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The Efficacy of Induction Treatment with a Cyclophosphamide- or Mycophenolate Mofetil-Based Regimen for Active Lupus Nephritis in Thailand: A Retrospective Cohort Study

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Keywords
Lupus nephritis · Cyclophosphamide · Mycophenolic acid · Induction therapy

Abstract
Introduction: Treating lupus nephritis is vital to reducing morbidity and mortality. In Thailand, comparative data on intravenous cyclophosphamide- and mycophenolate mofetil (MMF)-based induction therapies are limited. This study assessed renal remission outcomes for these regimens. ***Methods:*** We analyzed renal and patient outcomes in 89 individuals with biopsy-proven active lupus nephritis treated at Phramongkutklao Hospital between 2020 and 2023. Among the cohort, 55 patients received a cyclophosphamide regimen, and 34 were treated with an MMF regimen. ***Results:*** Baseline clinical characteristics were comparable between the two groups, except for higher hematuria and renal activity index, as well as lower C3 complement levels and renal chronicity in the cyclophosphamide group. The average doses administered were 0.55 ± 0.12 g/m^2 per dose for intravenous cyclophosphamide and 2.15 ± 0.31 g/day for MMF. By the 24th week, the overall remission rate (complete and partial remission) was 81.8% (45 patients) in the cyclophosphamide group and 85.3% (29 patients) in the MMF group (relative risk 1.01, 95% CI 0.82–1.23, p = 0.949). Proteinuria reduction from baseline at the 24th week was −54.1 ± 93.3% in the cyclophosphamide group and −69.4 ± 22.2% in the MMF group (relative risk 1.01, 95% CI 0.99–1.01, p = 0.465). Adverse events were similar across the two regimens. However, 1 patient in the cyclophosphamide group died, and three required dialysis. ***Conclusion:*** Induction therapy with cyclophosphamide- and MMF-based regimens demonstrated comparable efficacy and safety in achieving renal remission in patients with active lupus nephritis.

Introduction

Patients with proliferative lupus nephritis have significantly higher proportions of microscopic hematuria, proteinuria, hypertension, and impaired renal function, which correlate strongly with high activity and chronicity indices of lupus pathology [1]. End-stage renal disease is a major consequence of lupus nephritis. Among patients with proliferative lupus nephritis, the 15-year risk of end-stage renal disease was reported to be as high as 44% during the 2000s in developed countries [2]. Furthermore, this risk was notably higher in developing countries compared to developed ones.

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Prompt and appropriate initiation of immunosuppressive therapy is crucial to control the disease, improve renal outcomes, and reduce morbidity and mortality [3]. The disease course and response to immunosuppressive therapy vary by ethnicity. Epidemiological data on systemic lupus erythematosus (SLE) differ across countries in Asia. Asian patients with SLE are reported to have higher disease severity, activity, and organ damage, alongside increased morbidity, mortality, and susceptibility to renal involvement compared to other ethnicities in the Asia-Pacific region [4, 5].

The Kidney Disease: Improving Global Outcomes (KDIGO) Clinical Practice Guideline for lupus nephritis management recommends induction therapy with either intravenous cyclophosphamide or mycophenolate mofetil (MMF) for proliferative lupus nephritis [6]. A 2012 Cochrane review found MMF to potentially provide increased complete disease remission compared to IV cyclophosphamide, with an acceptable adverse event profile [7]. In studies involving Asian patients, both MMF and IV cyclophosphamide demonstrated comparable efficacy in achieving renal remission, with no significant difference in safety profiles [8, 9]. However, the limited focus of existing studies on Thai patients highlights a gap in understanding the comparative effectiveness and safety of these therapies in this demographic [10]. This study aimed to compare renal remission and safety outcomes between cyclophosphamide- and MMF-based induction therapies in Thai patients with biopsy-proven lupus nephritis.

