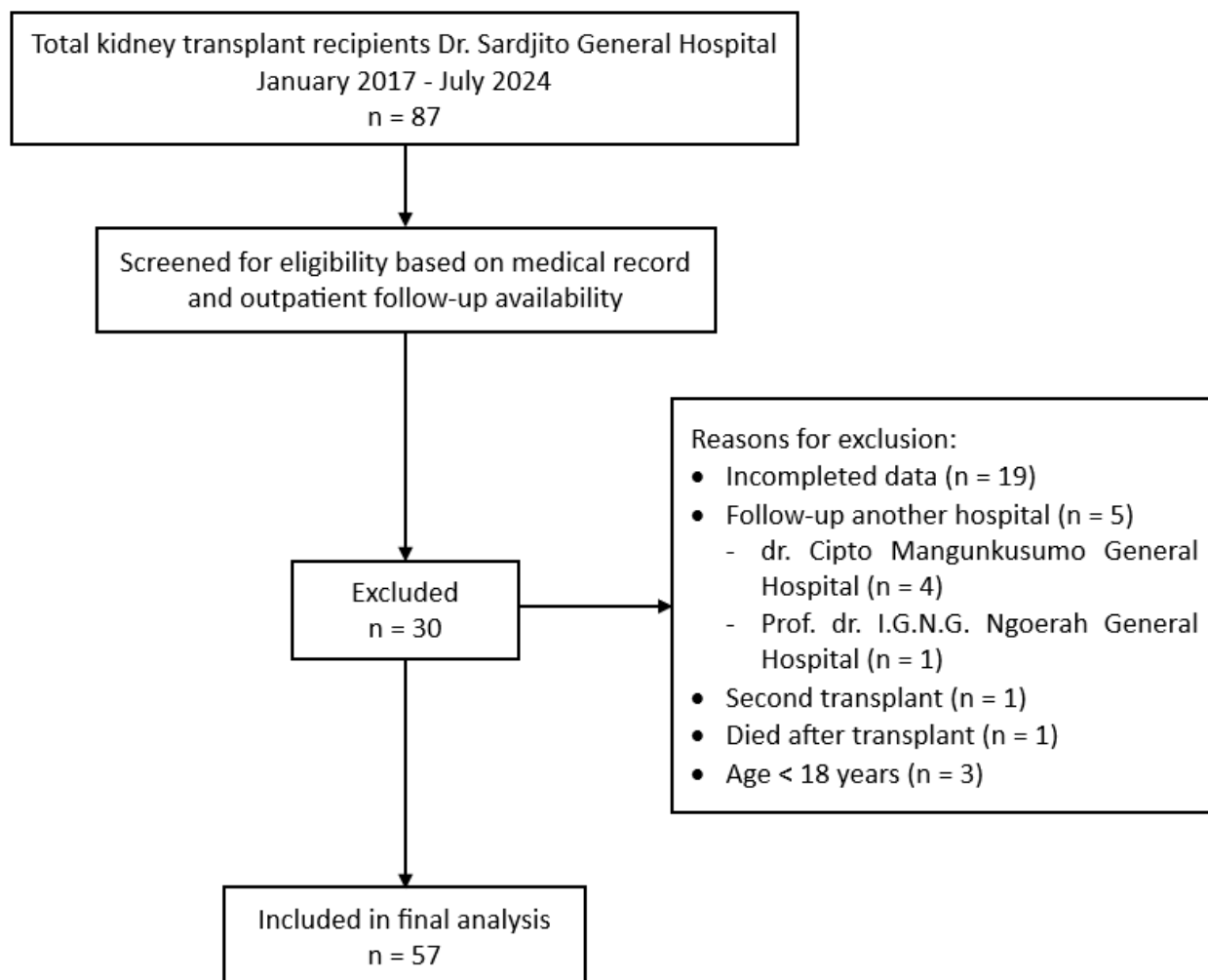


Figure 1 Selection Process of Kidney Transplant Recipients for Final Analysis.

Table 1 Basic Characteristics of Kidney Transplant Recipients and Donors.

