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Fulltext Information

13/1 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Mok CC; Ying KY; Yim CW; Siu YP; Tong KH; To CH; Ng WL

TI: Tacrolimus versus **mycophenolate mofetil** for induction therapy of **lupus nephritis**: a randomised **controlled trial** and long-term follow-up.

SO: Annals of the rheumatic diseases; VOL: 75 (1); p. 30-6 /201601/

AB: OBJECTIVE: To compare the efficacy of tacrolimus (TAC) and **mycophenolate mofetil** (MMF) for the initial therapy of **lupus nephritis** (LN).
METHODS (**STUDY** DESIGN): This is an open randomised **controlled** parallel group **study**.
METHODS: Adult patients with biopsy-confirmed active LN (class III/IV/V) were randomised to receive prednisolone (0.6 mg/kg/day for 6 weeks and tapered) in combination with either TAC (0.06-0.1 mg/kg/day) or MMF (2-3 g/day) for 6 months. Good responders were shifted to azathioprine for maintenance. The primary outcome was the rate of complete renal response (CR) at 6 months and the secondary outcomes included partial renal response, renal flares and decline of renal function over time.
RESULTS: 150 patients (92% women; aged 35.5±12.8 years; 81% class III/IV) were randomised (76 MMF, 74 TAC). At month 6, the rate of CR was 59% in the MMF and 62% in the TAC group (treatment difference: 3.0% (-12%, 18%); p=0.71). Major infective episodes occurred in 9.2% patients treated with MMF and in 5.4% patients treated with TAC (p=0.53). Maintenance therapy with azathioprine was given to 79% patients. After 60.8±26 months, proteinuric and nephritic renal flares developed in 24% and 18% of patients in the MMF group and 35% (p=0.12) and 27% (p=0.21) in the TAC group, respectively. The cumulative incidence of a composite outcome of decline of creatinine clearance by > =30%, development of chronic kidney disease stage 4/5 or death was 21% in the MMF and 22% in the TAC group of patients (p=0.35).
CONCLUSIONS: TAC is non-inferior to MMF, when combined with prednisolone, for induction therapy of active LN. With azathioprine maintenance for 5 years, a non-significant trend of higher incidence of renal flares and renal function decline is observed with the TAC regimen.
BACKGROUND (**TRIAL** REGISTRATION NUMBER): Hospital Authority Research Ethics Committee **Clinical Trial** Registry (HARECCTR0500018; Hong Kong) and US ClinicalTrials.gov (NCT00371319).

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AU: Liu Z; Zhang H; Liu Z; Xing C; Fu P; Ni Z; Chen J; Lin H; Liu F; He Y; He Y; Miao L; Chen N; Li Y; Gu Y; Shi W; Hu W; Liu Z; Bao H; Zeng C; Zhou M

TI: Multitarget therapy for induction treatment of **lupus nephritis**: a **randomized trial**.

SO: Annals of internal medicine; VOL: 162 (1); p. 18-26 /20150106/

AB: BACKGROUND: Treatment of **lupus nephritis** (LN) remains challenging.
OBJECTIVE: To assess the efficacy and safety of a multitarget therapy consisting of tacrolimus, **mycophenolate mofetil**, and steroid compared with intravenous cyclophosphamide and steroid as induction therapy for LN.
METHODS (DESIGN): 24-week **randomized**, open-label, **multicenter study**. (ClinicalTrials.gov: NCT00876616).
METHODS (SETTING): 26 renal centers in China.
METHODS (PATIENTS): Adults (aged 18 to 65 years) with biopsy-proven LN.
METHODS (INTERVENTION): Tacrolimus, 4 mg/d, and **mycophenolate mofetil**, 1.0 g/d, versus intravenous cyclophosphamide with a starting dose of 0.75 (adjusted to 0.5 to 1.0) g/m2 of body surface area every 4 weeks for 6 months.

Both groups received 3 days of pulse methylprednisolone followed by a tapering course of oral prednisone therapy.
METHODS (MEASUREMENTS): The primary end point was complete remission at 24 weeks. Secondary end points included overall response (complete and partial remission), time to overall response, and adverse events.
RESULTS: After 24 weeks of therapy, more patients in the multitarget group (45.9%) than in the intravenous cyclophosphamide group (25.6%) showed complete remission (difference, 20.3 percentage points [95% CI, 10.0 to 30.6 percentage points]; P < 0.001). The overall response incidence was higher in the multitarget group than in the intravenous cyclophosphamide group (83.5% vs. 63.0%; difference, 20.4 percentage points [CI, 10.3 to 30.6 percentage points]; P < 0.001), and the median time to overall response was shorter in the multitarget group (difference, -4.1 weeks [CI, -7.9 to -2.1 weeks]). Incidence of adverse events did not differ between the multitarget and intravenous cyclophosphamide groups (50.3% [91 of 181] vs. 52.5% [95 of 181]).
CONCLUSIONS (LIMITATION): The **study** was limited to 24 weeks of follow-up.
CONCLUSIONS: Multitarget therapy provides superior efficacy compared with intravenous cyclophosphamide as induction therapy for LN.
BACKGROUND (PRIMARY FUNDING SOURCE): National Basic Research Program of China, National Key Technology R&D Program.

Fulltext Information

13/3 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Ntali S; Bertsias G; Boumpas DT

TI: Cyclophosphamide and **lupus nephritis**: when, how, for how long?

SO: Clinical reviews in allergy & immunology; VOL: 40 (3); p. 181-91 /201106/

AB: Ever since the introduction of cyclophosphamide (CY), the management of **lupus nephritis** has dramatically changed, and its prognosis has greatly improved. Based on **randomized controlled** trials and long-term observational studies, pulse therapy with CY in combination with methyl-prednisolone (MP) is the "gold standard" of therapy for severe **lupus**. The realization of the significant gonadal toxicity intensified the efforts for the development of alternative immunosuppressive agents. In a large, **randomized controlled trial**, newer agents such as **mycophenolate mofetil** (MMF) have demonstrated comparable efficacy and less toxicity for moderately severe disease. To date, combinations of monthly pulses of CY with MP remain the gold standard for the induction of remission in severe **lupus**. For maintenance, less toxic agents such as azathioprine or MMF are equally effective and are routinely used in the current therapy of **lupus**.

Fulltext Information

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AU: Gu F; Wang D; Zhang H; Feng X; Gilkeson GS; Shi S; Sun L

TI: Allogeneic mesenchymal stem cell transplantation for **lupus nephritis** patients refractory to conventional therapy.

SO: Clinical rheumatology; VOL: 33 (11); p. 1611-9 /201411/

AB: Allogeneic mesenchymal stem cell transplantation (MSCT) has been shown to be clinically efficacious in the treatment of various autoimmune diseases. Here, we analyzed the role of allogeneic MSCT to induce renal remission in patients with active and refractory **lupus nephritis** (LN). This is an open-label and single-center **clinical trial** conducted from 2007 to 2010 in which 81 Chinese patients with active and refractory LN were enrolled. Allogeneic bone marrow- or umbilical cord-derived mesenchymal stem cells (MSCs) were administered intravenously at the dose of 1 million cells per kilogram of bodyweight. All patients were then monitored over the course of 12 months with periodic follow-up visits to evaluate renal remission, as well as possible adverse events. The primary outcome was complete renal remission (CR) and partial remission (PR) at each follow-up, as well as renal flares. The secondary outcome included renal activity score, total disease activity score, renal function, and serologic index. During the 12-month

follow-up, the overall rate of survival was 95 % (77/81). Totally, 60.5 % (49/81) patients achieved renal remission during 12-month visit by MSCT. Eleven of 49 (22.4 %) patients experienced renal flare by the end of 12 months after a previous remission. Renal activity evaluated by British Isles **Lupus** Assessment Group (BILAG) scores significantly declined after MSCT (mean ± SD, from 4.48 ± 2.60 at baseline to 1.09 ± 0.83 at 12 months), in parallel with the obvious amelioration of renal function. Glomerular filtration rate (GFR) improved significantly 12 months after MSCT (mean ± SD, from 58.55 ± 19.16 to 69.51 ± 27.93 mL/min). Total disease activity evaluated by Systemic **Lupus** Erythematosus Disease Activity Index (SLEDAI) scores also decreased after treatment (mean ± SD, from 13.11 ± 4.20 at baseline to 5.48 ± 2.77 at 12 months). Additionally, the doses of concomitant prednisone and immunosuppressive drugs were tapered. No transplantation-related adverse event was observed. Allogeneic MSCT resulted in renal remission for active LN patients within 12-month visit, confirming its use as a potential therapy for refractory LN.

Fulltext Information

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AU: Rivera F; Mérida E; Illescas ML; López-Rubio E; Frutos MA; García-Frías P; Ramos C; Sierra M; Baltar J; Lucas J; Oliet A; Vigil A; Fernández-Juárez G; Segarra A; Praga M

TI: **Mycophenolate** in refractory and relapsing **lupus nephritis**.

SO: American journal of nephrology; VOL: 40 (2); p. 105-12 /2014/

AB: BACKGROUND: **Mycophenolate** (MF) is effective as induction and maintenance treatment in patients with **lupus nephritis** (LN). This **study** evaluates the efficacy and safety of MF in patients with refractory and relapsing LN.
METHODS: Data were retrospectively obtained for 85 patients (35 refractory and 50 relapsing) from 11 nephrology departments in Spain. The primary endpoints were the incidence and cumulative number of renal responses and relapses and their relationship with baseline **clinical** and analytical data. The secondary endpoint was the appearance of side effects.
RESULTS: The main **clinical** and analytical variables were similar both in refractory and relapsing LN. Most of the patients had received cyclophosphamide, and all of them switched to MF. 74 patients (87%) achieved a response (69% partial, 31% complete). Age at starting MF, gender, pathological classification, body mass index, blood pressure, baseline renal function, and proteinuria were not associated with achieving response. After stopping MF, 3 of 19 patients (15.7%) relapsed, all at 6 months of follow-up. No differences were found between **clinical** and analytical variables and number of relapses. Side effects were unremarkable, except for 1 patient, who died of thrombocytopenia and ovarian hemorrhage.
CONCLUSIONS: Switching to MF from other immunosuppressive treatments is effective and safe in refractory and relapsing LN.

Fulltext Information

13/6 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Ward MM

TI: Recent **clinical** trials in **lupus nephritis**.

SO: Rheumatic diseases clinics of North America; VOL: 40 (3); p. 519-35, ix /201408/

AB: Recent **clinical** trials have provided evidence for the efficacy of low-dose intravenous cyclophosphamide and **mycophenolate mofetil** as induction treatment for patients with proliferative **lupus nephritis** in comparative trials with standard-dose intravenous cyclophosphamide. Trials of maintenance treatments have had more variable results, but suggest that the efficacy of **mycophenolate mofetil** may be similar to that of quarterly standard-dose intravenous cyclophosphamide and somewhat more efficacious than azathioprine. Differential responses to **mycophenolate mofetil** based on ethnicity suggest that it may be more effective in black and Hispanic patients. Rituximab was not

efficacious as an adjunct to induction treatment with **mycophenolate mofetil**.

Fulltext Information

13/7 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Furie R; Nicholls K; Cheng TT; Houssiau F; Burgos-Vargas R; Chen SL; Hillson JL; Meadows-Shropshire S; Kinaszczuk M; Merrill JT

TI: Efficacy and safety of abatacept in **lupus nephritis**: a twelve-month, **randomized**, double-blind **study**.

SO: Arthritis & rheumatology (Hoboken, N.J.); VOL: 66 (2); p. 379-89 /201402/

AB: OBJECTIVE: To compare the efficacy and safety of intravenous (IV) abatacept, a selective T cell costimulation modulator, versus placebo for the treatment of active class III or IV **lupus nephritis**, when used on a background of **mycophenolate mofetil** and glucocorticoids.
METHODS: This was a 12-month, **randomized**, phase II/III, **multicenter**, international, double-blind **study**. A total of 298 patients were treated in 1 of 3 IV treatment arms: placebo, abatacept at the standard weight-tiered dose (approximating 10 mg/kg), or abatacept at 30 mg/kg for 3 months, followed by the standard weight-tiered dose (abatacept 30/10). The primary end point, time to confirmed complete response, was a composite measure that required maintenance of glomerular filtration rate, minimal proteinuria, and inactive urinary sediment over the 52-week treatment period.
RESULTS: There were no differences among treatment arms in the time to confirmed complete response or in the proportion of subjects with confirmed complete response following 52 weeks of treatment. Treatment with abatacept was associated with greater improvements from baseline in anti-double-stranded DNA antibody, C3, and C4 levels. Among 122 patients with nephrotic-range proteinuria, treatment with abatacept resulted in an ~20-30% greater reduction in mean urinary protein-to-creatinine ratio compared with placebo. Abatacept was well tolerated; rates of deaths, serious adverse events, and serious infections were similar across treatment arms. Gastroenteritis and herpes zoster occurred more frequently with abatacept treatment.
CONCLUSIONS: Although the primary end point was not met, abatacept showed evidence of biologic activity and was well tolerated in patients with active class III or IV **lupus nephritis**.

Fulltext Information

13/8 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Moroni G; Raffiotta F; Trezzi B; Giglio E; Mezzina N; Del Papa N; Meroni P; Messa P; Sinico AR

TI: Rituximab vs **mycophenolate** and vs cyclophosphamide pulses for induction therapy of active **lupus nephritis**: a **clinical** observational **study**.

SO: Rheumatology (Oxford, England); VOL: 53 (9); p. 1570-7 /201409/

AB: OBJECTIVE: We report the first comparison between rituximab (RTX) and either MMF or CYC pulses in the treatment of active LN.
METHODS: Fifty-four patients with active LN received three methylprednisolone pulses for 3 consecutive days followed by oral prednisone and RTX 1 g at days 3 and 18 (17 patients) or MMF 2-2.5 g/day (17 patients) or six CYC pulses (0.5 g every fortnight) (20 patients). At 4 months MMF, AZA or ciclosporin were associated to prednisone as a consolidation/maintenance therapy in all groups. The outcomes of the three groups were compared at 3 and 12 months.
RESULTS: Patients in the RTX group were older, had a longer duration of SLE and LN, had more renal flares, had higher activity and had higher chronicity indexes at renal biopsy than the other two groups. Four patients in each group had acute renal dysfunction and ~50% had nephrotic syndrome. At 3 months, proteinuria was reduced by 50% in 58.8% of patients on RTX, in 64.7% on MMF and in 63.1% on CYC. At 12 months, complete remission was present in 70.6% of patients on RTX, in 52.9% on MMF, and in 65% on CYC. Partial remission was reached in 29.4% on RTX, 41.2% on MMF, and 25% on CYC.
CONCLUSIONS: RTX seems to be at least as effective as MMF and CYC pulses in

inducing remission. Considering that patients treated with RTX had more negative renal prognostic factors, this drug should be considered a viable alternative for the treatment of active LN.

Fulltext Information

13/9 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Condon MB; Ashby D; Pepper RJ; Cook HT; Levy JB; Griffith M; Cairns TD; Lightstone L

TI: Prospective observational single-centre cohort **study** to evaluate the effectiveness of treating **lupus nephritis** with rituximab and **mycophenolate mofetil** but no oral steroids.