Methods

This retrospective cohort study included data from 89 lupus nephritis patients – 55 treated with a cyclophosphamide-based regimen and 34 treated with an MMF-based regimen – from January 2020 to June 2023 at the Division of Nephrology, Department of Medicine, Phramongkutklao Hospital. The study was approved by the Institutional Review Board of the Royal Thai Army Medical Department (Approval No. IRBRTA 1294/2566) and conducted in accordance with the Declaration of Helsinki and the International Conference on Harmonization Guidelines for Good Clinical Practice.

Patients included in the study were aged 18 years or older and had biopsy-proven lupus nephritis (classes III, IV, or V). All patients received treatment and follow-up at Phramongkutklao Hospital for at least 24 weeks. The kidney biopsies were evaluated by renal pathologists using the 2018 Revision of the International Society of Nephrology/Renal Pathology Society (ISN/RPS) classification for lupus nephritis [11]. All patients were diagnosed with SLE based on the 2019 European League Against Rheumatism/American College of Rheumatology (EULAR/ACR) criteria.

Basic demographic and clinical data were collected, including gender, age, estimated glomerular filtration rate, prior use of renin-angiotensin-aldosterone system (RAAS) inhibitors, immunosuppressive drugs, antihypertensive medications, kidney biopsy findings, follow-up duration, mean arterial blood pressure, and initial proteinuria levels. The primary objective was to evaluate the response to cyclophosphamide or MMF in patients with lupus nephritis class III-IV or V, measured by changes in proteinuria. Remission was defined as follows:

- Complete remission (CR): return of serum creatinine to baseline and reduction of proteinuria (urine protein-to-creatinine ratio <0.5 g/day).
- Partial remission (PR): ≥50% reduction in baseline proteinuria (to <3.0 g/day if initially nephrotic) and stabilization/improvement of serum creatinine.
- Non-response (NR): persistent proteinuria (<50% reduction) and/or no improvement in serum creatinine after 24 weeks of treatment.

The sample size was calculated based on the Prasad study, long-term outcomes of lupus nephritis treated with regimens based on cyclophosphamide and MMF [9]. With a power of 90%, the sample size for each group was set at 89 patients, targeting a significance level of $p < 0.05$.

Statistical Analysis

Quantitative data were presented as means or medians, while categorical data were described as frequencies and percentages. Chi-square tests were used for categorical data comparisons, and continuous data were analyzed using independent *t* tests or Mann-Whitney U tests as appropriate. Statistical analyses were performed using STATA software, Version 14.0 (Stata Corp, College Station, TX, USA). A p value <0.05 was considered statistically significant.

Results

Eighty-nine patients were enrolled in the study. Among them, 55 patients received a cyclophosphamide-based regimen for induction therapy, with an average dosage of 0.55 ± 0.12 g/m^2. Specifically, 53 patients were treated with the NIH regimen, which involves monthly intravenous pulses of cyclophosphamide dosed at 0.5–1 g/m^2 for 6 months. Additionally, 2 patients received