Characteristics	n = 57	%
Gender		
Male	40	70.2
Female	17	29.8
Age (Years)		
18-39	32	56.1
40-64	25	43.9
BMI (kg/m ²)		
<30	49	86
≥30	8	14
Dialysis History		
Yes	56	98.2
No	1	1.8
Comorbidity		
Hypertension	44	77.2
Diabetes Mellitus & Hypertension	13	22.8

Marital Status		
Married	39	68.4
Not yet married	18	31.6
Educational Status		
High	31	54.4
Basic	22	38.6
Job Status		
Working	37	64.9
Not working	15	26.3
Insurance Status		
General	4	7
Government-subsidized National Health Insurance beneficiaries	3	5.3
Non-government-subsidized National Health Insurance beneficiaries	50	87.7
Blood Transfusion		
Yes	32	56.1
No	25	43.9
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Donor Demographic Data		
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Gender		
Male	31	56.4
Female	26	45.6
Age (Years)		
18-39	29	50.9
40-64	28	49.1
BMI (kg/m ²)		
<30	49	86
≥30	8	14
Comorbidities		
Hypertension	8	14
Diabetes Mellitus & Hypertension	2	3.5
No comorbid	47	82.5

During the 1-12 month post-kidney transplant monitoring period, adverse drug reactions were dominated by infectious complications, particularly urinary tract infections (UTIs), which were the most common observation (31.6%). Additionally, viral infections were detected, namely cytomegalovirus (CMV) infection (5.3%) and herpes zoster (3.5%), reflecting the impact of immunosuppression. Gastrointestinal complaints, specifically diarrhea, were recorded in 4 cases (7%). Non-infectious adverse effects were relatively rare and mild to moderate in severity, including tremors, dyslipidemia, and NODAT, each occurring in 2 cases (3.5%) (Table 2). Adverse drug reactions (ADRs) were identified from medical records and documented clinical notes. The suspected drug was determined based on the treating physician's assessment recorded in the medical records, taking into account the temporal relationship between drug administration and symptom onset, as well as clinical judgment documented during patient management. No formal

causality assessment scale (e.g., the Naranjo algorithm) was applied due to the study's retrospective design. The identification of suspected drugs was based on clinical documentation in the medical records, reflecting real-world clinical practice.

Table 2 Most Frequently Reported Adverse drug reactions During 1 to 12 Months.

Adverse drug reactions	Number of recipients (n)	Percentage (%)	Suspected drug
Urinary Tract Infection	18	31.6	Tacrolimus
CMV infection	3	5.3	Tacrolimus, MMF
Herpes Zoster	2	3.5	MMF
Diarrhea	4	7	MMF
Tremor	2	3.5	Tacrolimus
Dyslipidemia	2	3.5	Tacrolimus
NODAT	2	3.5	Tacrolimus, Prednisolone

All recipients received basiliximab induction therapy (100%) in combination with tacrolimus/MPA/steroid maintenance therapy. This pattern indicates that the center adopted an IL-2 receptor antagonist (IL2-RA)-based induction strategy to reduce the risk of early acute rejection, consistent with protocols for living-donor transplant recipients. The post-transplant immunosuppressive regimen was dominated by a combination of tacrolimus + mycophenolate sodium (MPS) + steroids 43/57 (75.4%), while the remaining used tacrolimus + MMF + steroids 14/57 (24.6%). The results show a protocol preference for the use of MPS as the main antiproliferative agent in combination with tacrolimus and steroids in standard triple therapy. The smaller proportion of MMF signifies that this choice was used selectively, for example, due to considerations of tolerability, availability, or clinical policy, ensuring that the total study population was relatively homogeneous on the MPS-based regimen (Figure 2). Some recipients were given other concomitant medications, including antidiabetics, antihypertensives, dyslipidemia medications, rifampicin, acyclovir, and antibiotics.

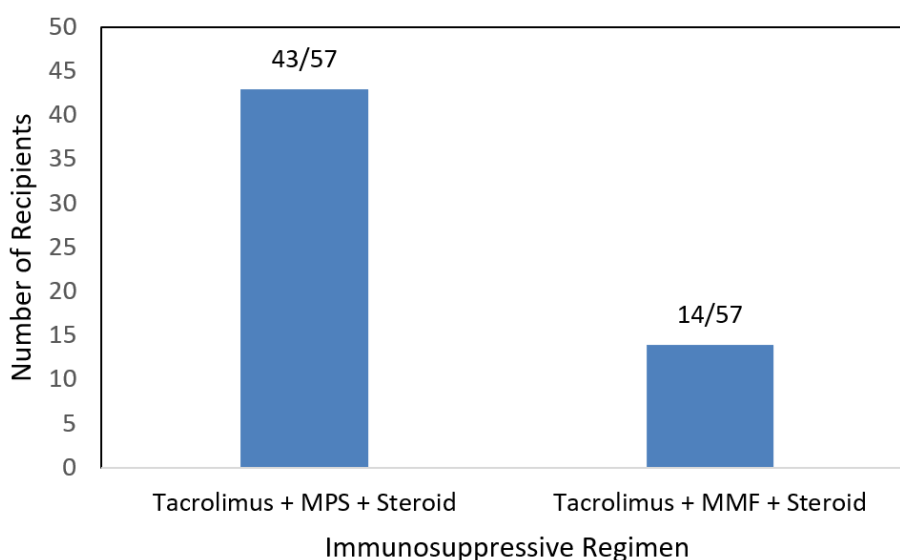


Figure 2 Immunosuppressive Therapy Regimen in Kidney Transplant Recipients.