SO: Annals of the rheumatic diseases; VOL: 72 (8); p. 1280-6 /201308/

AB: OBJECTIVE (OBJECTIVES): **Lupus nephritis** (LN) is a serious complication of systemic **lupus** erythematosus (SLE). All current treatment regimens include oral steroids, which are associated with severe adverse events and long-term damage. We have piloted a steroid-avoiding protocol (rituxilup) for the treatment of biopsy-proven active International Society of Nephrology/Renal Pathology Society (ISN/RPS) class III, IV, or class V LN.
METHODS: We report the findings from the first 50 consecutive patients, treated with 2 doses of rituximab (1 g) and methyl prednisolone (500 mg) on days 1 and 15, and maintenance treatment of **mycophenolate mofetil**. Patients on maintenance steroids or with life-threatening SLE or requiring dialysis were excluded. Renal remission was defined as serum creatinine no greater than 15% above baseline; complete biochemical remission (CR) was defined as urine protein : creatinine ratio (PCR)< 50 mg/mmol or partial remission (PR) if PCR> 50 mg/mmol but non-nephrotic and > 50% reduction.
RESULTS: A total of 45 (90%) patients achieved CR or PR by a median time of 37 weeks (range 4-200). Overall, 72% (n=36) achieved CR (median time 36 weeks (11-58)) and a further 18% (n=9) achieved persistent PR (median time 32 weeks (19-58)). By 52 weeks, CR and PR had been achieved in 52% (n=26) and 34% (n=17) respectively. In all, 12 relapses occurred in 11 patients, at a median time of 65.1 weeks (20-112) from remission. A total of 6/50 patients had systemic flares. Of the 45 responders, only 2 required > 2 weeks of oral steroids. Adverse events were infrequent; 18% were admitted, 10% for an infective episode.
CONCLUSIONS: The rituxilup cohort demonstrates that oral steroids can be safely avoided in the treatment of LN. If findings are confirmed, it could mark a step change in the approach to the treatment of LN.

Fulltext Information

13/10 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Mysler EF; Spindler AJ; Guzman R; Bijl M; Jayne D; Furie RA; Houssiau FA; Drappa J; Close D; Maciuca R; Rao K; Shahdad S; Brunetta P

TI: Efficacy and safety of ocrelizumab in active proliferative **lupus nephritis**: results from a **randomized**, double-blind, phase III **study**.

SO: Arthritis and rheumatism; VOL: 65 (9); p. 2368-79 /201309/

AB: OBJECTIVE: To investigate the efficacy and safety of ocrelizumab in patients with class III/IV **lupus nephritis** (LN).
METHODS: Patients were **randomized** 1:1:1 to receive placebo, 400 mg ocrelizumab, or 1,000 mg ocrelizumab given as an intravenous infusion on days 1 and 15, followed by a single infusion at week 16 and every 16 weeks thereafter, accompanied by background glucocorticoids plus either **mycophenolate mofetil** (MMF) or the Euro-**Lupus Nephritis Trial** (ELNT) regimen (cyclophosphamide followed by azathioprine). The **study** was terminated early due to an imbalance in serious infections in ocrelizumab-treated patients versus placebo-treated patients. We report week 48 efficacy data for patients receiving > =32 weeks of treatment (n = 223) and safety results for all treated patients (n = 378).
RESULTS: The overall renal response rate was 54.7%, 66.7%, 67.1%, and 66.9% in the placebo-treated, 400 mg ocrelizumab-treated, 1,000 mg ocrelizumab-treated, and combined ocrelizumab-treated groups, respectively. The associated

treatment difference versus placebo for the combined ocrelizumab-treated groups was 12.7% (95% confidence interval [95% CI] -0.8, 26.1) (P = 0.065), with similar differences observed for both ocrelizumab-treated groups. Ocrelizumab versus placebo treatment differences were apparent in patients receiving the background ELNT regimen, but not in those receiving background MMF. A numerically greater proportion of ocrelizumab-treated patients had a > =50% reduction in the urinary protein:urinary creatinine ratio at 48 weeks compared with placebo-treated patients (placebo-treated patients, 58.7%; 400 mg ocrelizumab-treated patients, 70.7%; 1,000 mg ocrelizumab-treated patients, 68.5%). Serious adverse events occurred in 27.2% of placebo-treated patients, 35.7% of 400 mg ocrelizumab-treated patients, and 22.0% of 1,000 mg ocrelizumab-treated patients. Corresponding serious infection rates (events/100 patient-years) were 18.7 (95% CI 12.2, 28.7), 28.8 (95% CI 20.6, 40.3), and 25.1 (95% CI 17.4, 36.1), respectively. The imbalance in serious infections with ocrelizumab occurred with background MMF but not with the background ELNT regimen.
CONCLUSIONS: In patients with active LN, overall renal response rates with ocrelizumab were numerically but not statistically significantly superior to those with placebo. Ocrelizumab treatment was associated with a higher rate of serious infections in the subgroup receiving background MMF.

Fulltext Information

13/11 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Kittanamongkolchai W; Rukrung C; Supasiri T; Lertjirachai I; Somparn P; Chariyavilaskul P; Avihingsanon Y

TI: Therapeutic drug monitoring of **mycophenolate mofetil** for the treatment of severely active **lupus nephritis**.

SO: Lupus; VOL: 22 (7); p. 727-32 /201306/

AB: BACKGROUND: Plasma **mycophenolic acid** (MPA) concentrations may predict therapeutic response in active **lupus nephritis** (LN). We determined the efficacy and safety of a concentration-**controlled** MPA regime in the treatment of severely active LN.
METHODS: In this prospective **study**, 19 biopsy-proven class III/IV LN patients were treated with **mycophenolate mofetil** (MMF) for 48 weeks. The MMF dosage was based on maximal plasma MPA concentration at 1-hour post dose (MPA-C1). All patients had plasma MPA-C1 levels monitored weekly until achieving the targeted level of > 13 mg/L. A low-dose steroid protocol was started at 0.5 mg/kg/day and rapidly tapered to 5 mg/day. Therapeutic response was evaluated at week 24 and week 48. MPA area-under-the curve (MPA-AUC0-12h) was measured at week 12 to verify the optimum dosage.
RESULTS: No death or end-stage kidney disease occurred in this **study**. Seventeen patients (89%) responded to therapy at week 24 with four (21%) patients having complete response. There was no renal relapse at week 48 and four more patients had converted from partial response to complete response. Seventy eight percent of patients achieved the recommended MPA-AUC0-12h level. No association between plasma MPA concentrations and adverse reactions or infections was found.
CONCLUSIONS: MPA-C1 may be a practical monitoring of MPA levels in patients with LN. It is convenient to monitor and may facilitate an optimum estimate of MPA exposure.

Fulltext Information

13/12 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Wofsy D; Hillson JL; Diamond B

TI: Comparison of alternative primary outcome measures for use in **lupus nephritis clinical** trials.

SO: Arthritis and rheumatism; VOL: 65 (6); p. 1586-91 /201306/

AB: OBJECTIVE: **Clinical** trials of therapies for **lupus nephritis** have used many different primary outcome measures, ranging from complete response to time to

end-stage renal disease. The objective of this **study** was to compare several possible outcome measures, using data from a large, **multicenter trial** of abatacept in **lupus nephritis**, to gain insight into which outcome measure, if any, was best able to discern differences among treatment groups.
METHODS: **Study** patients received either abatacept or placebo, on a background of **mycophenolate mofetil** and glucocorticoids. Using data from this **trial**, the following primary outcome measures at 24 and 52 weeks were compared: complete response rate, major **clinical** response rate, total response rate (complete plus partial response), improvement in proteinuria, improvement in estimated glomerular filtration rate, and frequency of treatment failure. Time to complete response was also evaluated.
RESULTS: Complete response rate, major **clinical** response rate, and time to complete response were the measures that best discriminated between the abatacept groups and placebo, and the sensitivities of these 3 measures were comparable. For these measures, sample sizes of 50 patients would have been sufficient to demonstrate a statistically significant difference between treatment and control at 52 weeks. Each of the other measures also discriminated between treatment and control, but much larger group sizes would have been required to determine statistical significance.
CONCLUSIONS: The choice of primary outcome measure can substantially influence the ability to detect therapeutic benefit in **lupus nephritis** trials. This **study** suggests that complete response rate, major **clinical** response rate at 52 weeks, and time to complete response may be the most sensitive outcome measures for detecting differences among therapeutic regimens.

Fulltext Information

13/13 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Hui M; Garner R; Rees F; Bavakunji R; Daniel P; Varughese S; Srikanth A; Andres M; Pearce F; Leung J; Lim K; Regan M; Lanyon P

TI: **Lupus nephritis**: a 15-year multi-centre experience in the UK.

SO: Lupus; VOL: 22 (3); p. 328-32 /201303/

AB: OBJECTIVE (OBJECTIVES): Our aim was to audit the outcome of **lupus nephritis** (LN) at three East Midlands centres.
METHODS: We undertook a retrospective review of all biopsy-proven LN types III-V 1995-2010.
RESULTS: In total, 61 patients with LN were identified, with a median follow-up of 68 months. LN was present at the time of systemic **lupus** erythematosus (SLE) diagnosis in 20 patients. The median time from SLE diagnosis to the first LN episode was 5.3 years. Some 35 patients received IV cyclophosphamide and 17 received **mycophenolate mofetil** (MMF) as induction therapy; 81.8% of those treated with cyclophosphamide and 81.3% with MMF had at least 'improved' according to the ACR-response criteria 6 months from induction; 33.3% and 37.5%, respectively, had a 'complete' response. MMF and azathioprine were the most frequently used maintenance therapy. We found that 32.8% experienced a flare after a mean post-induction time of 3.5 years, irrespective of the maintenance therapy used, and 43.8% of partial responders flared compared with 4.8% of complete responders. End-stage renal failure developed in 8.2%.
CONCLUSIONS: Overall, outcomes (response, flare-rate, end-stage renal failure) were comparable with European **clinical** studies. Partial responders are more likely to flare compared with complete responders. The results highlight that LN can occur, and flare, after many years of SLE, emphasizing the importance of continued vigilance for LN in all patients.

Fulltext Information

13/14 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Walsh M; Solomons N; Lisk L; Jayne DR

TI: **Mycophenolate mofetil** or intravenous cyclophosphamide for **lupus nephritis** with poor kidney function: a subgroup analysis of the Aspreva **Lupus** Management **Study**.

SO: American journal of kidney diseases : the official journal of the National Kidney Foundation; VOL: 61 (5); p. 710-5 /201305/

AB: BACKGROUND: **Mycophenolate mofetil** (MMF) frequently is used as an alternative to intravenous cyclophosphamide to treat **lupus nephritis**. Whether MMF is adequate for patients with severely decreased kidney function at the time of treatment is uncertain.
METHODS (**STUDY** DESIGN): We conducted a post hoc subgroup analysis of patients with low estimated glomerular filtration rates (eGFRs) from a large **trial** of MMF compared to cyclophosphamide in **lupus nephritis**.
METHODS (SETTINGS & PARTICIPANTS): We included all patients with an eGFR < 30 mL/min/1.73 m(2) from the Aspreva **Lupus** Management **Study** (ALMS).
METHODS (INTERVENTION): MMF (target, 3 g/d) compared to monthly intravenous cyclophosphamide (0.5-1 g/m(2)).
RESULTS (OUTCOMES): We compared the proportion of patients that responded to therapy and change in eGFR over 24 weeks.
METHODS (MEASUREMENTS): Response was evaluated by a decrease in proteinuria and stabilization or improvement of serum creatinine level.
RESULTS: Of 370 patients in ALMS, 32 were included in the subgroup analysis: 20 randomly assigned to MMF and 12 randomly assigned to cyclophosphamide treatment. The patients included were similar at baseline between groups. Four (20.0%) patients treated with MMF responded compared with 2 (16.7%) patients treated with cyclophosphamide (risk ratio, 1.2; 95% CI, 0.3-5.1; P = 0.9). eGFR in the MMF group improved more quickly than in the cyclophosphamide group, by 1.51 (95% CI, 0.99-2.02) mL/min/1.73 m(2) each week (P < 0.001). Serious adverse events occurred in 9 (45.0%) MMF-treated patients and 7 (63.6%) cyclophosphamide-treated patients (P = 0.5).
CONCLUSIONS (LIMITATIONS): Small sample size and post hoc subgroup of a larger **trial**.
CONCLUSIONS: We did not detect a difference in the primary outcome of response in patients with low eGFR treated with MMF or cyclophosphamide. However, MMF may result in quicker recovery of kidney function compared with those treated with cyclophosphamide. Larger studies including more patients with poor kidney function are warranted.

Fulltext Information

13/15 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Dooley MA; Houssiau F; Aranow C; D'Cruz DP; Askanase A; Roth DA; Zhong ZJ; Cooper S; Freimuth WW; Ginzler EM

TI: Effect of belimumab treatment on renal outcomes: results from the phase 3 belimumab **clinical** trials in patients with SLE.

SO: Lupus; VOL: 22 (1); p. 63-72 /201301/

AB: A pooled post-hoc analysis of the phase 3, **randomized**, placebo-**controlled** BLISS trials (1684 patients with active systemic **lupus** erythematosus (SLE)) was performed to evaluate the effect of belimumab on renal parameters in patients with renal involvement at baseline, and to explore whether belimumab offered additional renal benefit to patients receiving **mycophenolate mofetil** at baseline. In addition to belimumab or placebo, all patients received standard SLE therapy. Patients with severe active **lupus nephritis** were excluded from the trials. Over 52 weeks, rates of renal flare, renal remission, renal organ disease improvement (assessed by Safety of Estrogens in **Lupus** Erythematosus National Assessment-Systemic **Lupus** Erythematosus Disease Activity Index and British Isles **Lupus** Assessment Group), proteinuria reduction, grade 3/4 proteinuria, and serologic activity favored belimumab, although the between-group differences in most renal outcomes were not significant. Among the 267 patients with renal involvement at baseline, those receiving **mycophenolate mofetil** or with serologic activity at baseline had greater renal organ disease improvement with belimumab than with placebo. Limitations of this analysis included the small patient numbers and the post-hoc nature of this pooled analysis. The results suggest that belimumab may offer renal benefit in patients with SLE. Further **study** is warranted in patients with severe active **lupus nephritis**.

Fulltext Information

13/16 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Miettunen PM; Pistorio A; Palmisani E; Ravelli A; Silverman E; Oliveira S; Alessio M; Cuttica R; Mihaylova D; Espada G; Pasic S; Insalaco A; Ozen S; Porras O; Sztajnbok F; Lazarevic D; Martini A; Ruperto N

TI: Therapeutic approaches for the treatment of renal disease in juvenile systemic **lupus** erythematosus: an international multicentre PRINTO **study**.