Table 1. Baseline characteristics between cyclophosphamide and MMF groups

Parameters	Total (*N* = 89)	Cyclophosphamide (*N* = 55)	MMF (*N* = 34)	*p* value
Age, years	34.7±12.6	33.9±12.7	35.9±12.5	0.478
Sex, *n* (%)				
Male	18 (20.2)	12 (21.8)	6 (17.6)	0.364
Female	71 (79.8)	43 (78.2)	28 (82.4)	
Onset to LN diagnosis, months	4.5±11.3	5.6±12.1	2.8±9.8	0.267
Class of LN, *n* (%)				
III	14 (15.7)	7 (12.7)	7 (20.6)	0.031
IV	8 (9)	8 (14.5)	0 (0)	
III or IV[a]	16 (18)	9 (16.4)	7 (20.6)	
III+V	30 (33.7)	22 (40.0)	8 (23.5)	
IV+V	20 (22.5)	8 (14.5)	12 (35.3)	
V	1 (1.1)	1 (1.8)	0 (0)	
Activity index (out of 24)	4.6±4.3	6.2±4.3	1.9±2.7	0.006
Chronicity index (out of 12)	3.1±2.1	2.4±1.8	4.6±2.0	0.004
Systolic blood pressure, mm Hg	139.7±22.1	142.7±23.3	134.7±19.4	0.097
Diastolic blood pressure, mm Hg	83.2±14.4	86.2±15.4	78.4±11.2	0.012
Hemoglobin, g/dL	10.6±2.2	10.4±2.3	11.0±2.0	0.169
WBC, $\times 10^3$	8.7±3.9	8.6±3.7	8.9±4.2	0.653
Lymphocyte, %	16.4±9.4	15.3±8.5	18.1±10.6	0.172
Total lymphocyte count	1,281.1±793.9	1,168.9±615.2	1,462.8±1,003.4	0.090
Platelet, $\times 10^3$	277±96	276±108	278±73	0.943
Creatinine at diagnosis, mg/dL	1.4±1.1	1.5±1.2	1.1±0.9	0.126
UPCR at presentation, g/g Cr	4.0±2.4	4.1±2.3	3.8±2.4	0.595
Hematuria >3 RBC/cmm, *n* (%)	62 (69.7)	43 (78.2)	19 (55.9)	0.026
Leucocyturia >10 WBC/cmm, *n* (%)	8 (9)	7 (12.7)	1 (2.9)	0.117
C3, mg/dL	0.64±0.29	0.59±0.30	0.73±0.26	0.028
C4, mg/dL	0.14±0.13	0.13±0.13	0.16±0.12	0.375
Antinuclear antibody (positive), *n* (%)	89 (100)	55 (100)	34 (100)	N/A
Anti-ds-DNA (positive; titer > 80), *n* (%)	24 (27)	12 (21.8)	12 (35.3)	0.164
Average dose		0.55±0.12	2.15±0.31	

Data are presented as mean and standard deviation, or as indicated. LN, lupus nephritis; UPCR, urine protein-to-creatinine ratio. [a]The diagnosis from kidney biopsy should reflect either Class III or Class IV LN, given the inadequate glomerular sample size in the tissues.

the EuroLupus regimen, which consists of a fixed dose of 500 mg of cyclophosphamide administered every 2 weeks, totaling 6 doses. Thirty-four patients received induction therapy based on MMF, with an average dosage of 2.15 ± 0.31 g/day. The average prednisolone dose during the initial 2–3 months of treatment ranged from 0.6 to 0.8 mg/kg/day orally. Baseline clinical characteristics, including demographics and biochemical parameters, were similar between the cyclophosphamide and MMF groups. However, the activity index was significantly higher in cyclophosphamide patients (6.15 ± 4.33 vs. 1.91 ± 2.7; $p = 0.006$). Hematuria was also more frequent in the cyclophosphamide group (78.2% vs. 55.9%; $p = 0.026$), and complement C3 levels were lower (0.59 ± 0.3 vs. 0.73 ± 0.26; $p = 0.028$) (Table 1).

The overall remission rate was 81.8% in the cyclophosphamide group and 85.3% in the MMF group, with no significant difference between the groups

Table 2. Treatment response rate between two induction regimens

	Cyclophosphamide (*N* = 55)	MMF (*N* = 34)	RR (95% CI)	*p* value
Overall remission	45 (81.8)	29 (85.3)	1.01 (0.82, 1.23)	0.949
CR	22 (40.0)	15 (44.1)	1.1 (0.67, 1.81)	0.702
PR	23 (41.8)	14 (41.2)	0.98 (0.59, 1.64)	0.952
Non-responsive to treatment	10 (18.2)	5 (14.7)	0.81 (0.3, 2.17)	0.670

Data are presented as *n* (%) and relative risk with 95% CI.