4. Discussion

The analyzed recipients were predominantly male (70.2%) and aged 18-39 years (56.1%), with the majority having a non-obese nutritional status (BMI < 30 kg/m²: 86%). Nearly all recipients had a history of dialysis (98.2%), with hypertension as the most common comorbidity (77.2%), followed by a combination of diabetes mellitus and hypertension (22.8%). Most recipients were married (68.4%), had higher levels of education (54.4%), were employed (64.9%), and were covered by non-government-subsidized national health insurance (87.7%). More than half had a history of blood transfusion (56.1%). Donor characteristics indicated a generally favorable clinical profile, with a slight predominance of male donors (56.4%) and a relatively balanced age distribution (18-39 years: 50.9%; 40-64 years: 49.1%). Most donors had a BMI < 30 kg/m² (86%) and no comorbidities (82.5%), with smaller proportions having hypertension (14%) or combined diabetes mellitus and hypertension (3.5%). Overall, the study population represented recipients of productive age with hypertension as the primary comorbidity, and donors with clinically suitable conditions for transplantation (Table 1).

This pattern is consistent with several previous reports that found a predominance of male recipients in the kidney transplant population [21]. Most recipients had hypertension as a comorbidity, consistent with the profile of ESKD recipients in general [22]. All donors in this study were alive, reflecting kidney transplant practices in Indonesia, similar to the practices in several Asian countries, with the number of living donors appearing very high. Living donors provide better graft outcomes and lower immunological risks than cadaveric donors [23, 24]. Consequently, the profile of living donors in this study contributed to the stable clinical characteristics of the recipients.

In this study, basiliximab induction was administered to all patients (100%) according to the living-donor kidney transplant protocol. The high utilization of basiliximab, an interleukin-2 receptor antagonist (IL-2RA), reflects an effort to mitigate the risk of early acute rejection while maintaining a more favorable safety profile than lymphocyte-depleting agents such as anti-thymocyte globulin (ATG) [25]. International Kidney Disease: Improving Global Outcomes (KDIGO) guidelines recommend basiliximab as the first-line induction agent for kidney transplant recipients at low immunologic risk, given the higher infection risk associated with cell-depleting induction agents such as anti-thymocyte globulin (ATG) [26]. However, several studies have suggested that omitting induction therapy in low-risk recipients may reduce the incidence of post-transplant infections [27]. Therefore, the decision to administer basiliximab induction was likely based on a careful assessment of immunologic risk.

All recipients in this study received a maintenance immunosuppression regimen consisting of tacrolimus and mycophenolic acid derivatives such as MMF or MPS, along with corticosteroids. The findings demonstrate that a tacrolimus-based triple regimen combined with either mycophenolate sodium (MPS) or mycophenolate mofetil (MMF) remains the predominant maintenance therapy, consistent with standard immunosuppressive protocols in kidney transplantation [28, 29]. No recipients received cyclosporine, indicating a shift toward tacrolimus as the calcineurin inhibitor of choice. The widespread use of tacrolimus is driven by its greater effectiveness in preventing rejection compared to cyclosporine. The standard triple regimen of tacrolimus, MMF and steroids is effective in suppressing acute rejection [30]. The absence of cyclosporine or mTOR inhibitor use in this cohort reflects the homogeneity of the therapeutic approach and the potential for better outcomes, as evidenced by low acute rejection rates. Other studies reported that most recipients

(68-75%) received triple therapy with tacrolimus-MMF-steroids, supporting the current results, which describe this regimen as the gold standard for maintenance immunosuppression therapy with high efficacy in suppressing rejection.

The predominance of MPS-based regimens observed in this study may reflect institutional preferences, drug availability, and clinical considerations related to tolerability. Although gastrointestinal complaints, such as diarrhea, were observed, the relatively small number of cases and the absence of direct comparison between MPS and MMF limit further interpretation. Therefore, no definitive conclusion can be drawn regarding the comparative tolerability of antiproliferative agents in this study.