SO: Annals of the rheumatic diseases; VOL: 72 (9); p. 1503-9 /20130901/

AB: OBJECTIVE (OBJECTIVES): To evaluate therapeutic approaches and response to therapy in juvenile systemic **lupus** erythematosus (SLE) with renal involvement in a large prospective international cohort from four geographic areas.
METHODS: New onset and flared patients with active renal disease (proteinuria > =0.5 g/24 h) were enrolled in 2001-2004. Therapeutic approaches and disease activity parameters were analysed at baseline, 6, 12 and 24 months. Response was assessed by the PRINTO/ACR criteria.
RESULTS: 218/557 (79.8% female subjects, 117 new onset and 101 flared) patients with active renal disease were identified; 66 patients were lost to follow-up and 11 died. Mean age at disease onset for new onset group was higher than for flared group (13.1 vs 10.2 years, p< 0.0001). At baseline, both groups had similar renal activity with similar median doses of corticosteroids (1.0-0.76 mg/kg/day). Cyclophosphamide (43.1%) and azathioprine (22%) were the most common immunosuppressive drugs. At baseline, South American patients received higher doses of corticosteroids than in other areas in new onset (median 1.16 vs 0.8-1 mg/kg/day) while cyclophosphamide use was similar in all four regions in the new onset group. There were no differences regarding the use of azathioprine or **mycophenolate mofetil** worldwide. PRINTO 70 response was reached in a greater percentage of new onset versus flared patients (74.8% vs 53.3%; p=0.005) at 6 months while at 24 months ACR 90 was reached by 69.9% and 56.1%, respectively.
CONCLUSIONS: New onset and flared juvenile SLE improved similarly over 24 months with minimal differences in therapeutic approaches worldwide.

Fulltext Information

13/17 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Schmalzing M; Kötter I

TI: Mycophenolat scheint Azathioprin in der Erhaltungstherapie bei Lupusnephritis überlegen.
[**Mycophenolate mofetil** seems to be superior to azothioprine in maintenance therapy of **lupus nephritis**].

SO: Zeitschrift fur Rheumatologie; VOL: 71 (9); p. 813-5 /201211/

Fulltext Information

13/18 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Sundel R; Solomons N; Lisk L

TI: Efficacy of **mycophenolate mofetil** in adolescent patients with **lupus nephritis**: evidence from a two-phase, prospective **randomized trial**.

SO: Lupus; VOL: 21 (13); p. 1433-43 /201211/

AB: The safety and efficacy of **mycophenolate mofetil** (MMF) were evaluated in adolescent patients with systemic **lupus** erythematosus and active or active/chronic class III-V **lupus nephritis**. During the 24-week induction phase, patients were **randomized** to oral MMF (target dose 3.0 g/day) or intravenous cyclophosphamide (IVC) (0.5-1.0 g/m(2)/month), plus prednisone. Response was defined as a decrease in 24-hour urine protein:creatinine ratio (P:Cr) to < 3 in patients with baseline nephrotic range proteinuria, or by > = 50% if subnephrotic baseline proteinuria, and stabilization (± 25%) or improvement in serum creatinine. In the 36-month maintenance phase, induction therapy responders were **randomized** 1:1 to MMF (1.0 g twice daily) or oral azathioprine (AZA) (2

mg/kg/day), plus prednisone. In the induction phase, 10 patients received MMF and 14 received IVC; 15 (62.5%) achieved treatment response (MMF, 7 (70%); IVC, 8/15 (57.1%); p = 0.53, odds ratio (95% confidence interval) 2.0 (0.2, 15.5)). There was a non-statistically significant difference in maintenance of response to MMF (7/8; 87.5%) versus AZA (3/8; 37.5%). Seven patients withdrew (MMF, 2; AZA, 5). During both phases, rates of serious adverse events were similar in both arms. During both phases treatment response with MMF was as effective as the comparator.

Fulltext Information

13/19 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Wofsy D; Hillson JL; Diamond B

TI: Abatacept for **lupus nephritis**: alternative definitions of complete response support conflicting conclusions.

SO: Arthritis and rheumatism; VOL: 64 (11); p. 3660-5 /201211/

AB: OBJECTIVE: Recent **clinical** trials in **lupus nephritis** have all used different criteria to assess complete response. The objective of this analysis was to compare several previously proposed criteria, using the same data set from a large **trial** of abatacept in **lupus nephritis** (IM101075). In so doing, we sought to determine which criteria are most sensitive to differences among treatment groups and to further examine the potential of abatacept in **lupus nephritis**.
METHODS: Patients in the IM101075 **trial** received abatacept at 1 of 2 different dose regimens or placebo, both on a background of **mycophenolate mofetil** and corticosteroids. Using data from this **trial**, we assessed rates of complete response at 12 months according to 5 sets of criteria, from 1) the **trial** protocol, 2) the Aspreva **Lupus** Management **Study** (ALMS) **trial** of **mycophenolate mofetil**, 3) the **Lupus Nephritis** Assessment with Rituximab (LUNAR) **trial** of rituximab, 4) an ongoing National Institutes of Health **trial** of abatacept (Abatacept and Cyclophosphamide Combination: Efficacy and Safety **Study** [ACCESS]), and 5) published recommendations of the American College of Rheumatology.
RESULTS: According to the complete response definition from the IM101075 **study** protocol, there was no difference among treatment groups in the IM101075 **study**. In contrast, according to the ALMS, LUNAR, and ACCESS criteria, rates of complete response among patients in the IM101075 **study** were higher in both treatment groups relative to control. The largest differences were obtained with use of the LUNAR criteria (complete response rate of 6% in the control group, compared to 22% and 24% in the 2 abatacept groups).
CONCLUSIONS: The choice of definition of complete response can determine whether a **lupus nephritis trial** is interpreted as a success or a failure. The results of this analysis provide an evidence-based rationale for choosing among alternative definitions and offer a strong rationale for conducting further studies of abatacept in **lupus nephritis**.

Fulltext Information

13/20 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Weidenbusch M; Römmele C; Schröttle A; Anders HJ

TI: Beyond the LUNAR **trial**. Efficacy of rituximab in refractory **lupus nephritis**.

SO: Nephrology, dialysis, transplantation : official publication of the European Dialysis and Transplant Association - European Renal Association; VOL: 28 (1); p. 106-11 /201301/

AB: BACKGROUND: The treatment of **lupus nephritis** (LN) remains problematic because the current treatment regimen based on unspecific immunosuppressants such as steroids, cyclophosphamide and **mycophenolate** has significant side effects and is often inefficient. B-cell ablation with the chimeric anti-CD20 antibody rituximab (RTX) has been considered as an alternative treatment option but the **randomized controlled** LUNAR **trial** failed to show any additive effect of RTX beyond a steroid-**mycophenolate mofetil** (MMF) combination for LN type III/IV/V in incident patients. At present, no such **trial** is available for the use of

RTX in refractory LN.
METHODS: We analysed existing evidence on this topic by performing a systematic analysis of reports that document outcomes of RTX treatment for refractory LN.
RESULTS: Out of 233 reports, we selected 26 for analysis, which described 300 patients with a mean follow-up of 60 weeks. The complete or partial response criteria were met by 87% of patients with LN class III, 76% with class IV and 67% with class V, respectively. Mixed classes responded in 76% of patients. RTX induced complete responses in 60% (type III), 45% (type IV), 40% (type V) and 24% (mixed types), respectively.
CONCLUSIONS: Our systematic review of existing evidence suggests that RTX effectively induces remission of LN in patients who have not achieved remission with standard therapies. Another **randomized controlled trial** should be conducted to test the efficacy of RTX in refractory LN.

Fulltext Information

13/21 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Hogan J; Schwenk MH; Radhakrishnan J

TI: Should **mycophenolate mofetil** replace cyclophosphamide as first-line therapy for severe **lupus nephritis**?

SO: Kidney international; VOL: 82 (12); p. 1256-60 /201212/

AB: Available treatments for severe (class III, IV, and V) **lupus nephritis** (LN) have expanded greatly over the last 40 years. In the 1970s and 1980s, cyclophosphamide (CYC), in combination with glucocorticoids, gained favor as induction and maintenance therapy for severe LN. However, the adverse event profile of CYC led to the search for other medications for severe LN. Beginning in the late 1990 s, **mycophenolate mofetil** (MMF) was introduced as induction and maintenance therapy for severe LN. This review discusses the **clinical trial** results, pharmacology, cost-effectiveness, and adverse effect profiles of CYC compared to MMF for induction and maintenance therapy for severe LN. The authors conclude that MMF should be considered first-line induction and maintenance treatment therapy for severe LN, although CYC may have a place under specific **clinical** and economic circumstances.

Fulltext Information

13/22 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Ginzler EM; Wax S; Rajeswaran A; Copt S; Hillson J; Ramos E; Singer NG

TI: Atacicept in combination with MMF and corticosteroids in **lupus nephritis**: results of a prematurely terminated **trial**.

SO: Arthritis research & therapy; VOL: 14 (1); p. R33 /2012/

AB: BACKGROUND (INTRODUCTION): Atacicept is a soluble, fully human, recombinant fusion protein that inhibits B cell-stimulating factors APRIL (a proliferation-inducing ligand) and BLyS (B-lymphocyte stimulator). The APRIL- LN **study** aimed to evaluate the efficacy and safety of atacicept in patients with active **lupus nephritis** (LN), receiving newly initiated corticosteroids (CS) and **mycophenolate mofetil** (MMF).
METHODS: This was a **randomized**, double-blind, placebo-**controlled** Phase II/III, 52-week **study**. At screening (Day -14), patients initiated high-dose CS (the lesser of 0.8 mg/kg/day or 60 mg/day prednisone) and MMF (1 g daily, increased by 1 g/day each week to 3 g daily). From Day 1, atacicept (150 mg, subcutaneously, twice weekly for 4 weeks, then weekly) was initiated with MMF along with a tapered dose of CS.
RESULTS: The **trial** was terminated after the enrollment of six patients, due to an unexpected decline in serum immunoglobulin G (IgG) and the occurrence of serious infections. Efficacy was thus not evaluated. By Day 1, serum IgG levels had declined substantially in patients then **randomized** to atacicept (n = 4) compared with placebo (n = 2). Patients receiving atacicept also had more severe proteinuria on Day -14 than those on placebo. Lymphocyte counts were low at screening in all patients. IgG decline continued following initiation (Day 1) of

atacicept. Three atacicept-treated patients developed serum IgG below the protocol-defined discontinuation threshold of 3 g/l, two of whom developed serious pneumonia.
CONCLUSIONS: Future studies are needed to characterize the safety, efficacy, and pharmacodynamic response of atacicept in LN patients.
BACKGROUND (**TRIAL** REGISTRATION): ClinicalTrials.gov: NCT00573157.

Fulltext Information

13/23 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Yap DY; Yu X; Chen XM; Lu F; Chen N; Li XW; Tang CS; Chan TM

TI: Pilot 24 month **study** to compare **mycophenolate mofetil** and tacrolimus in the treatment of membranous **lupus nephritis** with nephrotic syndrome.

SO: Nephrology (Carlton, Vic.); VOL: 17 (4); p. 352-7 /201205/

AB: OBJECTIVE (AIM): This pilot **study** compared **mycophenolate mofetil** (MMF) and tacrolimus (Tac) in the treatment of severe membranous **lupus nephritis** (MLN).
METHODS: This was a 24 month prospective, **randomized**, open-label multi-centre exploratory **study** on Chinese patients with biopsy-proven pure Class V MLN with nephrotic syndrome. Patients were **randomized** to treatment with either MMF or Tac, both in combination with prednisolone and the efficacy and tolerability outcomes were examined.
RESULTS: Sixteen patients were included, seven in the MMF and nine in the Tac treatment arm. At 24 months the complete response, partial response and overall response rates were 57.1% vs. 11.1% (P = 0.049), 14.3% vs. 44.4% (P = 0.197) and 71.4% vs. 55.6% (P = 0.515) in the MMF and Tac groups, respectively. The two groups had similar reduction of proteinuria and longitudinal profiles of serum albumin and creatinine levels. Serum creatinine remained stable in both groups, except in two patients who had a transient increase associated with high Tac blood levels. Adverse events in the MMF group included herpes zoster in one patient and reversible leucopenia in another, while in the Tac group four patients had severe infections and one developed new onset diabetes. No relapse occurred during the **study** period.
CONCLUSIONS: Both MMF and Tac when combined with corticosteroids are effective treatment options for severe MLN.

Fulltext Information

13/24 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Rovin BH; Furie R; Latinis K; Looney RJ; Fervenza FC; Sanchez-Guerrero J; Maciuca R; Zhang D; Garg JP; Brunetta P; Appel G

TI: Efficacy and safety of rituximab in patients with active proliferative **lupus nephritis**: the **Lupus Nephritis** Assessment with Rituximab **study**.

SO: Arthritis and rheumatism; VOL: 64 (4); p. 1215-26 /201204/

AB: OBJECTIVE: To evaluate the efficacy and safety of rituximab in a **randomized**, double-blind, placebo-**controlled** phase III **trial** in patients with **lupus nephritis** treated concomitantly with **mycophenolate mofetil** (MMF) and corticosteroids.
METHODS: Patients (n = 144) with class III or class IV **lupus nephritis** were **randomized** 1:1 to receive rituximab (1,000 mg) or placebo on days 1, 15, 168, and 182. The primary end point was renal response status at week 52.
RESULTS: Rituximab depleted peripheral CD19+ B cells in 71 of 72 patients. The overall (complete and partial) renal response rates were 45.8% among the 72 patients receiving placebo and 56.9% among the 72 patients receiving rituximab (P = 0.18); partial responses accounted for most of the difference. The primary end point (superior response rate with rituximab) was not achieved. Eight placebo-treated patients and no rituximab-treated patients required cyclophosphamide rescue therapy through week 52. Statistically significant improvements in serum complement C3, C4, and anti-double-stranded DNA (anti-dsDNA) levels were observed among patients treated with rituximab. In both treatment groups, a reduction in anti-dsDNA levels greater than the median reduction was associated with reduced proteinuria. The rates of serious adverse

events, including infections, were similar in both groups. Neutropenia, leukopenia, and hypotension occurred more frequently in the rituximab group.
CONCLUSIONS: Although rituximab therapy led to more responders and greater reductions in anti-dsDNA and C3/C4 levels, it did not improve **clinical** outcomes after 1 year of treatment. The combination of rituximab with MMF and corticosteroids did not result in any new or unexpected safety signals.

Fulltext Information

13/25 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Stoenoiu MS; Aydin S; Tektonidou M; Ravelingien I; le Guern V; Fiehn C; Remy P; Delahousse M; Petera P; Quémeneur T; Vasconcelos C; D'Cruz D; Gilboe IM; Jadoul M; Karras A; Depresseux G; Guillevin L; Cervera R; Cosyns JP; Houssiau FA

TI: Repeat kidney biopsies fail to detect differences between azathioprine and **mycophenolate mofetil** maintenance therapy for **lupus nephritis**: data from the MAINTAIN **Nephritis Trial**.

SO: Nephrology, dialysis, transplantation : official publication of the European Dialysis and Transplant Association - European Renal Association; VOL: 27 (5); p. 1924-30 /201205/

AB: BACKGROUND: In the MAINTAIN **Nephritis Trial**, azathioprine (AZA) and **mycophenolate mofetil** (MMF) were compared as maintenance immunosuppressive treatment of proliferative **lupus nephritis** (LN) after a short-course of intravenous cyclophosphamide. Here, we compare the pathological findings on repeat kidney biopsies between the two groups.
METHODS: Per protocol, repeat renal biopsies were obtained in 30 patients (16 AZA and 14 MMF) at 2 years (±6 months). Baseline and follow-up biopsies were graded according to the International Society of Nephrology/Renal Pathological Society (ISN/RPS) classification. The activity and chronicity indices (AI, CI) were calculated using two different semiquantitative scoring systems (Morel-Maroger and National Institutes of Health). Statistics were performed by non-parametric tests.
RESULTS: The **clinical** characteristics of the 30 re-biopsied patients only marginally differ from the entire MAINTAIN cohort (105 patients). **Clinical** baseline and follow-up characteristics of AZA- and MMF-treated re-biopsied patients did not differ. Time (SD) to repeat renal biopsy was 25.0 (2.0) and 26.5 (3.3) months in AZA and MMF patients, respectively. More patients had normal renal biopsies or Classes I/II/V LN at follow-up compared to baseline and conversely, less patients had Class IV LN at follow-up. In both groups, the AI statistically decreased at follow-up compared to baseline, while the CI slightly, but significantly, increased. No differences could be detected between the groups.
CONCLUSIONS: Centralized pathological analyses, including ISN/RPS classification and comparisons of AI/CI, failed to find differences between MMF and AZA at 2 years, a result well in line with the absence of difference in long-term **clinical** outcome reported elsewhere.

