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Research Article

Comparative Analysis of Adverse Effects and Graft Rejection Rates of Azathioprine versus Mycophenolate in Kidney Transplant Recipients: A Retrospective Study

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Abstract
Azathioprine, one of the oldest immunosuppressive agents, has been widely used for preventing graft rejection, while mycophenolate mofetil has shown superior efficacy in preventing acute rejection in randomized controlled trials. However, both drugs share significant side effects, such as bone marrow suppression and an increased risk of cytomegalovirus infection. This study aimed to compare the effectiveness and safety of azathioprine and mycophenolate mofetil in kidney transplantation. A retrospective observational study was conducted at Ahmed Gasim Teaching Hospital, involving adult kidney transplant recipients in 2021 who received either azathioprine or mycophenolate as part of their maintenance immunosuppressive regimen. Data were collected and analyzed using SPSS software, with statistical significance defined as a p-value of less than 0.05. The results revealed that 81% of azathioprine recipients and 70.6% of mycophenolate recipients experienced adverse effects. The incidence of acute rejection was low in both groups (17.2% for azathioprine and 25% for mycophenolate), with survival rates close to 100% in both groups (98.3% for azathioprine and 98.5% for mycophenolate). No significant differences were found between the two groups in terms of patient survival, adverse effect occurrence, or rejection rates. The study concludes that both azathioprine and mycophenolate are equally effective in preventing acute graft rejection and achieving high survival rates, with no significant difference in overall outcomes.

Keywords: Graft Rejection Rate, Azathioprine, Mycophenolate Mofetil, Emergency Medicine, Adverse Effects.

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1. Introduction

The use of immunosuppressive therapy is considered a breakthrough in kidney transplantation (Westhoff *et al*., 2016). Before its adoption, kidney transplants were primarily restricted to identical twins (Sayegh *et al*., 2004). Patients with transplanted kidneys must remain on immunosuppressive therapy for life to prevent graft rejection (Oberbauer *et al*., 2020). Azathioprine is one of the oldest immunosuppressive agents still in use. This medication has been utilized to treat various conditions, including rheumatic disorders and hematologic malignancies (Maltzman *et al*., 2003). In 1962, azathioprine was first included in a clinical trial as an immunosuppressant for kidney transplantation (Murray *et al*., 1963). By early 1963, it was established that azathioprine and prednisolone had additive effects, suggesting that graft rejection could be reversible. Consequently, "double drug therapy" became the standard immunosuppressive regimen for nearly two decades (Muntean *et al*., 2013). In the early 1980s, cyclosporine emerged and significantly increased the one-year graft survival rate from 60% to 80%. By the early 1990s, tacrolimus became a substitute therapy (Webster *et al*., 2005).

Randomized controlled trials conducted in the 1990s demonstrated the superiority of mycophenolate mofetil over azathioprine in preventing acute graft rejection (Clayton *et al*., 2012). Mycophenolate showed a greater immunosuppressive effect than azathioprine, driving global healthcare systems to adopt mycophenolate instead of azathioprine for kidney transplants. However, the higher cost of mycophenolate necessitates a thorough evaluation of the comparative impacts of both medications (Wagner *et al*., 2015).

Medications used to suppress immunity can have significant adverse effects. These can be categorized into two primary domains: the generalized immunosuppression that increases the risk of infections, and the specific side effects associated with each drug (Sayegh *et al*., 2004). Possible side effects of azathioprine include bone marrow suppression, megaloblastic anemia (Lennard et al., 1984), and pure red cell aplasia (Old *et al*., 1978). Common side effects of mycophenolate include gastrointestinal issues, drug-induced blood cytopenia, and an increased likelihood of cytomegalovirus (CMV) infection (Khalil *et al*., 2018, Wang *et al*., 2004), with approximately 35% of patients on mycophenolate experiencing diarrhea (Sekmek *et al*., 2021).

A study noted that most published research did not reveal clear long-term differences between mycophenolate and azathioprine regarding patient mortality or graft loss, despite mycophenolate's superiority in preventing early acute rejection. The authors emphasized that factors such as immune risk, safety profiles, and costs should be considered when choosing between mycophenolate and azathioprine therapy (Clayton *et al*., 2012).

A Cochrane Library review found that mycophenolate outperformed azathioprine in graft survival and prevention of acute rejection. However, the authors cautioned that these advantages must be balanced against potential drawbacks, such as the risk of tissue-invasive CMV disease (Wagner et al., 2015). Another study comparing the benefit-risk ratio of mycophenolate and azathioprine in elderly kidney transplant patients found that mycophenolate was more effective in preventing late graft rejection and improving patient outcomes, concluding its superiority in efficacy without increasing the risk of death (Meier-Kriesche *et al*., 2004). Furthermore, a systematic review examined the safety profile of mycophenolate compared to azathioprine, noting that the greater long-term immunosuppressive effect of mycophenolate balances the risks of associated adverse events (Wang *et al*., 2004).