Table 3. Renal outcomes between two induction regimens

	Cyclophosphamide (*N* = 55)	MMF (*N* = 34)	RR (95% CI)	*p* value
Mean changes in proteinuria from baseline at the 12th week, g/g Cr	−1.73±2.47	−2.03±2.08	0.97 (0.83, 1.12)	0.645
Mean percentage change in proteinuria from baseline at the 12th week, %	−34.33±69.82	−51.76±31.92	1 (0.99, 1)	0.278
Mean changes in serum creatinine from baseline at the 12th week, mg/dL	−0.28±0.69	−0.04±0.2	1.99 (0.82, 4.83)	0.129
Mean changes in proteinuria from baseline at the 24th week, g/g Cr	−2.63±2.49	−2.75±2.24	0.99 (0.86, 1.14)	0.849
Mean percentage change in proteinuria from baseline at the 24th week, %	−54.10±93.33	−69.42±22.18	1 (0.99, 1.01)	0.465
Mean changes in serum creatinine from baseline at the 24th week, mg/dL	−0.30±0.89	−0.20±0.74	1.1 (0.72, 1.69)	0.655
Death	1 (1.8)	0	N/A	0.429
Dialysis	3 (5.4)	0	N/A	0.166

Data are presented as mean and standard deviation, *n* (%), and relative risk with 95% CI.

(cyclophosphamide: CR 40%, PR 41.8%, NR 18.2%; MMF: CR 44.1%, PR 41.2%, NR 14.7%) (Table 2). The mean percentage change in proteinuria from baseline at the 12th and 24th weeks was −34.33 ± 69.82% and −54.10 ± 93.33% in the cyclophosphamide group, and −51.76 ± 31.92% and −69.42 ± 22.18% in the MMF group, respectively (Table 3). Changes in serum creatinine and proteinuria were comparable between the two groups (Fig. 1).

Adverse effects were more frequent in the cyclophosphamide group, including serious infection, leukopenia, and pancytopenia (Table 4). Serious infections were more common in the cyclophosphamide group but did not reach statistical significance. The MMF group experienced more diarrhea and hepatitis. Three patients in the cyclophosphamide group required dialysis, and 1 patient died due to severe hospital-acquired pneumonia.

Discussion

This retrospective study focused on the renal outcomes following induction therapy for lupus nephritis using cyclophosphamide and MMF regimens. Both regimens achieved remission rates of up to 80%, with no statistically significant differences in remission rates between the two treatments. We observed that most patients who experienced adverse events during induction therapy with cyclophosphamide did so due to leukopenia, infections, and sepsis.

Our study provides valuable real-world insights into the treatment of active lupus nephritis in Thailand using currently available medications. We have observed a notably high remission rate in our cohort, underscoring the effectiveness of the treatment strategies employed. It is noteworthy that the decision-making process in the

cyclophosphamide-treated group may have been influenced by the higher disease activity observed. Interestingly, despite a higher degree of chronicity in the MMF group, we found comparable remission rates between both treatment arms at the 6-month follow-up, suggesting that chronicity may not significantly impact short-term outcomes. The observed high rates of renal remission align closely with previously reported outcomes in the Thai population [10]. Studies from Malaysia, India, and Korea have also demonstrated the efficacy of MMF combined with corticosteroids in treating mild to severe proliferative lupus nephritis [12–14]. However, variations in treatment response between cyclophosphamide and MMF have been noted in meta-analyses, highlighting geographical differences [15]. For example, studies conducted in Asia have not consistently shown MMF to be superior, whereas studies outside Asia often report higher rates of CR with MMF, possibly influenced by genetic, environmental, or disease-specific factors unique to these populations [16].

Our findings align with the lack of significant differences in overall remission rates between cyclophosphamide and MMF regimens. Changes in serum creatinine and proteinuria during the study also showed no significant differences, suggesting that both regimens are equally effective in improving renal function and reducing proteinuria. However, a noteworthy finding was the higher baseline activity index in the cyclophosphamide group (6.15 ± 4.33 vs. 1.91 ± 2.7, $p = 0.006$), indicating more severe disease at the outset in these patients, potentially influencing treatment outcomes and adverse effects.