Fulltext Information

13/26 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Dooley MA; Jayne D; Ginzler EM; Isenberg D; Olsen NJ; Wofsy D; Eitner F; Appel GB; Contreras G; Lisk L; Solomons N

TI: **Mycophenolate** versus azathioprine as maintenance therapy for **lupus nephritis**.

SO: The New England journal of medicine; VOL: 365 (20); p. 1886-95 /20111117/

AB: BACKGROUND: Maintenance therapy, often with azathioprine or **mycophenolate mofetil**, is required to consolidate remission and prevent relapse after the initial control of **lupus nephritis**.
METHODS: We carried out a 36-month, **randomized**, double-blind, double-dummy, phase 3 **study** comparing oral **mycophenolate mofetil** (2 g per day) and oral azathioprine (2 mg per kilogram of body weight per day), plus placebo in each group, in patients who met response criteria during a 6-month induction **trial**. The **study** group underwent repeat randomization in a 1:1 ratio. Up to 10

mg of prednisone per day or its equivalent was permitted. The primary efficacy end point was the time to treatment failure, which was defined as death, end-stage renal disease, doubling of the serum creatinine level, renal flare, or rescue therapy for **lupus nephritis**. Secondary assessments included the time to the individual components of treatment failure and adverse events.
RESULTS: A total of 227 patients were randomly assigned to maintenance treatment (116 to **mycophenolate mofetil** and 111 to azathioprine). **Mycophenolate mofetil** was superior to azathioprine with respect to the primary end point, time to treatment failure (hazard ratio, 0.44; 95% confidence interval, 0.25 to 0.77; P = 0.003), and with respect to time to renal flare and time to rescue therapy (hazard ratio, < 1.00; P < 0.05). Observed rates of treatment failure were 16.4% (19 of 116 patients) in the **mycophenolate mofetil** group and 32.4% (36 of 111) in the azathioprine group. Adverse events, most commonly minor infections and gastrointestinal disorders, occurred in more than 95% of the patients in both groups (P = 0.68). Serious adverse events occurred in 33.3% of patients in the azathioprine group and in 23.5% of those in the **mycophenolate mofetil** group (P = 0.11), and the rate of withdrawal due to adverse events was higher with azathioprine than with **mycophenolate mofetil** (39.6% vs. 25.2%, P = 0.02).
CONCLUSIONS: **Mycophenolate mofetil** was superior to azathioprine in maintaining a renal response to treatment and in preventing relapse in patients with **lupus nephritis** who had a response to induction therapy. (Funded by Vifor Pharma [formerly Aspreva]; ALMS ClinicalTrials.gov number, NCT00377637.).

Fulltext Information

13/27 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Zeher M; Doria A; Lan J; Aroca G; Jayne D; Boletis I; Hiepe F; Prestele H; Bernhardt P; Amoura Z

TI: Efficacy and safety of enteric-coated **mycophenolate** sodium in combination with two glucocorticoid regimens for the treatment of active **lupus nephritis**.

SO: Lupus; VOL: 20 (14); p. 1484-93 /201112/

AB: **Mycophenolic acid**, in combination with glucocorticoids, has been shown in a series of trials to be safe and effective for treatment of **lupus nephritis**. Regimens that permit glucocorticoid dose reduction without loss of efficacy would be advantageous. MyLupus was a 24-week, multicentre, open-label, **study** in patients with active proliferative **lupus nephritis** treated with enteric-coated **mycophenolate** sodium (EC-MPS), **randomized** to standard-dose (n = 42) or reduced-dose (n = 39) glucocorticoids. Complete response at week 24, the primary endpoint, was achieved in 19.8% (16/81) of patients (19.0% standard-dose, 20.5% reduced-dose; lower limit of 97.5% CI for the difference -15.9%, p = 0.098, i.e. non-inferiority was not shown). Partial response occurred in 42.0% of patients (34/81). From baseline to week 24, the mean global British Isles **Lupus** Assessment Group (BILAG) score decreased from 14.0 ± 5.4 to 5.0 ± 3.8 (p < 0.001). The incidence of adverse events was 80.2% (65/81), most frequently gastrointestinal complications (31/81, 38.3%). Infections were reported in 57.1% and 35.9% of standard- and reduced-dose glucocorticoid patients, respectively (p = 0.056), with herpes zoster in 16.7% and 0% (p = 0.012). Three patients discontinued **study** medication due to adverse events. This exploratory **study** suggests that EC-MPS may facilitate glucocorticoid reduction without loss of efficacy in patients with active **lupus nephritis**, but results require confirmation in a **controlled**, longer-term **study** versus the current standard of care.

Fulltext Information

13/28 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Koo HS; Kim YC; Lee SW; Kim DK; Oh KH; Joo KW; Kim YS; Ahn C; Han JS; Kim S; Chin HJ

TI: The effects of cyclophosphamide and **mycophenolate** on end-stage renal disease and death of **lupus nephritis**.

SO: Lupus; VOL: 20 (13); p. 1442-9 /201111/

AB: Debate continues about the optimal treatment modality of **lupus nephritis** (LN). We compared the efficacy and safety of intravenous cyclophosphamide (CYC) and **mycophenolate mofetil** (MMF) for LN treatment in Korea. After searching for systemic **lupus** erythematosus (SLE) patients diagnosed between 1998 and 2007 with the diagnostic code of ICD10, we selected the 71 patients who were treated with CYC or MMF without any other immunosuppressant except systemic steroid. Composite outcome was defined as progression to end-stage renal disease (ESRD) and/or all-cause mortality. The initial manifestations of the CYC group were more severe than those of the MMF group. The mean daily MMF dose was 980 ± 100 mg for 21.67 ± 18.25 months. The mean monthly dose per CYC pulse therapy was 850 ± 30 mg for 17.04 ± 13.15 months. The incidence of composite outcome was 5/20 (25%) in the MMF group and 4/51 (7.8%) in the CYC group. The relative risk (RR) for composite outcome in the CYC group was 0.249 (95% CI for RR: 0.067-0.934, p = 0.039) compared with the MMF group with Cox's hazard proportional analysis. In Kaplan-Meier analysis, the probability of composite outcome was lower in the CYC group than in the MMF group (Log rank test p-value = 0.026). The results of this retrospective **study** suggest that intravenous CYC therapy may be more efficacious in averting ESRD and death than MMF. These results need to be confirmed in a larger **randomized controlled trial**.

Fulltext Information

13/29 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Li X; Ren H; Zhang Q; Zhang W; Wu X; Xu Y; Shen P; Chen N

TI: **Mycophenolate mofetil** or tacrolimus compared with intravenous cyclophosphamide in the induction treatment for active **lupus nephritis**.

SO: Nephrology, dialysis, transplantation : official publication of the European Dialysis and Transplant Association - European Renal Association; VOL: 27 (4); p. 1467-72 /201204/

AB: BACKGROUND: Although the use of aggressive immunosuppression has improved both patient and renal survival of patients with **lupus nephritis** (LN), the optimal treatment of LN remains challenging. The objective of this **study** is to assess the efficacy and safety of **mycophenolate mofetil** (MMF) and tacrolimus compared with intravenous cyclophosphamide (IVC) as induction therapies for active **lupus nephritis** (ALN).
METHODS: In this open-label, 24-week prospective **study**, 60 patients with biopsy-proven ALN (Classes III, IV, V or combination) were randomly assigned to receive MMF, tacrolimus or IVC in combination with corticosteroids. The remission of proteinuria, systemic **lupus** erythematosus disease active index and adverse events were compared.
RESULTS: The response rates at 24 weeks were 70% (14/20) in the MMF group, 75% (15/20) in the tacrolimus group and 60% (12/20) in the IVC group (P> 0.05). The complete remission rates were also similar in the three groups (40, 45 and 30%, respectively; P> 0.05). There were more cases of infection in the IVC group (8/20) and the MMF group (8/20) than the tacrolimus group (3/20) and more hyperglycemia in the tacrolimus group (5/20) than the other two groups (2 or 3/20), but the results were not statistically significant among the three groups. Proteinuria decreased and serum albumin increased more quickly in the patients treated with tacrolimus (P=0.0051 and P=0.048).
CONCLUSIONS: This pilot **study** suggests that both MMF and tacrolimus are possible alternatives to IVC as induction therapies for ALN in Chinese patients. Tacrolimus possibly results in a faster resolution of proteinuria and hypoalbuminemia. Further studies are necessary to determine the optimal dosage and duration of the therapies.

Fulltext Information

13/30 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Dall'Era M; Stone D; Levesque V; Cisternas M; Wofsy D

TI: Identification of biomarkers that predict response to treatment of **lupus nephritis** with **mycophenolate mofetil** or pulse cyclophosphamide.

SO: Arthritis care & research; VOL: 63 (3); p. 351-7 /201103/

AB: OBJECTIVE: There is a need to identify **clinical** characteristics and/or biomarkers that can predict treatment outcome in **lupus nephritis**. To this end, we utilized data from the Aspreva **Lupus** Management **Study** to identify possible baseline and early predictors of renal response to **mycophenolate mofetil** (MMF) or intravenous (IV) cyclophosphamide (CYC).
METHODS: Patients with class III-V **lupus nephritis** were **randomized** to MMF or IV CYC. We assessed predictors of renal response, including baseline demographic, **clinical**, laboratory, and histologic characteristics, as well as early **clinical** and laboratory data, obtained within the first 2 months of therapy. Odds ratios (ORs) and 95% confidence intervals for renal response were calculated for each putative predictor.
RESULTS: Normalization of C3, C4, or both by week 8 was strongly predictive of renal response at week 24 (ORs 2.5, 2.6, and 2.9, respectively; $P < 0.05$). Reduction in proteinuria by > =25% by week 8 was predictive of renal response at week 24 (OR 3.2, $P < 0.05$). Reduction in anti-double-stranded DNA (anti-dsDNA) by week 8 was not predictive of renal response. Only 3 baseline characteristics (C4 level, time since diagnosis of **lupus nephritis**, and estimated glomerular filtration rate [GFR]) were predictive of renal response; the remaining characteristics (age, age at **lupus nephritis** onset, time since diagnosis of systemic **lupus** erythematosus, sex, histopathologic class, anti-dsDNA antibody level, C3 level, level of proteinuria, and use of angiotensin-converting enzyme inhibitors, statins, or hydroxychloroquine) were not.
CONCLUSIONS: This **study** demonstrates that baseline C4 level, time since diagnosis of **lupus nephritis**, baseline estimated GFR, early normalization of complement, and reduction in proteinuria independently predict renal response to therapy at 6 months.

Fulltext Information

13/31 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Laskari K; Mavragani CP; Tzioufas AG; Moutsopoulos HM

TI: **Mycophenolate mofetil** as maintenance therapy for proliferative **lupus nephritis**: a long-term observational prospective **study**.

SO: Arthritis research & therapy; VOL: 12 (6); p. R208 /2010/

AB: BACKGROUND (INTRODUCTION): While the role of **mycophenolate mofetil** (MMF) in the management of **lupus nephritis** has been increasingly recognized, limited information is available regarding its efficacy and safety as a long-term maintenance treatment. The aim of the present **study** was to evaluate the efficacy and safety profile of MMF as maintenance therapy for proliferative **lupus nephritis**.
METHODS: Thirty-three consecutive patients with proliferative **lupus nephritis** received induction therapy with five to seven monthly intravenous (iv) pulses of cyclophosphamide (CYC) plus iv steroids followed by oral MMF 2 g/day as maintenance therapy for a median time of 29 months (range 9 to 71 months). Primary end points were the achievement of renal remission, complete renal remission, disease remission - renal and extrarenal -, the occurrence of renal relapse, chronic renal failure and death. Secondary end points were the extrarenal disease activity and drug adverse events. The **clinical** and laboratory parameters were compared during follow-up by means of nonparametric statistical tests. Time to event analysis was performed according to the Kaplan-Meier method.
RESULTS: A significant improvement of all renal parameters was observed at the end of the induction treatment and at the latest follow-up compared to baseline. The rate of patients achieving renal remission until the end of follow-up was 73%, whereas that of complete renal remission was 58%. The median survival times in the Kaplan-Meier analyses were 7 and 16 months, respectively. Remission was maintained in all but four (12%) patients who relapsed within 19 to 39 months after initial response. At the end of follow-up, 51% of the patients had reached disease remission. The median survival time of disease remission was 18 months. Extrarenal manifestations were well **controlled** in most of the patients. In one patient receiving MMF, extrarenal activity led to treatment discontinuation. Non

life-threatening drug adverse events developed in 18 patients (58%) and included infections, amenorrhea, myelotoxicity, gastrointestinal complications, hypercholesterolemia, alopecia and drug intolerance. None of the patients developed chronic renal insufficiency or died from any cause.
CONCLUSIONS: MMF appeared to be efficacious and safe as maintenance treatment for proliferative **lupus nephritis**.

Fulltext Information

13/32 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Touma Z; Gladman DD; Urowitz MB; Beyene J; Uleryk EM; Shah PS

TI: **Mycophenolate mofetil** for induction treatment of **lupus nephritis**: a systematic review and **metaanalysis**.

SO: The Journal of rheumatology; VOL: 38 (1); p. 69-78 /201101/

AB: OBJECTIVE: to systematically review the efficacy and safety of **mycophenolic acid** and **mycophenolate mofetil** (MMF) compared to cyclophosphamide (CYC) for the induction treatment of **lupus nephritis** (LN).
METHODS: medline, Embase, the Cochrane Center Register of **Controlled** Trials, and abstracts presented in major international conferences were searched for **randomized controlled** trials. The primary outcome was renal remission (complete, partial, and overall) and secondary outcomes were adverse events during **study** period and longterm followup data. Data were compared between groups and relative risk (RR) and 95% CI were calculated.
RESULTS: four trials of a total of 618 patients were included. MMF was not superior to CYC for renal remission (partial RR 0.94, 95% CI 0.80 to 1.12; complete RR 0.67, 95% CI 0.35 to 1.28, and overall RR 0.89, 95% CI 0.71 to 1.10). There was a significant reduction in alopecia (RR 5.77, 95% CI 1.56 to 21.38) and amenorrhea (RR 6.64, 95% CI 2.00 to 22.07) with the use of MMF compared to CYC. These results should be interpreted with caution given the width of the CI. There was no significant difference for infections, leukopenia, gastrointestinal symptoms, herpes zoster, endstage renal disease, and death among groups during **study** period and longterm followup data.
CONCLUSIONS: we could not show that MMF is superior to CYC for the induction treatment of LN. Patients treated with MMF showed reduced risk of certain side effects. MMF can be used as an alternative to CYC for the induction treatment of LN.