Ongoing research into the effectiveness and safety of azathioprine versus mycophenolate is vital for optimizing kidney transplantation strategies. Mycophenolate shows superior efficacy in preventing acute graft rejection and improving graft survival but comes with higher costs and specific adverse effects, such as gastrointestinal issues and increased risk of cytomegalovirus infection. Conversely, azathioprine, while older and less costly, has known side effects like bone marrow suppression and megaloblastic anemia. This research aims to help clinicians make informed decisions, ultimately improving patient outcomes.

2. Methodology

2.1. Study Design and Setting

This interventional retrospective hospital-based study was conducted at the Cardiac Surgery and Renal Transplantation Center of Ahmed Gasim Teaching Hospital in Sudan, which was founded in 1994 and is located in Khartoum North City, Khartoum State.

2.2. Study Population and Selection criteria

The study included all medical records of kidney transplant recipients (KTRs) aged 18 to 70 years who were admitted to the hospital between January and December 2021 and received immunosuppressive regimens containing azathioprine or mycophenolate as maintenance therapy. Patients with incomplete medical records were excluded from the study.

2.3. Sample Size and Sampling Method

Total coverage of medical records was applied using established inclusion and exclusion criteria. In total, 126 patients were included in the study: 58 patients were treated with azathioprine, and 68 received mycophenolate.

2.4. Data Collection

Data were collected using a self-constructed data collection sheet. The form consisted of two parts: the first part captured the socio-demographic and clinical characteristics of the participants, while the second part involved details about the immunosuppressant regimen, including adverse effects, incidence rates, graft rejection data, and patient survival.

2.5. Data Analysis

Data were analyzed using the Statistical Package for Social Sciences (SPSS) for Windows, version 25.0 (IBM Corp, Armonk, NY, USA), and Microsoft Excel. Descriptive statistics were presented in tables as counts and percentages. The chi-square test was performed to assess associations between independent variables, with results deemed significant at a P value of less than 0.05.

2.6. Ethical Considerations

The study was carried out following the guidelines set forth in the Declaration of Helsinki. Ethical approval (FPEC-37-2021) was granted by the Research Board of the Faculty of Pharmacy at Khartoum University, and additional authorization was obtained from the administration of Ahmed Gasim Teaching Hospital. Since the study was retrospective, informed consent was not required. Data collection ensured strict privacy and confidentiality, and patients' names and other personal identifiers were not recorded.

3. Results

3.1. Demographics and Clinical Characteristics

The study included 126 kidney transplant recipients, predominantly male (68.3%), with a majority aged between 31 and 60 years (66.7%). Most donors were first-degree relatives (83.3%). The body mass index (BMI) varied, with 20.6% classified as underweight, 17.5% normal, and 48.4% not reported (Table 1). The causes of renal failure were diverse, with the most common being uncertain (62.7%), followed by hypertension (15.1%) (Table 2).

Table 1. Socio-demographics and clinical characteristics of the studied population (N=126)**.**

Variable	Categories of the variable	Frequency (%)
Age (years)	18 – 30	39 (31)
	31 - 60	84 (66.7)
	> 60	3 (2.4)
Gender	Male	86 (68.3)
	Female	40 (31.7)
Body Mass Index (BMI)	Underweight	26 (20.6)
	Normal	22 (17.5)
	Overweight	12 (9.5)
	Obese	5 (4)
	Not reported	61 (48.4)
Donor relative	First degree	105 (83.3)
	Second degree	18 (14.3)
	Not relative	3 (2.4)
HLA mismatching	**Azathioprine (N= 58)**	
	020	1 (1.7)
	100	4 (6.9)
	101	2 (3.4)
	110	8 (13.8)
	111	13 (22.4)
	121	1 (1.7)
	011	2 (3.4)
	010	3 (5.2)
	001	1 (1.7)
	000	23 (39.7)
	Mycophenolate mofetil (N= 68)	
	101	3 (4.4)
	110	2 (2.9)
	111	39 (57.4)
	121	4 (5.9)
	221	1 (1.5)
	011	9 (13.2)
	010	3 (4.4)
	001	1 (1.5)
	000	6 (8.8)

3.2. Adverse Effects of Azathioprine and Mycophenolate

Among patients treated with azathioprine, 81% reported side effects, with pancytopenia being the most common (32.8%) (Table 3). In contrast, 70.6% of mycophenolate patients experienced side effects, predominantly diarrhea (39.7%). Notably, diarrhea had a significant onset within the first month for 60.5% of those affected (Table 4).