A significant concern with cyclophosphamide therapy is the heightened susceptibility to infections, including severe cases that may lead to hospitalization or death [17, 18]. This risk is particularly pronounced in patients receiving high doses or prolonged courses of cyclophosphamide therapy. Cyclophosphamide-induced leukopenia, a reduction in white blood cell counts, further exacerbates infection risks. Studies have demonstrated that patients treated with MMF experience less frequent leukopenia compared to those treated with cyclophosphamide [19]. Consistent with these findings, our study observed higher infection rates in the cyclophosphamide group, though the differences did not reach statistical significance. Notably, mortality due to severe adverse drug reactions, such as sepsis and hospital-acquired pneumonia, occurred exclusively in the cyclophosphamide group. These results underscore the need for close monitoring of infections during cyclophosphamide induction therapy, particularly in patients with high disease

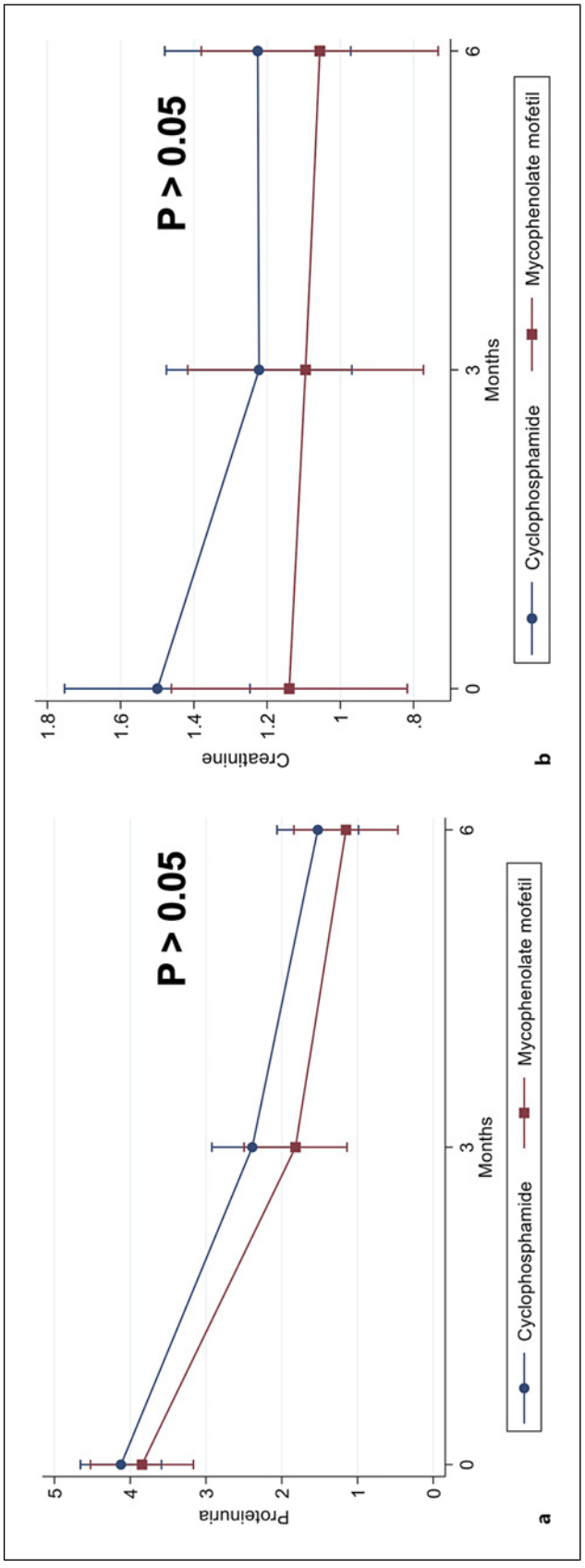

Fig. 1. **a** Mean changes in proteinuria (g/g Cr). **b** Mean changes in serum creatinine (mg/dL) between the cyclophosphamide and MMF groups ($p > 0.05$).