Fulltext Information

13/33 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Houssiau FA; D'Cruz D; Sangle S; Remy P; Vasconcelos C; Petrovic R; Fiehn C; de Ramon Garrido E; Gilboe IM; Tektonidou M; Blockmans D; Ravelingien I; le Guern V; Depresseux G; Guillevin L; Cervera R

TI: Azathioprine versus **mycophenolate mofetil** for long-term immunosuppression in **lupus nephritis**: results from the MAINTAIN **Nephritis Trial**.

SO: Annals of the rheumatic diseases; VOL: 69 (12); p. 2083-9 /201012/

AB: BACKGROUND: Long-term immunosuppressive treatment does not efficiently prevent relapses of **lupus nephritis** (LN). This investigator-initiated randomised **trial** tested whether **mycophenolate mofetil** (MMF) was superior to azathioprine (AZA) as maintenance treatment.
METHODS: A total of 105 patients with **lupus** with proliferative LN were included. All received three daily intravenous pulses of 750 mg methylprednisolone, followed by oral glucocorticoids and six fortnightly cyclophosphamide intravenous pulses of 500 mg. Based on randomisation performed at baseline, AZA (target dose: 2 mg/kg/day) or MMF (target dose: 2 g/day) was given at week 12. Analyses were by intent to treat. Time to renal flare was the primary end point. Mean (SD) follow-up of the intent-to-treat population was 48 (14) months.
RESULTS: The baseline **clinical**, biological and pathological characteristics of patients allocated to AZA or MMF did not differ. Renal flares were observed in 13 (25%) AZA-treated and 10 (19%) MMF-treated patients. Time to renal flare, to severe systemic flare, to benign flare and to renal remission did not statistically

differ. Over a 3-year period, 24 h proteinuria, serum creatinine, serum albumin, serum C3, haemoglobin and global disease activity scores improved similarly in both groups. Doubling of serum creatinine occurred in four AZA-treated and three MMF-treated patients. Adverse events did not differ between the groups except for haematological cytopenias, which were statistically more frequent in the AZA group (p=0.03) but led only one patient to drop out.
CONCLUSIONS: Fewer renal flares were observed in patients receiving MMF but the difference did not reach statistical significance.

Fulltext Information

13/34 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Kazyra I; Pilkington C; Marks SD; Tullus K

TI: **Mycophenolate mofetil** treatment in children and adolescents with **lupus**.

SO: Archives of disease in childhood; VOL: 95 (12); p. 1059-61 /201012/

AB: Safety and efficacy data are presented on the use of **mycophenolate mofetil** (MMF) in 26 children and adolescents with **lupus**. Data include therapy before and 12 months after starting MMF. 18 of 26 patients had biopsy-proved **lupus nephritis**. Group 1 were commenced on MMF induction and/or maintenance therapy (n=14), group 2 converted from azathioprine because of inadequate disease control (n=12). 73% of all (10 (71%) group 1 and 10 (83%) group 2) patients experienced a significant improvement in British Isles **Lupus** Assessment Group score (from median 9.0 to 3.0). Children with hypocomplementaemia increased their C3 significantly in both groups (0.53-1.15 for group 1 and 0.63-1.2 g/l for group 2, p=0.001), and C4 level only in group 1 (0.08-0.17, p=0.01). Renal function and albuminuria improved in those with active **nephritis** (p< =0.01). Significant improvements were seen in both groups in haemoglobin, erythrocyte sedimentation rate and lymphocyte counts. Prednisolone dose was weaned in both groups, p< 0.05. Side-effects were seen in four patients, but none was judged to be severe enough to discontinue treatment. MMF treatment in this cohort of children with **lupus** seemed to be safe, well tolerated and effective.

Fulltext Information

13/35 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Rabrenovic V; Poskurica M; Kovacevic Z; Nesic V; Savin M; Mitic B; Dimkovic N; Cuckovic C; Vujic D; Pljesa S; Perunicic-Pekovic G; Curic S; Mitic I; Ratkovic M; Marinkovic J; Jovanovic D

TI: Treatment of **lupus nephritis** by **mycophenolate mofetil**.

SO: Kidney & blood pressure research; VOL: 33 (4); p. 297-303 /2010/

AB: OBJECTIVE (BACKGROUND/AIMS): **Mycophenolate mofetil** (MMF) has been increasingly used for the treatment of **lupus nephritis** (LN). The aim of this **study** was to examine the efficacy and safety of MMF used with low doses of corticosteroids as maintenance therapy in patients with LN.< /AbstractText>
METHODS: The **study** covered 35 patients, most of them with proliferative types of LN (5 WHO class III, 26 class IV), while 1 had class V and 3 class VI **nephritis**. MMF was administered in the dose of 1.5-2 g/24 h and prednisone at 10-20 mg/day. The treatment effects were followed over a 12-month period.
RESULTS: After 3 months of therapy significant reduction in proteinuria was achieved (2.1 +/- 2.4 g/24 h vs. 1.0 +/- 1.0 g/24 h, p < 0.01) and maintained to the end of the **study**. In parallel, a significant rise in serum albumin, a fall of cholesterol and a significant increase in mean glomerular filtration rate were noted. Complete remission was achieved in 16 patients (45.7%), including all patients in class III and V plus 10 patients in class IV. Not a single adverse effect was observed.
CONCLUSIONS: MMF combined with low doses of steroids is an effective and safe treatment for the maintenance of stable remission of LN.

Fulltext Information

13/36 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Aragon E; Chan YH; Ng KH; Lau YW; Tan PH; Yap HK

TI: Good outcomes with **mycophenolate**-cyclosporine-based induction protocol in children with severe proliferative **lupus nephritis**.

SO: Lupus; VOL: 19 (8); p. 965-73 /201007/

AB: The outcomes of children with severe proliferative **lupus nephritis** (LN) were examined using a new **mycophenolate** and cyclosporine-based (MMF-CSA) induction protocol. Sixteen children with LN (WHO class III and IV), 31.3% of whom required dialysis at induction, were retrospectively studied. Median MMF dose was 942 mg/m(2)/day. Thirteen patients (81%) with persistent proteinuria received CSA. **Clinical** and laboratory parameters were compared at pre-induction, 6 and 12 months. Treatment outcome was defined by Systemic **Lupus** Erythematosus Disease Activity Index (SLEDAI), renal function, haematuria, proteinuria and serological markers (complements C3, C4 and anti-dsDNA). Comparing these parameters at induction, 6 months and 12 months, respectively, SLEDAI (25.4 +/- 8.7 versus 3.2 +/- 2.9 versus 2.9 +/- 2.8), serum C3 (47 +/- 21 versus 107 +/- 27 versus 111 +/- 38 mg/dl), C4 (12 +/- 14 versus 23 +/- 14 versus 22 +/- 11 mg/dl) and urine protein (6.97 +/- 7.09 versus 0.98 +/- 1.56 versus 0.21 +/- 0.13 g/ day/1. 73 m(2)) improved significantly ($p < 0.05$). Anti-dsDNA titres decreased in 73% by 6 and 12 months ($p < 0.05$). Complete renal remission was achieved in 7/16 (43.8%) at 6 months and 12/16 (75%) at 12 months, the rest achieving partial remission with no treatment failures. In conclusion, a combination MMF-CSA protocol is an effective therapeutic alternative for induction of children with severe proliferative LN, resulting in significant **clinical** and serological improvement with minimal adverse effects.

13/37 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Lertdumrongluk P; Somparn P; Kittanamongkolchai W; Traitanon O; Vadcharavivad S; Avihingsanon Y

TI: Pharmacokinetics of **mycophenolic acid** in severe **lupus nephritis**.

SO: Kidney international; VOL: 78 (4); p. 389-95 /201008/

AB: **Mycophenolic acid** (MPA) is an effective treatment for active **lupus nephritis** despite its variable efficacy in different ethnic groups. Here we tested whether pharmacokinetic monitoring may help to optimize dosing of MPA in an Asian population. Patients with biopsy-proven class III or IV **lupus nephritis** (ISN/RPS category) were treated with **mycophenolate mofetil** or enteric-coated **mycophenolate** sodium. One month after initiating treatment we measured plasma MPA levels in eight samples taken over a 12-h period after drug administration. The mean area under the time-dependent curve for MPA of responding patients was significantly higher than those not responding. Successful treatment was seen in patients with areas > 45 mg h/l. The dosage of the drug was not related to MPA pharmacokinetics. In the **mycophenolate mofetil** group, however, MPA-area under the curve was positively, and significantly, correlated with trough or 1 h after dose concentrations and associated with a therapeutic response. Thus, our **study** shows that MPA pharmacokinetics were positively correlated with therapeutic responses of **mycophenolate**, suggesting that controlling the concentrations may improve its therapeutic efficacy in **lupus nephritis**. As the absorption and pharmacokinetic peak of enteric-coated tablets is slower, it is important to take different formulations into account when determining optimal MPA concentrations.

13/38 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Weng MY; Weng CT; Liu MF

TI: The efficacy of low-dose **mycophenolate mofetil** for treatment of **lupus nephritis** in Taiwanese patients with systemic **lupus** erythematosus.

SO: Clinical rheumatology; VOL: 29 (7); p. 771-5 /201007/

AB: **Mycophenolate mofetil** (MMF) has recently been introduced as an

immunosuppressive agent for the treatment of glomerulonephritis with systemic **lupus** erythematosus (SLE) and the data have been encouraging. However, response to MMF treatment appears to differ ethnically. Therefore, we determined efficacy and safety of low-dose MMF for Taiwanese patients with **lupus nephritis**. We studied 36 **lupus nephritis** patients who were treated with MMF. The dose started at 0.5 g/day and we collected the data from patients who received up to 1 g/day MMF. Outcome measures were 24 h for proteinuria, serum creatinine, C3/C4 levels, and anti-dsDNA titers collected at the baseline and at 3-month treatment intervals. Daily urinary protein significantly decreased from 6.15 +/- 4.28 g to 2.69 +/- 2.36 g at the last visit (P < 0.01) in spite of the significant absence of changes in serum creatinine levels. The response rate was 65.7% including five (14.3%) cases of complete remission and 18 (51.4%) cases of partial remission. The concomitant oral prednisolone dose decreased significantly from 20.07 +/- 11.78 mg/day to 13.93 +/- 6.79 mg/day at 6 months (P < 0.01). The level of C3 increased significantly from 59.46 +/- 32.73 to 71.99 +/- 25.81 (P < 0.01) and the anti-dsDNA antibody titer decreased from 161.71 +/- 221.42 to 46.57 +/- 117.47 (P < 0.01). No severe adverse effects were observed in the **study**. Low-dose MMF (0.5 to 1 g/day) combined with glucocorticoids appears to be a safe and effective therapy for **lupus nephritis** in Taiwanese patients. Our results suggest that **lupus nephritis** in Oriental patients might respond to lower doses of MMF than Caucasians.

Fulltext Information

13/39 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: El-Shafey EM; Abdou SH; Shareef MM

TI: Is **mycophenolate mofetil** superior to pulse intravenous cyclophosphamide for induction therapy of proliferative **lupus nephritis** in Egyptian patients?

SO: Clinical and experimental nephrology; VOL: 14 (3); p. 214-21 /201006/

AB: BACKGROUND: Recent studies have suggested that **mycophenolate mofetil** (MMF) may offer advantages over intravenous cyclophosphamide (IVC) for the treatment of **lupus nephritis**. The aim of this **study** was to evaluate the efficacy of MMF compared with IVC in the induction therapy of proliferative **lupus nephritis**.
METHODS: We randomly assigned 47 patients with newly diagnosed active proliferative **lupus nephritis** class III or IV to open-label oral MMF 2 g/day for 6 months or intravenous cyclophosphamide 0.5-1 g/m(2) monthly for 6 months in addition to corticosteroids.
RESULTS: In the intention-to-treat analysis, 14 of the 24 patients (58.33%) receiving MMF and 12 of the 23 patients receiving cyclophosphamide (52.17%) had remission (P = 0.48); complete remission occurred in 6 of the 24 patients (25%) and 5 of the 23 patients (21.74%), respectively (P = 0.53). Improvements in packed cell volume, the erythrocyte sedimentation rate, anti-double-stranded DNA antibodies titer (anti-dsDNA), serum complement, proteinuria, urinary activity, renal function, serum soluble interleukin-2 receptor alpha concentration and the systemic **lupus** activity measure score were similar in both groups. Two patients assigned to MMF and another patient assigned to IVC developed end-stage renal failure with commencement of dialysis. Adverse events were similar. Major infections occurred in two patients in each group. There was no difference in gastrointestinal side effects, but more diarrhea occurred in those receiving MMF.
CONCLUSIONS: In this 24-week **trial**, MMF or IVC combined with corticosteroids demonstrated equal efficacy in inducing remission of proliferative **lupus nephritis**.

Fulltext Information

13/40 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Ginzler EM; Wofsy D; Isenberg D; Gordon C; Lisk L; Dooley MA

TI: Nonrenal disease activity following **mycophenolate mofetil** or intravenous cyclophosphamide as induction treatment for **lupus nephritis**: findings in a **multicenter**, prospective, **randomized**, open-label, parallel-group **clinical trial**.

SO: Arthritis and rheumatism; VOL: 62 (1); p. 211-21 /201001/

AB: OBJECTIVE: To assess the effect of **mycophenolate mofetil** compared with intravenous pulses of cyclophosphamide on the nonrenal manifestations of **lupus nephritis**.
METHODS: Patients with active **lupus nephritis** (renal biopsy class III, IV, or V) were recruited for the **study** (n = 370) and treated with **mycophenolate mofetil** (target dosage 3 gm/day) or intravenous cyclophosphamide (0.5-1.0 gm/m(2)/month), plus tapered prednisone, for 24 weeks. Nonrenal outcomes were determined using measures of whole body disease activity, including the British Isles **Lupus** Assessment Group (BILAG) disease activity index, the Safety of Estrogens in **Lupus** Erythematosus: National Assessment (SELENA) version of the Systemic **Lupus** Erythematosus Disease Activity Index (SLEDAI), and immunologic variables.
RESULTS: Both treatments were effective on whole body disease activity in the systems examined, as indicated by changes in the classic BILAG index. With either treatment, remission was induced, notably in the mucocutaneous, musculoskeletal, cardiovascular/respiratory, and vasculitis systems, and flares were rare, as measured by the SELENA-SLEDAI. Levels of complement C3, C4, and CH50 and titers of anti-double-stranded DNA antibodies were normalized after treatment with either **mycophenolate mofetil** or intravenous cyclophosphamide.
CONCLUSIONS: In addition to the efficacy of both treatments on the renal system, this analysis showed that remission could also be induced in other systems. There was no clear difference in efficacy between **mycophenolate mofetil** and intravenous cyclophosphamide in ameliorating either the renal or nonrenal manifestations. **Mycophenolate mofetil** is, therefore, a suitable alternative to cyclophosphamide for the treatment of renal and nonrenal disease manifestations in patients with biopsy-proven **lupus nephritis**.

13/41 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Radhakrishnan J; Moutzouris DA; Ginzler EM; Solomons N; Siempos II; Appel GB

TI: **Mycophenolate mofetil** and intravenous cyclophosphamide are similar as induction therapy for class V **lupus nephritis**.