Table 2. Causes of renal failure among the studied population (N=126)

Cause of renal failure	Frequency (%)
Acute kidney injury	1 (0.8)
Bilateral renal stenosis	1 (0.8)
Chronic glomerulonephritis (CGN)	5 (4.0)
Complicated malaria	2 (1.6)
Focal segmental glomerulosclerosis	1 (0.8)
Focal segmental glomerulosclerosis + bladder stone	1 (0.8)
Focal segmental glomerulosclerosis +SLE	1 (0.8)
Gout nephropathy	1 (0.8)
Hypertension	19 (15.1)
Hypertension +diabetes mellitus	2 (1.6)
Hypertension + Focal segmental glomerulosclerosis	1 (0.8)
Hypertension + renal stone	1 (0.8)
Membranoproliferative glomerulonephritis (MPGN)	1 (0.8)
Polycystic kidney	2 (1.6)
Polycystic kidney+ renal stone	1 (0.8)
Recurrent urinary tract infections	1 (0.8)
Recurrent renal stone	6 (4.8)
Uncertain cause	79 (62.7)
Total	126 (100)

3.3. Management Strategies of Adverse effects

Management of azathioprine-related pancytopenia involved withholding the drug for 13.8% of patients, 14.7% of patients with therapy replacement (4 of them by mycophenolate and 1 by sirolimus) and dose reductions for 6.9% patients (Table 3). In mycophenolate patients, the majority (52.6%) managed diarrhea through dose reductions, and 22.1% by therapy replacement (azathioprine), while 39.5% did not change their medication (Table 4).

Table 3. Azathioprine side effects and management of pancytopenia among patients on azathioprine (N=58)

Variable	Frequency (%)
Occurrence of side effects (N=58)	
Yes	47 (81)
No	11 (19)
Side effects (N= 47)	
Pancytopenia only	19 (32.8)
Infection only	13 (22.4)
Both pancytopenia and infection	15 (25.9)
Management of pancytopenia (N= 34)	
Hold drug	8 (13.8)
Decrease in dose	4 (6.9)
Replaced	5 (8.6)
Not replaced	16 (27.6)
Not reported	1 (1.7)

3.4. Incidence of Acute Rejection and Survival Rates

Among the patients admitted to emergency department, the incidence of acute rejection was 17.2% for azathioprine patients and 25% for those on mycophenolate. Most rejections occurred within the first six months (Table 5). Regarding survival rates, almost all patients on azathioprine and mycophenolate were survived (98.3% and 98.5% respectively).

Table 4. Mycophenolate side effects, onset and management of diarrhea among patients using mycophenolate (N= 68)

Variable	Frequency (%)
Occurrence of side effects (N=68)	
Yes	48 (70.6)
No	20 (29.4)
Side effects (N= 48)	

Infection only	10 (14.7)
Diarrhea only	27 (39.7)
Both infection and diarrhea	11 (16.2)
Onset of diarrhea (N= 38)	
0-1 month	23 (60.5)
1-2 months	8 (21.1)
2-3 months	7 (18.4)
Management of diarrhea (N= 38)	
Hold drug	1 (2.6)
Decrease in dose	20 (52.6)
Replaced	0 (0.0)
Not replaced	15 (39.5)
Not reported	2 (5.3)

Table 5. Incidence, time and type of acute rejection in patients used azathioprine and mycophenolate therapy (N= 126)

Variable		**Azathioprine (N= 58)**	**Mycophenolate (N= 68)**
		Frequency (%)	**Frequency (%)**
Incidence of rejection	**Yes**	10 (17.2)	17 (25)
	No	48 (82.8)	51 (75)
		Azathioprine (N= 10)	**Mycophenolate (N= 17)**
Time of rejection	**0 - 6 months**	6 (60)	14 (82.4)
	7-12 months	1 (10)	2 (11.8)
	19-24 months	3 (30)	1 (5.9)

3.5. Association with Safety and Patient Survival

As shown in Table 6. statistical analysis revealed no significant differences between the two treatment groups concerning the occurrence of side effects (p = 0.215), incidence of rejection (p = 0.290), or patient survival rates (98.3% for azathioprine vs. 98.5% for mycophenolate, p = 0.910).

Table 6. Comparison between azathioprine and mycophenolate in safety and incidence of rejection and patient survival (N= 126)

Type of treatment		**Azathioprine (n= 58)**		**Mycophenolate (n= 68)**		***p*- value**
		Yes	No	Yes	No	
Frequency side effect	Count	47	11	48	20	0.215
	% within type of treatment	81.0%	19.0%	70.6%	29.4%	
Incidence of rejection	Count	10	48	17	51	0.290
	% within type of treatment	17.2%	82.8%	25.0%	75.0%	
Patient survival	Count	57	1	67	1	0.910
	% within type of treatment	98.3%	1.7%	98.5%	1.5%	

4. Discussion

This cross-sectional study investigated the efficacy of mycophenolate mofetil compared to azathioprine as maintenance immunosuppressive agents in kidney transplantation, amid conflicting data on their comparative effectiveness. It included 126 renal transplant recipients, predominantly male (66.7%) and aged 31 to 66 years, with most donors being first-degree relatives. The study highlighted a significant prevalence of hypertension among patients, many of whom were on medication for co-morbid conditions. Notably, the cause of renal failure was uncertain for many participants, reflecting the high prevalence of chronic kidney disease in middle- and lower-income countries, where a substantial number of cases lack identifiable etiology (Gunawardena *et al*. 2021).