Table 4. Adverse events between two induction regimens

Adverse events	Cyclophosphamide (*N* = 55)	MMF (*N* = 34)	RR (95% CI)	*p* value
Serious infection	6 (10.9)	2 (5.8)	0.54 (0.12, 2.52)	0.421
Leukopenia	4 (7.2)	0	N/A	0.108
Pancytopenia	1 (1.8)	0	N/A	0.429
Diarrhea	1 (1.8)	3 (8.8)	4.85 (0.53, 44.79)	0.121
Alopecia	4 (7.2)	0	N/A	0.108
Hepatitis	0	1 (2.9)	N/A	0.201
Hemorrhagic cystitis	1 (1.8)	0	N/A	0.429
Menstrual irregularity	1 (1.8)	0	N/A	0.429
Infertility	0	0	N/A	
Combined serious adverse events (serious infection, leukopenia, pancytopenia)	11 (20.0)	2 (5.8)	3.4 (0.80–14.42)	0.067

Data are presented as *n* (%) and relative risk with 95% CI.

activity. Adverse effects such as diarrhea and hepatitis were more frequent in the MMF group, while leukopenia and pancytopenia were higher in the cyclophosphamide group. These observations reflect the established side effect profiles of both regimens and highlight the importance of individualized treatment planning. Selection of induction therapy should consider factors such as disease severity, patient comorbidities, and the risk of adverse effects. For patients with more severe disease activity, vigilant monitoring for infections and cytopenias is critical.

This study has several limitations. First, the small sample size may not fully represent the diversity of the Thai population. Second, being a retrospective study, it is inherently susceptible to biases and confounding factors. We were unable to compare outcomes between the NIH and EuroLupus regimens due to the limited number of patients in each subgroup. Additionally, the higher baseline activity index in the cyclophosphamide group may have influenced the results, necessitating cautious interpretation.

The decision to compare outcomes despite these differences was rooted in the retrospective nature of our study design. We aimed to capture real-world clinical scenarios where treatment assignment often reflects non-random factors and is influenced by disease severity at presentation. Larger prospective studies are essential to validate these findings and explore potential geographic variations in treatment response. Future comparative studies focusing on different cyclophosphamide regimens could offer further insights into optimizing induction therapy strategies.

Conclusion

This study contributes valuable insights into lupus nephritis management in Thailand, highlighting the efficacy and safety considerations of cyclophosphamide and MMF as induction therapies. While both regimens were effective, treatment decisions should account for individual patient factors and regional variations.

Acknowledgments

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Statement of Ethics

The study was approved by the Institutional Review Board of the Royal Thai Army Medical Department (approval No. IRBRTA 1294/2566) and conducted in accordance with the Declaration of Helsinki and the International Conference on Harmonization Guidelines for Good Clinical Practice. This study was granted an exemption from requiring written informed consent by the Institutional Review Board of the Royal Thai Army Medical Department (IRB RTA 1294/

2566). The Committee reviewed the study and confirmed that it complies with ethical standards, including the World Medical Association Declaration of Helsinki.

Conflict of Interest Statement

The authors declare that no competing interests exist.

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Author Contributions

P.P., O.S., and B.S. contributed to the concept and design of the study. P.P. and B.S. contributed to data acquisition, analysis, and interpretation of the data. P.P. wrote the first draft of the manuscript. All authors approved the final version submitted.

Data Availability Statement

The data that support the findings of this study are not publicly available due to the risk of participant identification and the need to protect the privacy of research participants but are available from the corresponding author upon reasonable request.

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