SO: Kidney international; VOL: 77 (2); p. 152-60 /201001/

AB: Class V **lupus nephritis** (LN) occurs in one-fifth of biopsy-proven cases of systemic **lupus** erythematosus. To **study** the effectiveness of treatments in this group of patients, we pooled analysis of two large **randomized controlled multicenter** trials of patients with diverse ethnic and racial background who had pure class V disease. These patients received **mycophenolate mofetil** (MMF) or intravenous cyclophosphamide (IVC) as induction therapy for 24 weeks, with percentage change in proteinuria and serum creatinine as end points. Weighted mean differences, pooled odds ratios, and confidence intervals were calculated by using a random-effects model. A total of 84 patients with class V disease were divided into equal groups, each group had comparable entry variables but one received MMF and one received IVC. Within these groups, 33 patients on MMF and 32 patients on IVC completed 24 weeks of treatment. There were no differences between the groups in mean values for the measured end points. Similarly, no difference was found regarding the number of patients who did not complete the **study** or who died. In patients with nephrotic syndrome, no difference was noted between those treated with MMF and IVC regarding partial remission or change in urine protein. Hence we found that the response to MMF as induction treatment of patients with class V LN appears to be no different from that to IVC.

13/42 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Isenberg D; Appel GB; Contreras G; Dooley MA; Ginzler EM; Jayne D; Sánchez-Guerrero J; Wofsy D; Yu X; Solomons N

TI: Influence of race/ethnicity on response to **lupus nephritis** treatment: the ALMS **study**.

SO: Rheumatology (Oxford, England); VOL: 49 (1); p. 128-40 /201001/

AB: OBJECTIVE: To compare the efficacy and safety of **mycophenolate mofetil** (MMF) and intravenous cyclophosphamide (IVC) as induction treatment for **lupus nephritis** (LN), by race, ethnicity and geographical region.
METHODS: A total of 370 patients with active Class III-V LN received MMF (target dose 3.0 g/day) or IVC (0.5-1.0 g/m(2)/month), plus tapered prednisone, for 24 weeks. Renal function, global disease activity, immunological complement (C3 and C4) and anti-dsDNA levels are the outcomes that were assessed in this **study**.
RESULTS: MMF was not superior to IVC as induction treatment (primary objective). There were important pre-specified interactions between treatment and race (P = 0.047) and treatment and region (P = 0.069) (primary endpoint). MMF and IVC response rates were similar for Asians (53.2 vs 63.9%; P = 0.24) and Whites (56.0 vs 54.2%; P = 0.83), but differed in the combined Other and Black group (60.4 vs 38.5%; P = 0.03). Fewer patients in the Black (40 vs 53.9%; P = 0.39) and Hispanic (38.8 vs 60.9%; P = 0.011) groups responded to IVC. Latin American patients had lower response to IVC (32 vs 60.7%; P = 0.003). Baseline disease characteristics were not predictive of response. The incidence of adverse events (AEs) was similar across groups. Serious AEs were slightly more prevalent among Asians.
CONCLUSIONS: MMF and IVC have similar efficacy overall to short-term induction therapy for LN. However, race, ethnicity and geographical region may affect treatment response; more Black and Hispanic patients responded to MMF than IVC. As these factors are inter-related, it is difficult to draw firm conclusions about their importance.

Fulltext Information

13/43 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Dittrich K; Ross S; Benz K; Amann K; Dötsch J

TI: Experience with **mycophenolate mofetil** as maintenance therapy in five pediatric patients with severe systemic **lupus** erythematosus.

SO: Klinische Padiatrie; VOL: 221 (7); p. 425-9 /200912/

AB: Maintenance therapy of severe pediatric systemic **lupus** erythematosus (SLE) usually consists of azathioprine and prednisone . In adult SLE patients **mycophenolate mofetil** (MMF) is successfully used, superiority to azathioprine has not been shown yet. We hypothesized that a maintenance therapy with MMF is able to decrease disease activity as well as the dose of glucocorticoid needed in children and adolescents with SLE. Five girls with a mean age of 13.9 (range 12-15) years were treated with 1.2+/-0.20 g/m (2) MMF daily on individual medical decision. Three patients had severe renal (WHO IV) and one severe cerebral involvement. Three patients with frequent flares on azathioprine maintenance therapy were switched to MMF, two patients with severe renal and cerebral manifestation received MMF additionally after induction therapy. Flares, steroid dosage, and disease activity (SLEDAI) were monthly registered in all patients. The number of flares decreased from 1.28 to 0.25 episodes per patient year during a mean follow-up period of 39 (range 36-42) months after MMF initiation. In parallel prednisone dose could be reduced from 10.80+/-5.25 to 3.25+1.18 mg/d (p< 0.01). SLEDAI score dropped from 15.20+/-2.8 before MMF to 3.60+/- 0.9 at the last visit under MMF (p< 0.001). No severe adverse event occurred. In our cohort of five pediatric patients MMF was effective and safe for maintenance therapy of SLE over a period of 3.5 years. MMF seems to be successful in preventing flares even in adolescents having unfavorable course on azathioprine treatment before. This observation should be confirmed by a **randomized multicenter clinical trial**.

Fulltext Information

13/44 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Appel GB; Contreras G; Dooley MA; Ginzler EM; Isenberg D; Jayne D; Li LS; Mysler E; Sánchez-Guerrero J; Solomons N; Wofsy D

TI: **Mycophenolate mofetil** versus cyclophosphamide for induction treatment of

lupus nephritis.

SO: Journal of the American Society of Nephrology : JASN; VOL: 20 (5); p. 1103-12 /200905/

AB: Recent studies have suggested that **mycophenolate mofetil** (MMF) may offer advantages over intravenous cyclophosphamide (IVC) for the treatment of **lupus nephritis**, but these therapies have not been compared in an international **randomized**, **controlled trial**. Here, we report the comparison of MMF and IVC as induction treatment for active **lupus nephritis** in a multinational, two-phase (induction and maintenance) **study**. We randomly assigned 370 patients with classes III through V **lupus nephritis** to open-label MMF (target dosage 3 g/d) or IVC (0.5 to 1.0 g/m(2) in monthly pulses) in a 24-wk induction **study**. Both groups received prednisone, tapered from a maximum starting dosage of 60 mg/d. The primary end point was a prespecified decrease in urine protein/creatinine ratio and stabilization or improvement in serum creatinine. Secondary end points included complete renal remission, systemic disease activity and damage, and safety. Overall, we did not detect a significantly different response rate between the two groups: 104 (56.2%) of 185 patients responded to MMF compared with 98 (53.0%) of 185 to IVC. Secondary end points were also similar between treatment groups. There were nine deaths in the MMF group and five in the IVC group. We did not detect significant differences between the MMF and IVC groups with regard to rates of adverse events, serious adverse events, or infections. Although most patients in both treatment groups experienced **clinical** improvement, the **study** did not meet its primary objective of showing that MMF was superior to IVC as induction treatment for **lupus nephritis**.

Fulltext Information

13/45 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Falcini F; Capannini S; Martini G; La Torre F; Vitale A; Mangiantini F; Nacci F; Cerinic MM; Cimaz R; Zulian F

TI: **Mycophenolate mofetil** for the treatment of juvenile onset SLE: a **multicenter study**.

SO: Lupus; VOL: 18 (2); p. 139-43 /200902/

AB: **Mycophenolate mofetil** (MMF) has proved to be an efficacious and safe therapy in adult **lupus nephritis**. Recently, this drug has been suggested as a possible new alternative treatment also for juvenile-onset SLE (juvenile-SLE). A **multicenter study** has been performed to evaluate the efficacy and safety of MMF in controlling the disease activity in children and adolescents with juvenile-SLE. Our results show that MMF was effective in reducing the disease activity or as a steroid-sparing agent in 14 of 26 patients (54%), stabilised the disease in 8 (31%) and was ineffective in 4 (15%). In particular, in patients without renal involvement, a good response was registered in 9 of 13 patients (69%). Among those patients with renal involvement, MMF was effective in 5 of 13 patients (38%), partially effective in 4 (31%) and ineffective in 4 (31%). No severe side effects have been observed; only two patients stopped the drug because of severe diarrhoea and abdominal pain. With the limits of a retrospective **study**, MMF seems to be effective and safe for the treatment of juvenile-SLE, especially in patients with no renal involvement.

Fulltext Information

13/46 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Joy MS; Hilliard T; Hu Y; Hogan SL; Dooley MA; Falk RJ; Smith PC

TI: Pharmacokinetics of **mycophenolic acid** in patients with **lupus nephritis**.

SO: Pharmacotherapy; VOL: 29 (1); p. 7-16 /200901/

AB: OBJECTIVE (**STUDY** OBJECTIVES): To evaluate and describe the pharmacokinetics of **mycophenolic acid** and its metabolite, **mycophenolic acid** glucuronide (MPAG), in patients with **lupus nephritis**, and to determine the effects of **clinical** parameters (urinary protein excretion as measured by the urinary protein:creatinine ratio, serum albumin level, and creatinine clearance) and demographic variables (age, race, sex) on the pharmacokinetics of total and

unbound **mycophenolic acid** and MPAG.
METHODS (DESIGN): Pharmacokinetic analysis.
METHODS (SETTING): University-affiliated general **clinical** research center.
METHODS (PATIENTS): Eighteen patients with biopsy-confirmed **lupus nephritis** who were receiving maintenance therapy with **mycophenolic acid** for at least 2 weeks.
METHODS (INTERVENTION): Plasma and urine samples were collected for 24 hours and were assayed by high-performance liquid chromatography with ultraviolet detection.
RESULTS (MEASUREMENTS AND MAIN RESULTS): Time to maximum concentration was variable (0.5-8 hrs). Mean +/- SD fraction of unbound **mycophenolic acid** was 2.6 +/- 1.9%, and oral clearance (Cl/F) was about 2-fold higher (343 +/- 200 ml/min) than previously reported. Multiple regression analysis showed that Cl/F of **mycophenolic acid** was predicted by creatinine clearance and serum albumin level: ln Cl/F = 5.358 + 0.0092 (creatinine clearance) - 0.078 (ranked albumin), R(2)=51.1%, p=0.0195. Patients with urinary protein excretion of 1 g/day or higher had lower minimum (trough) concentrations and area under the concentration-time curve (AUC(0-12)) profiles and higher Cl/F values compared with patients with urinary protein excretion of less than 1 g/day. Patients with serum albumin levels less than 4 g/dl had higher **mycophenolic acid** unbound clearance and MPAG renal clearance from 0-12 hours versus those with serum albumin levels of 4 g/dl or greater. Recycling AUC (AUC(6-12)), as well as sex and age (both equally), predicted renal clearance of MPAG.
CONCLUSIONS: Both creatinine clearance and serum albumin level were identified as primary contributors to **mycophenolic acid** exposure and should be considered when evaluating dosages. The results of future studies should clarify the interactions of other variables on drug exposure and treatment responses. Clinicians need to be mindful of **clinical** changes that occur throughout the course of **lupus nephritis** in order to maintain efficacy and reduce toxicity from **mycophenolic acid** therapy.

13/47 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Navaneethan SD; Viswanathan G; Strippoli GF

TI: Treatment options for proliferative **lupus nephritis**: an update of **clinical trial** evidence.

SO: Drugs; VOL: 68 (15); p. 2095-104 /2008/

AB: Systemic **lupus** erythematosus involves the kidney in up to 60% of patients, and if untreated, may result in complete loss of kidney function. In this article, we review meta-analyses and **clinical trial** data on the therapeutic options for proliferative **lupus nephritis**, and complete a meta-analysis of the use of **mycophenolate mofetil** (MMF) compared with cyclophosphamide-based regimens. **Clinical** trials have found that cyclophosphamide-based regimens result in a decreased risk of end-stage renal disease, but are associated with significant toxicity in **lupus nephritis**. Even though the survival advantage of the US National Institutes of Health and Euro-**Lupus** regimens based on intravenous and oral cyclophosphamide has not been established, these approaches are broadly adopted in proliferative **lupus nephritis**. Recent studies have confirmed the therapeutic equivalence and potential comparative superiority of MMF and cyclophosphamide in induction of remission in patients with **lupus nephritis**. Use of MMF resulted in a lower incidence of infection and loss of gonadal function compared with cyclophosphamide regimens. Cyclophosphamide plus corticosteroids could represent the induction agents of choice in patients with severe **lupus nephritis**, whereas MMF could be used as an induction agent in patients with mild disease, patients who wish to preserve fertility and those at high risk of infections. However, given the complexity of disease activity in patients with **lupus nephritis**, the initial treatment options need to be individualized and altered based on the subsequent treatment response. Ongoing **clinical** trials will provide further evidence.

Fulltext Information

13/48 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: F L; Y T; X P; L W; H W; Z S; H Z; Z H

TI: A prospective multicentre **study** of **mycophenolate mofetil** combined with prednisolone as induction therapy in 213 patients with active **lupus nephritis**.

SO: Lupus; VOL: 17 (7); p. 622-9 /200807/

AB: **Mycophenolate mofetil** (MMF) with prednisolone has been associated with high remission rates when used as induction treatment for **lupus nephritis**. This prospective, multicentre, cohort **study** investigates the efficacy and safety of this regimen over 24 weeks in 213 Chinese patients with active **lupus nephritis** (Classes III, IV, V or combination). Baseline activity index (AI) was 6.91+/-3.33 and chronicity index (CI) was 1.9+/-1.2. The remission rate was 82.6% at 24 weeks (complete remission, 34.3%; partial remission, 48.4%). There were significant (P< 0.01) improvements in kidney function shown by reductions in proteinuria, serum albumin, serum creatinine and creatinine clearance, as well as in systemic **lupus** erythematosus disease activity index (SLEDAI) scores. Independent risk factors influencing remission were pathological classification (including Class V and III or Class V and IV **nephritis**) and elevated serum creatinine at baseline (OR 2.967, 95% CI: 1.479-6.332, P=0.001 and OR 1.007, 95% CI: 1.002-1.011, P=0.001, respectively). Patients with concomitant membranous features on biopsy had a lower remission rate than those with Class III and IV **nephritis** (66.7% vs 87.3%, P=0.002). Renal biopsy was repeated in 25 patients following treatment. There was a transition to less severe pathological morphologies in majority of subjects. Infections were monitored throughout treatment: eight patients (3.8%) experienced bacterial infections, whereas herpes zoster occurred in seven patients. Nine patients (4.2%) suffered from gastrointestinal upset, which resolved without discontinuation of MMF. One patient became leucopenic, whereas another died from active disease unrelated to kidney symptoms. MMF combined with prednisolone is an effective and well-tolerated induction treatment for patients with active **lupus nephritis** and for controlling SLE systemic activity.

Fulltext Information

13/49 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Traitanon O; Avihingsanon Y; Kittikovit V; Townamchai N; Kanjanabuch T; Praditpornsilpa K; Wongchinasri J; Tungsanga K; Eiam-Ong S

TI: Efficacy of enteric-coated **mycophenolate** sodium in patients with resistant-type **lupus nephritis**: a prospective **study**.