In Sudan, maintenance immunosuppressive therapy for kidney transplant recipients is tailored to the patient's immunological risk level. Low-risk patients receive a combination of tacrolimus, azathioprine, and prednisolone, while intermediate and high-risk patients are treated with tacrolimus, mycophenolate, and prednisolone. The standard dose for azathioprine is 1.5 mg/kg/day, given as a single evening dose, whereas mycophenolate is typically dosed at 1 gram twice daily (Elzain *et al*., 2021). In this study, 46% of patients were in the azathioprine group and 54% received mycophenolate. However, most patients in the azathioprine group were administered a fixed dose of 100 mg daily, regardless of body weight, which deviates from the recommended dosing guidelines.

A comparative study published in 2009 found no significant differences in patient survival or renal transplant function between those treated with azathioprine and those treated with mycophenolate. Additionally, the risks of adverse events, such as cytomegalovirus infection, anemia, leukopenia, and malignancy, were similar between the two groups

(Knight *et al*., 2009). This aligns with the current study, which showed that 81% of patients on azathioprine experienced side effects, compared to 70.6% of patients on mycophenolate, with no statistically significant difference (P-value = 0.215).

Infection is a common complication after transplantation, but routine prophylaxis with trimethoprim/sulfamethoxazole has significantly reduced its incidence among transplant patients (Varughese *et al*., 2020). In this study, 48.3% of patients on azathioprine developed infections post-transplant, compared to 32.4% of those on mycophenolate. This contrasts with another study that found a higher incidence of surgical infections in patients receiving mycophenolate mofetil (Odorico *et al*., 1998).

Possible side effects of azathioprine include bone marrow suppression, leading to conditions such as leukopenia, myelosuppression, or pancytopenia (Maddocks *et al*., 1986, Chan *et al.*, 1987). In this study, the incidence of pancytopenia was 58.6%, with some patients also experiencing infections. Management strategies included withholding medication for 23.5% of patients, dose reduction for 11.8%, and switching to mycophenolate or sirolimus for 14.7%. These findings align with other studies indicating that azathioprine-induced leukopenia usually occurs within the first five weeks post-transplant and often resolves with dose adjustments or temporary discontinuation of the drug (Chan *et al*., 1987). One study indicated a higher risk of diarrhea in patients treated with mycophenolate (Knight *et al*., 2009), while another found that regimens including tacrolimus and mycophenolate mofetil significantly increased the risk of non-infectious diarrhea, which in turn doubled the risk of graft loss and patient mortality (Bunnapradist et al., 2008). In the current study, 55.9% of patients receiving mycophenolate experienced diarrhea, with most cases occurring within the first month of treatment.

In a recent trial involving renal transplant patients with severe diarrhea, about 50% of patients resolved their symptoms without adjusting their immunosuppressive regimens. Altering these regimens may increase the risk of acute rejection, so it’s crucial to explore other causes of gastrointestinal issues before making changes (Davies *et al*., 2007). The study found that dose reduction was the most effective management for diarrhea in patients on mycophenolate. The incidence of acute rejection was 17.2% in the azathioprine group and 25% in the mycophenolate group, with no significant difference between the two (P-value = 0.290). These results align with another trial indicating that mycophenolate does not provide advantages over azathioprine in preventing acute rejection (Remuzzi *et al*., 2004). Furthermore, nearly all patients in both groups survived, supporting the notion that mycophenolate does not increase mortality risk compared to azathioprine (Meier-Kriesche *et al*., 2004).

Despite the valuable insights provided by this study, several limitations must be acknowledged. The retrospective nature of the study may introduce biases related to the accuracy and reliability of the collected data. Additionally, since the research was conducted at a single hospital, its findings may not be generalizable to other settings or populations. Furthermore, the study's short duration may not adequately capture the long-term outcomes and complications associated with azathioprine and mycophenolate. These limitations highlight the need for further research on a larger scale to provide a more comprehensive evaluation of the efficacy and safety of azathioprine versus mycophenolate in kidney transplantation.

5. Conclusion

This study revealed that both azathioprine and mycophenolate are effective in preventing acute graft rejection and achieving high patient survival rates, with no significant difference in overall survival between the two medications. Further research is needed to gain a better understanding of the long-term outcomes and complications associated with these immunosuppressive therapies.

Availability of data

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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