During the 1-12 months post-transplant observation period, adverse drug reactions were predominantly infection-related complications associated with immunosuppressive therapy. Urinary tract infections (UTIs) were the most frequently observed (31.6%), followed by viral infections, including cytomegalovirus (CMV) (5.3%) and herpes zoster (3.5%). These findings are consistent with previous studies showing that immunosuppressive therapy increases susceptibility to opportunistic infections by suppressing the host immune response. Importantly, these events should be interpreted as complications of immunosuppressive therapy rather than direct pharmacological adverse reactions attributable to a single agent. A previous study reported that the incidence of UTIs in the first year post-transplantation ranges from 20-80%, thereby considered the most common post-transplant infection [31, 32]. In addition to UTIs, viral infections such as CMV and herpes zoster were also found at lower rates (5.3% and 3.5%, respectively). Without prophylaxis, the incidence of CMV infection can reach 8-35% (specifically in the first 3-6 months), but is reduced to around 5-10% with antiviral prophylaxis [33]. The incidence of herpes zoster (3.5%) in this study was lower than the reported incidence in unvaccinated populations (9-10%) [34], showing the importance of antiviral prophylaxis and vaccination to reduce the risk of opportunistic infections.

Non-infectious adverse drug reactions, including tremor, dyslipidemia, and new-onset diabetes after transplantation (NODAT), were relatively infrequent and generally mild to moderate. Tacrolimus-induced tremor is reported in 3.5% of cases, similar to post-transplant dyslipidemia and NODAT at 3.5% each. These findings are consistent with the known safety profiles of calcineurin inhibitors, particularly tacrolimus, which has been associated with metabolic disturbances and neurotoxic effects [35-39]. Previous studies indicate that tacrolimus-related neurological side effects, including tremors, can be managed with gradual dose adjustments and may improve over time [40]. However, the present study did not include a detailed evaluation of tacrolimus blood levels or longitudinal kidney function parameters. Therefore, any relationship between drug exposure and adverse outcomes cannot be conclusively established.

To further contextualize post-transplant complications, vascular complications such as transplant renal artery stenosis (TRAS) have also been reported in the literature as important contributors to graft dysfunction and clinical outcomes, highlighting the multifactorial nature of post-transplant morbidity. This underscores the need for comprehensive monitoring beyond immunosuppressive therapy alone [41].

Several limitations should be acknowledged. First, the retrospective design relies on the completeness and accuracy of medical records, which may introduce information bias. Second, the identification of suspected drugs was based on clinical documentation without the use of standardized causality assessment tools, potentially introducing subjectivity. Third, the study focused on descriptive analysis without evaluating drug exposure levels or long-term clinical

outcomes, limiting causal inference. Fourth, the exclusion of patients with post-transplant mortality may introduce survivorship bias and limit the generalizability of the findings, particularly in relation to safety interpretation. Despite these limitations, this study provides valuable real-world insights into the use of immunosuppressants and associated clinical events at a tertiary referral transplant center in Indonesia. The findings may serve as a baseline for future analytical studies and support the development of context-specific pharmacovigilance strategies.

5. Conclusion

This study demonstrates that tacrolimus-based triple immunosuppressive therapy, predominantly combined with mycophenolate sodium, is the most commonly used regimen among kidney transplant recipients. During the early post-transplant period, clinical events were primarily dominated by infection-related complications, reflecting the immunosuppressed condition of recipients. Non-infectious adverse drug reactions were relatively infrequent and generally mild. However, due to the descriptive nature of this study and the absence of comparative analysis between different immunosuppressive agents, no definitive conclusions can be drawn regarding the superiority or tolerability of specific regimens. These findings highlight the importance of continuous monitoring and pharmacovigilance in kidney transplant recipients and provide preliminary real-world data to support future research and optimization of immunosuppressive therapy in Indonesia.

Author Contributions

Conceptualisation: I, L; Methodology: I, L, MP; Formal Analysis: I, L, MP, A; Data curation: I, L, MP; Writing-original draft: I, L; Writing-review and editing: I, L, MP, ZW.

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Competing Interests

The authors disclose no conflict.

AI-Assisted Technologies Statement

Artificial intelligence (AI) is used for basic grammar correction and language refinement to improve the readability of the text in the manuscript. Specifically, OpenAI's ChatGPT is used to improve the readability and clarity of the text. All scientific content, data analysis, data interpretation, and conclusions related to research on induction, immunosuppressive regimens, and side effects were developed independently by the author. Used to generate, modify, or interpret scientific content, data, analysis, and conclusions were developed independently by the author. The

authors have reviewed the entire text to ensure its accuracy and take full responsibility for the content of the manuscript.

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