SO: Lupus; VOL: 17 (8); p. 744-51 /200808/

AB: The role of **mycophenolate mofetil** (MMF) is still controversial in the treatment of cyclophosphamide-resistant proliferative **lupus nephritis** (PLN). Enteric-coated **mycophenolate** sodium (EC-MPS) has less gastrointestinal adverse effects than MMF and is, therefore, increasingly utilised in organ transplantation. The aim of this **study** was to compare the efficacy and safety of EC-MPS versus an extended-course of intravenous cyclophosphamide (ED-IVCY) in resistant-type PLN. Thirty-one, biopsy-proven PLN, patients who failed to respond to an induction of IVCY were enrolled in a prospective, open-labelled, historically **controlled study**. Patients received 6 month of EC-MPS (720 mg b.i.d.) treatment. The patients in the ED-IVCY group, collected from a database, received a repeated 6-month course of monthly IVCY 0.5-1 g/m(2) of body surface area. Both groups received 0.5-1 mg/kg/day of prednisolone. Primary outcomes were partial or complete responses. A repeated kidney biopsy was performed to evaluate the histological response. No serious adverse events or patient deaths were observed during the **study**. Both groups had comparable baseline characteristics. At 6 months, the EC-MPS group had a comparable response rate with the ED-IVCY group. There were significantly less adverse events in the EC-MPS group. Repeated biopsies showed significant improvement in the EC-MPS group. EC-MPS provides salutary efficacy and safety in the treatment of resistant-type PLN and can be a suitably alternative

treatment to ED-IVCY.

Fulltext Information

13/50 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Bao H; Liu ZH; Xie HL; Hu WX; Zhang HT; Li LS

TI: Successful treatment of class V+IV **lupus nephritis** with multitarget therapy.

SO: Journal of the American Society of Nephrology : JASN; VOL: 19 (10); p. 2001-10 /200810/

AB: Treatment of class V+IV **lupus nephritis** remains unsatisfactory despite the progress made in the treatment of diffuse proliferative **lupus nephritis**. In this prospective **study**, 40 patients with class V+IV **lupus nephritis** were randomly assigned to induction therapy with **mycophenolate mofetil**, tacrolimus, and steroids (multitarget therapy) or intravenous cyclophosphamide (IVCY). Patients were treated for 6 mo unless complete remission was not achieved, in which case treatment was extended to 9 mo. An intention-to-treat analysis revealed a higher rate of complete remission with multitarget therapy at both 6 and 9 mo (50 and 65%, respectively) than with IVCY (5 and 15%, respectively). At 6 mo, eight (40%) patients in each group experienced partial remission, and at 9 mo, six (30%) patients receiving multitarget therapy and eight (40%) patients receiving IVCY experienced partial remission. There were no deaths during this **study**. Most adverse events were less frequent in the multitarget therapy group. Calcineurin inhibitor nephrotoxicity was not observed, but three patients developed new-onset hypertension with multitarget therapy. In conclusion, multitarget therapy is superior to IVCY for inducing complete remission of class V+IV **lupus nephritis** and is well tolerated.

Fulltext Information

13/51 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Milewski M; Jakiela B; Zólcinski M; Chmielewska A; Musial J

TI: Mykofenolan mofetylu w leczeniu podtrzymujacym u chorych z nefropatia toczniowa.
[**Mycophenolate mofetil** maintenance therapy in **lupus nephritis**].

SO: Polskie Archiwum Medycyny Wewnetrznej; VOL: 116 (4); p. 947-54 /200610/

AB: BACKGROUND (INTRODUCTION): The aim of this **study** was to assess **clinical** efficacy and changes in immunological parameters during maintenance therapy with **mycophenolate mofetil** (MMF) in patients with **lupus nephritis**.
METHODS: Patients (n = 7) with systemic **lupus** erythematosus (SLE) and proliferative nephropathy confirmed by renal biopsy, in whom disease remission was induced with intravenous cyclophosphamide, received MMF (2 x 500 mg daily) for 3 months. **Clinical** and immunological parameters as well as drug tolerance were assessed before, and after 1 and 3 months of MMF therapy.
RESULTS: MMF therapy lead to a decrease in disease activity index (SLEDAI), and maintenance of previously achieved reduction of proteinuria, improvement of renal function and immunological parameters. These changes were associated with decrease in the number of activated T cells and increase in B cells. The titer of anti-dsDNA antibodies was reduced in 5 out of 7 patients.
CONCLUSIONS: Mycofenolate **mofetil** is effective in the maintenance therapy oflupus **nephritis**. A 3-month MMF treatment allows for sustained beneficial immunological profile achieved in induction therapy.

Fulltext Information

13/52 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Fujinaga S; Ohtomo Y; Hara S; Umino D; Someya T; Shimizu T; Kaneko K

TI: Maintenance therapy with **mycophenolate mofetil** for children with severe **lupus nephritis** after low-dose intravenous cyclophosphamide regimen.

SO: Pediatric nephrology (Berlin, Germany); VOL: 23 (10); p. 1877-82 /200810/

AB: Although recent studies on adults with **lupus nephritis** indicate that **mycophenolate mofetil** (MMF) may be effective in maintaining remission for

patients who previously received short-term intravenous cyclophosphamide (IVCY) induction therapy, the experience with the new immunosuppressive agent in children with severe **lupus nephritis** has not been as satisfactory thus far. To assess the efficacy and safety of maintenance therapy with MMF, we prospectively analyzed four patients with biopsy-proven severe **lupus nephritis** (three girls, one boy; mean age 12 years; two with class IIIA, two with class IVG(A); mean duration of **lupus nephritis** 7 months) receiving MMF for at least 6 months after induction treatment. These patients had been treated previously with 6 months of low-dose IVCY combined with oral mizoribine and steroids for induction, followed by therapy with MMF adjusted to maintain predose **mycophenolic acid** (C0-MPA) levels at 2-5 mcg/ml. Mean follow-up after staring MMF was 27.5 months (range 6-41). The mean MMF dose required was 405 +/- 49 mg/m(2) per 12 h, which maintained mean C0-MPA levels of 3.3 +/- 0.41 mcg/ml. No patient experienced renal flares during maintenance therapy with MMF, which permitted a significant reduction in mean prednisolone dose from 11.9 +/- 1.3 to 3.9 +/- 2.6 mg/day (P = 0.003). No significant gastrointestinal or hematologic side effects of MMF were noted. This preliminary **study** demonstrates that maintenance therapy with MMF after a low-dose IVCY regimen appears to be a promising intervention without adverse effects in children with severe **lupus nephritis**. These data should be confirmed by a prospective **randomized multicenter clinical trial**.

Fulltext Information

13/53 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Sinclair A; Appel G; Dooley MA; Ginzler E; Isenberg D; Jayne D; Wofsy D; Solomons N

TI: **Mycophenolate mofetil** as induction and maintenance therapy for **lupus nephritis**: rationale and protocol for the **randomized**, **controlled** Aspreva **Lupus** Management **Study** (ALMS).

SO: Lupus; VOL: 16 (12); p. 972-80 /2007/

AB: The Phase III Aspreva **Lupus** Management **Study** (ALMS) will investigate **mycophenolate mofetil** (MMF) therapy for **lupus nephritis** (LN). Eligibility criteria include: 12-75 years of age; diagnosis of systemic **lupus** erythematosus according to revised American College of Rheumatology criteria; and biopsy-demonstrated LN (Class III-V). **Randomized** patients will receive open-label induction therapy with MMF or cyclophosphamide in combination with corticosteroids for 24 weeks. The primary efficacy endpoint is treatment response [decreased proteinuria and stabilized (within 25% of baseline) or improved serum creatinine level]. Patients achieving response or complete remission (normalization of all parameters) will be rerandomized to double-blind, placebo-**controlled** maintenance treatment with MMF or azathioprine, both plus corticosteroids. The maintenance phase primary endpoint is time to treatment failure. To detect a 15% rate improvement in the MMF group compared with cyclophosphamide, and to provide 90% power, a total of 358 patients will be required for the induction phase. On the basis of a projected 278 rerandomized patients, the maintenance phase will have 90% power to detect a difference between treatment groups assuming azathioprine and MMF three-year failure rates of 59.5% and 40.7%, respectively. Aspreva **Lupus** Management **Study** may provide invaluable comparative data on the efficacy and safety of MMF as LN induction and maintenance therapy.

Fulltext Information

13/54 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Urowitz MB; Ibañez D; Ali Y; Gladman DD

TI: Outcomes in patients with active **lupus nephritis** requiring immunosuppressives who never received cyclophosphamide.

SO: The Journal of rheumatology; VOL: 34 (7); p. 1491-6 /200707/

AB: OBJECTIVE: To assess outcomes in patients with **lupus nephritis** treated with immunosuppressives compared to those treated with cyclophosphamide in a cohort **study** and in a matched cohort **study**.

METHODS: Patients with active renal disease treated with immunosuppressive/cytotoxic medications were selected from the University of Toronto **Lupus** Clinic database. Five outcomes were evaluated: all-cause mortality, renal failure, reversal of active renal disease, relapse of active renal disease, and toxicity.
RESULTS: There were no differences in the outcomes of death, renal failure, reversal or relapse of active renal disease, or toxicity in those using or not using cyclophosphamide.
CONCLUSIONS: Antimetabolites should be considered standard of care for patients with **lupus nephritis** both for induction and for maintenance therapy.

Fulltext Information

13/55 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Dooley MA; Falk RJ

TI: Human **clinical** trials in **lupus nephritis**.

SO: Seminars in nephrology; VOL: 27 (1); p. 115-27 /200701/

AB: Improved patient survival after treatment of **lupus nephritis** with corticosteroids, immunosuppressants, and renal replacement therapy allows greater emphasis on long-term management issues. In particular, the recent focus has been on therapies to treat **nephritis** with fewer adverse effects compared with cyclophosphamide and immunosuppressive regimens. Issues complicating **clinical trial** design in **lupus nephritis** have severely limited comparisons across trials. These issues, including recognition and stratification of high-risk populations, comparable remission and response criteria, and appropriate use and interpretation of activity and damage indices have been the subject of much discussion and emerging consensus. **Mycophenolate mofetil** (MMF) has been used in the field of transplantation for more than 10 years. After initial anecdotal reports describing the benefits of MMF in the treatment of **lupus nephritis**, **randomized controlled** trials have established a role for MMF in the treatment of **lupus nephritis**. A host of newer agents including rituximab, abatacept, and monoclonal antibodies blocking costimulatory targets are in current **clinical** trials for **lupus nephritis**. As long-term outcomes in **lupus nephritis** improve, the toxicity of therapy and risk of relapse become increasingly important determinants of the choice of therapeutic agents.

Fulltext Information

13/56 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Sahin GM; Sahin S; Kantarci G; Ergin H

TI: **Mycophenolate mofetil** treatment for therapy-resistant glomerulopathies.

SO: Nephrology (Carlton, Vic.); VOL: 12 (3); p. 285-8 /200706/

AB: BACKGROUND: The management of steroid-resistant glomerulopathies remains a **clinical** problem. In this **trial**, we report a **clinical** observation of 43 patients treated with **mycophenolate mofetil** (MMF) for steroid-resistant glomerulopathies.
METHODS: All patients underwent renal biopsies, and immunofluorescence and light microscopy examinations were conducted in all cases. All patients had been treated with prednisone at a dose of 1 mg/kg per day for at least 8 weeks. Of the 43 patients, 16 were treated with cyclophosphamide and five were treated with cyclosporine A before MMF started. The primary **study** outcomes were the change in the urinary protein excretion, serum creatinine, comparing the levels at the start of MMF treatment with those at the end of the MMF treatment period. Changes in renal function were also estimated with Modification of Diet in Renal Failure calculation. Wilcoxon signed-ranks test was used as appropriate to compare data from the start with data at the end of the treatment period.
RESULTS: The primary glomerular diseases represented included membranoproliferative glomerulonephritis in 23.2%, membranous glomerulonephritis in 18.6%, IgA nephropathy in 13.9%, focal segmental glomerulosclerosis in 9.3%, **lupus nephritis** (systemic **lupus** erythematosus) in 25.6% and pauci-immune glomerulopathy in 9.3% of patients. The mean follow-

up time was 28.9+/-12 months. Before MMF treatment, 16 patients (37%) had nephrotic range proteinuria and 11 (26%) had renal insufficiency. The urinary protein before MMF treatment was 3.3+/-2.6 g/dL (0.6-9.6) and decreased significantly to 0.87+/-1.1 g/dL (0-5.5) at the end of the MMF treatment period (P=0.02). During treatment, complete remission was seen in 27 patients, partial remission in 10 patients and MMF failure in six patients. The serum creatinine level decreased significantly from 1.29+/-0.55 mg/dL (0.6-3.0) to 1.14+/-0.38 mg/dL (0.5-2.4) post MMF therapy (P=0.046). Using the four-variable Modification of Diet in Renal Failure formula, the glomerular filtration rate increased from 71.5+/-28 mL/min per 1.73 m2 to 78.1+/-27 mL/min per 1.73 m2 (P=0.021). Renal insufficiency resolved in seven of the 11 (63.6%) patients with renal insufficiency initially, two with membranoproliferative glomerulonephritis, two with membranous glomerulonephritis, one with focal segmental glomerulosclerosis, four with pauci-immune glomerulopathy, two with systemic **lupus** erythematosus **nephritis**, and in two patients de novo renal insufficiency developed. CONCLUSIONS: In general, MMF was well tolerated, and most of the patients achieved remission and improvement of renal functions. MMF treatment appeared to offer benefits to problematic patients refractory to conventional therapies for glomerulopathies.

Fulltext Information

13/57 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Wang J; Hu W; Xie H; Zhang H; Chen H; Zeng C; Liu Z; Li L

TI: Induction therapies for class IV **lupus nephritis** with non-inflammatory necrotizing vasculopathy: **mycophenolate mofetil** or intravenous cyclophosphamide.

SO: Lupus; VOL: 16 (9); p. 707-12 /2007/

AB: The presence of renal noninflammatory necrotizing vasculopathy (NNV) is often associated with a severe form of **lupus nephritis** (LN), which is unresponsive to standard therapy. We conducted a 6-month **randomized**, prospective, open-label **trial** comparing **mycophenolate mofetil** (MMF) (1.5-2.0 g/day) with monthly i.v. cyclophosphamide (CTX) (0.75-1.0 g/m2) as induction therapy for class IV LN with NNV. The primary and second end points were complete remission (CR) and partial remission (PR), respectively. Of 20 patients recruited, nine were randomly assigned to MMF and 11 to CTX. The baseline characteristics between groups were not significant. CR was achieved in four patients (44.4%) receiving MMF and in none of the patients receiving CTX (P = 0.026). PR was achieved in two patients (22.2%) in the MMF group and three patients (27.2%) in the CTX group. The total remission rate (CR + PR) in the MMF and CTX group was 66.6 and 27.2%, respectively (P = 0.17). MMF was more effective than i.v. CTX in reducing proteinuria and haematuria. Adverse events were significantly less frequent with MMF than with CTX (P = 0.028). MMF was superior to i.v. CTX in inducing CR of LN with NNV and had a more favourable safety profile.

Fulltext Information

13/58 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Grcevska L; Popovska MM; Dzikova S; Ristovska V; Polenakovic M

TI: Role of **mycophenolate mofetil** in the treatment of **lupus nephritis**.

SO: Annals of the New York Academy of Sciences; VOL: 1110; p. 433-8 /200709/

AB: **Mycophenolate mofetil** (MMF) is an immunosuppressive drug successfully used for the prevention of acute and chronic rejection of renal allografts, as well as in the therapy of glomerular disorders. We treated three groups of patients with **lupus nephritis**: the first group of patients had a high histologic activity index (AI), 13.4 +/- 2.34; the second group of patients had a high histologic chronicity index (CI), 6.0 +/- 0.7; and the third group consisted of only two patients, one with low AI (3.5) and another with low CI (1.5). The patients were treated for 2 years. MMF was initiated at a dose of 2 g/daily for the first 6 months and the dose was decreased to 1.5 g/daily for the further 18 months. Steroids, 0.4 mg/kg/day, were the concomitant therapy for the first 6 months, with slow tapering for the

further 18 months. Patients with high AI presented significant decrease of serum creatinine after 2 years, 286 +/- 112.95 to 131.2 +/- 44.65 micromol/L. Two of the patients, with acute oligoanuria, were withdrawn from dialysis treatment. Significant improvement was also noted, 6.97 +/- 1.81 to 0.9 +/- 0.31 g/day. Patients with high CI had nonsignificant decrease of serum creatinine, 178.5 +/- 47.73 to 129.25 +/- 22.88 micromol/L, and significant improvement of proteinuria, 4.63 +/- 1.57 to 1.14 +/- 0.39 g/day. The patient with low AI showed recovery of renal function (serum creatinine from 196 to 72 micromol/L) and alleviation of proteinuria, 7.93 to 3.4 g/day. The patient with low CI did not respond to the therapy and renal function slowly worsened. MMF has emerged as a promising therapeutic approach for both the induction and maintenance phase in patients with **lupus nephritis**.

Fulltext Information

13/59 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Grcevska L; Polenakovic M

TI: **Mycophenolate mofetil** in the treatment of glomerular diseases.

SO: Prilozi / Makedonska akademija na naukite i umetnostite, Oddelenie za bioloski i medicinski nauki = Contributions / Macedonian Academy of Sciences and Arts, Section of Biological and Medical Sciences; VOL: 28 (1); p. 57-68 /200707/

AB: OBJECTIVE (AIM): Treatment of primary glomerular diseases may be unsuccessful or have potential toxicities. **Mycophenolate mofetil** (MMF) is a new, relatively non-toxic drug. It has been introduced as an immunosuppressive drug, but it also has effects on non-immune cells (vascular smooth muscle cells, fibrocytes). Therefore, we evaluated the use of MMF for the treatment of glomerular diseases at different stages of the disease.
METHODS: The daily dosage of MMF was 2 for the first 6 months and 1.5 g for a further 18 months, combined with steroids. The follow-up period was two years.
RESULTS: 18 patients with **lupus nephritis** were treated. Patients with a high histological activity index showed a significant decrease of serum creatinine ($p < 0.05$) and proteinuria ($p < 0.01$), while patients with a high chronicity index showed only a decrease of proteinuria ($p < 0.05$). 15 patients with membranous nephropathy were treated. They showed stable renal function and a significant decrease of proteinuria ($p < 0.05$). Complete remission was achieved only in patients with MMF as a first choice drug. 4 patients with focal segmental glomerulosclerosis did not show any significant decrease of proteinuria, while the nephrotic syndrome in minimal change nephropathy (3 patients) showed a complete recovery. Partial improvement of the nephrotic syndrome was noted in 5 patients with membranoproliferative glomerulonephritis and in 4 patients with crescentic glomerulonephritis. Patients with crescentic glomerulonephritis also presented a significant decrease of serum creatinine ($p < 0,05$). MMF in 3 patients with IgA nephropathy grade I showed a significant improvement of the nephrotic syndrome. In grade III (5 patients) the response was partial.
CONCLUSIONS: We can conclude that MMF in our patients showed both actions, as an immunosuppressive drug in the early stages of the disease, and as an anti-fibrotic agent in the chronic phase of the disease.

Fulltext Information

13/60 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Suría S; Checa MD

TI: Micofenolato **mofetil** en el tratamiento de la nefritis lúpica en pacientes con fracaso, intolerancia o recidivas tras tratamiento con esteroides y ciclofosfamida. [**Mycophenolate mofetil** in the treatment of **lupus nephritis**, in patients with failure, intolerance or relapses after treatment with steroids and cyclophosphamide].

SO: Nefrologia : publicacion oficial de la Sociedad Espanola Nefrologia; VOL: 27 (4); p. 459-65 /2007/

AB: Intravenous cyclophosphamide (IVCP) in combination with oral steroids (ST) is the most widely accepted therapy for severe **lupus nephritis** (LN); however, its side

effects, lack of response and relapses, have led to other treatment alternatives. being sought. **Mycophenolate mofetil** (MMF) has been shown to be effective in these cases. We studied the course over 12 months of 28 patients with LN WHO class III(n=3), IV(n=22) or V(n=3), with 38,1 +/- 11,4 tears of age, proteinuria 4,2 +/- 2,6 g /24 hours and serum creatinine 1,4 +/- 0,8 mg/dL, who, after being initially treated with ST and IVCP, showed no response(n=21), frequent relapses(n=6), or adverse side effects(n=1). All patients were treated with MMF in doses of 1000 to 2000 mg/day combined with ST or cyclosporine for one year. Four patients withdrew from treatment before the end of the follow-up. None of the patients who completed the **study** showed changes in hematologic parameters. Creatinine and creatinine clearance remained stable. Resulted in a significant improvement; serum albumine (3 +/- 0,8 vs 3,9 +/- 0,5 g/dL) p< 0.01, and decreased of proteinuria (4,2 +/- 2,6 vs 1,8 +/- 2,2 g/ 24 hours) p< 0.05, complement fractions improvement significantly, C3 and CH50 p< 0.05, C4 p< 0.01. Antinuclear antibodies (ANA) and anti-DNA antibodies decreased significantly (p< 0.05). During follow-up, a reduction in the ST dose was achieved: 18.3 +/- 10,5 vs 10,1 +/- 4,1 mg/24h (p< 0.01). Three mild side effects related to MMF were observed and only 1 case required discontinuation of treatment. We concluded that MMF is a useful drug in the treatment and control of **lupus nephritis**, which also allows for a significant reduction in the dose of ST, with minimal side effects.

Fulltext Information

13/61 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Borba EF; Guedes LK; Christmann RB; Figueiredo CP; Gonçalves CR; Bonfá E

TI: **Mycophenolate mofetil** is effective in reducing **lupus** glomerulonephritis proteinuria.

SO: Rheumatology international; VOL: 26 (12); p. 1078-83 /200610/

AB: **Mycophenolate mofetil** (MMF) significantly reduces proteinuria in experimental model of human membranous nephropathy (Heymann **nephritis**). Twenty consecutive SLE patients with persistent isolated severe proteinuria and/or proteinuric flare were studied for 18 months of MMF therapy. All of them presented stable renal function and 12 had biopsy proven membranous glomerulonephritis (WHO class V). The starting daily dose for MMF was 1.5 g to a maximum of 3 g. Patients were divided into: partial response, > or=50% decrease of baseline proteinuria; complete response, normal proteinuria levels (less than 0.3 g/24 h); flare, increase of at least 50% of the mean baseline proteinuria. All 20 SLE patients (100%) presented a 50% reduction of baseline proteinuria which was achieved in 8.2+/-3.3 months of MMF therapy, at a mean daily dose of 2.3+/-0.5 g. A significant decrease in 24-h protein excretion was observed compared to entry (3.47+/-1.26 vs. 1.33+/-0.67 g, P< 0.0001) as well as a correspondent increase of serum albumin (3.2+/-0.4 vs. 3.7+/-0.4 mg/dl, P=0.02) and reduction of prednisone dose (33.7+/-20.0 to 18.6+/-14.1 mg/day, P=0.01). Complete response was observed in 11 SLE patients (55%) in 12.2+/-3.0 months of therapy with a significant decrease in proteinuria (P< 0.0001), prednisone dose (P< 0.0001) and an increase of serum albumin (P=0.003). Interestingly, initial proteinuria or serum albumin levels did not identify patients with complete response and those with partial response at the end of the **study** (P=0.543 and 0.657, respectively). Our pilot prospective **study** suggests that MMF appears to be effective in reducing severe persistent proteinuria in **lupus** glomerulonephritis, even in patients unresponsive to other immunosuppressive treatments.

Fulltext Information

13/62 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Elliott JR; Manzi S

TI: Induction therapy for active **lupus nephritis**: **mycophenolate mofetil** is superior to cyclophosphamide.

SO: Nature clinical practice. Rheumatology; VOL: 2 (7); p. 354-5 /200607/

Fulltext Information

13/63 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Adu D

TI: Treatment of proliferative **lupus nephritis**: a changing landscape.

SO: Kidney international; VOL: 70 (4); p. 616-8 /200608/

AB: Grootscholten et al. report a **randomized controlled trial** comparing azathioprine plus intravenous methylprednisolone and oral prednisolone (AZA group) with intermittent intravenous cyclophosphamide and oral prednisolone (CY group) in patients with proliferative **lupus nephritis**. AZA-treated patients were more likely to develop non-sustained doubling of their serum creatinine, although not significantly so, and significantly more likely to have a relapse of their **nephritis** than CY-treated patients.

Fulltext Information

13/64 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Grootscholten C; Ligtenberg G; Hagen EC; van den Wall Bake AW; de Glas-Vos JW; Bijl M; Assmann KJ; Bruijn JA; Weening JJ; van Houwelingen HC; Derksen RH; Berden JH

TI: Azathioprine/methylprednisolone versus cyclophosphamide in proliferative **lupus nephritis**. A **randomized controlled trial**.

SO: Kidney international; VOL: 70 (4); p. 732-42 /200608/

AB: Until recently, intravenous cyclophosphamide pulses with oral corticosteroids were regarded standard therapy for proliferative **lupus nephritis** (LN). Azathioprine, a less toxic alternative, was never proven to be inferior. In the first Dutch **lupus nephritis study** (enrollment between 1995 and 2001), we **randomized** 87 proliferative LN patients to either cyclophosphamide pulses (750 mg/m(2), 13 pulses in 2 years) combined with oral prednisone (CY) or to azathioprine (2 mg/kg/day in 2 years) combined with intravenous pulses of methylprednisolone (3 x 3 pulses of 1000 mg) and oral prednisone (AZA). After a median follow-up of 5.7 years (interquartile range 4.1-7.2 years), doubling of serum creatinine was more frequent in the AZA group, although not statistically significant (relative risk (RR): 4.1, with 95% confidence interval (95% CI): 0.8-20.4). Relapses occurred more often in the AZA group (RR: 8.8, 95% CI: 1.5-31.8). Creatinine and proteinuria at last visit did not differ between the two treatment arms. Moreover, 88.4% of the patients in the AZA arm were still free of cyclophosphamide treatment. During the first 2 years, the frequency of remission was not different, but infections, especially herpes zoster virus infections (HZV) were more frequent in the AZA group. Parameters for ovarian function did not differ between the two groups. In conclusion, in this open-label **randomized controlled trial**, cyclophosphamide was superior to azathioprine with regard to renal relapses and HZV. At last follow-up, there were no differences in serum creatinine or proteinuria between the two groups. However, since our **study** lacked sufficient power, longer follow-up is needed to reveal putative differences.

Fulltext Information

13/65 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Dooley MA

TI: Mycophenylate **mofetil**: what role in the treatment of **lupus**?

SO: Lupus; VOL: 15 (3); p. 179-82 /2006/

AB: Improved patient survival following **lupus nephritis** with the institution of corticosteroids, immunosuppressants and renal replacement therapy allows greater emphasis on long-term management issues. In particular, the recent focus has been on therapies to treat **nephritis** with fewer adverse effects of cyclophosphamide-including immunosuppressive regimens. **Mycophenolate mofetil** (MMF) has been used in the field of transplantation for more than 10 years. Following initial anecdotal reports describing benefits of MMF in the treatment of **lupus nephritis**, **randomized**, **controlled** trials have established a role for MMF in the treatment of **lupus nephritis**. MMF use to treat other **lupus**

manifestations has been evaluated only in anecdotal case reports or series with few well-designed trials. Issues complicating **clinical trial** design in **lupus** including appropriate use and interpretation of activity and damage indices, comparable remission and response criteria and stratification of high risk populations have been the subject of much discussion and emerging consensus. As long-term outcomes in **lupus** improve, the toxicity of therapy and risk of relapse become increasingly important determinants of choice of therapeutic agents.

Fulltext Information

13/66 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Robak E; Sysa-Jedrzejowska A; Wozniacka A

TI: Postepy i perspektywy leczenia ukladowego tocznia rumieniowatego. [Progress and perspectives in the treatment of systemic **lupus** erythematosus].

SO: Przeglad lekarski; VOL: 62 (9); p. 894-9 /2005/

AB: Systemic **lupus** erythematosus (SLE) is an autoimmune disease that predominantly affects women in childbearing age. SLE tissue damage is mediated by autoantibodies, complement activation and immune complexes deposition. The disease is diagnosed on the basis of its **clinical** manifestations and the demonstration of characteristic immunological phenomena, especially antinuclear antibodies. Management of the disease includes regular monitoring of disease activity, avoidance of predisposing factors and therapy guided by the activity and severity of the leading organ manifestation. Treatment ranges from nonsteroidal antirheumatic drugs to intensive treatment with cytotoxic agents. Corticosteroids form the basis of all regimens. Antimalarials and azathioprine are important for treating mild and moderate SLE cases, especially for the long time. Cyclophosphamide given intravenously is the current gold standard for severe **lupus nephritis**. More recently new strategies for immunosuppression in SLE, that interfere with the syntesis of DNA and nucleotides have been developed (such as **mycophenolate mofetil**, fludarabine and cladribine). Other agents like cyclosporine and tacrolimus inhibit effect of the activation signals for T cells by inhibition of calcineurin. Some monoclonal antibodies against cytokines or components of the complement system interfere with the effector phase of the immune response. Abetimus (LJP-394) inhibits the production of anti-dsDNA antibodies and may prevent glomerulonephritis caused by anti-DNA containing immune complexes. Somatic gene therapy is also a novel approach in autoimmune disorders and my be a valuable method of SLE therapy in the future. The adrenal steroid prasterone (DHEA) has also shown benefitial effects in mild to moderate SLE. Finally, autologous stem cell transplantation can induce tolerance to self-antigens and cause significant improvement in SLE patients. However, new therapeutic strategies must be tested according to the established principles of **clinical trial** methods.

Fulltext Information

13/67 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Ginzler EM; Dooley MA; Aranow C; Kim MY; Buyon J; Merrill JT; Petri M; Gilkeson GS; Wallace DJ; Weisman MH; Appel GB

TI: **Mycophenolate mofetil** or intravenous cyclophosphamide for **lupus nephritis**.

SO: The New England journal of medicine; VOL: 353 (21); p. 2219-28 /20051124/

AB: BACKGROUND: Since anecdotal series and small, prospective, **controlled** trials suggest that **mycophenolate mofetil** may be effective for treating **lupus nephritis**, larger trials are desirable.
METHODS: We conducted a 24-week **randomized**, open-label, noninferiority **trial** comparing oral **mycophenolate mofetil** (initial dose, 1000 mg per day, increased to 3000 mg per day) with monthly intravenous cyclophosphamide (0.5 g per square meter of body-surface area, increased to 1.0 g per square meter) as induction therapy for active **lupus nephritis**. A change to the alternative regimen was allowed at 12 weeks in patients who did not have an early response. The **study** protocol specified adjunctive care and the use and tapering of

corticosteroids. The primary end point was complete remission at 24 weeks (normalization of abnormal renal measurements and maintenance of baseline normal measurements). A secondary end point was partial remission at 24 weeks. RESULTS: Of 140 patients recruited, 71 were randomly assigned to receive **mycophenolate mofetil** and 69 were randomly assigned to receive cyclophosphamide. At 12 weeks, 56 patients receiving **mycophenolate mofetil** and 42 receiving cyclophosphamide had satisfactory early responses. In the intention-to-treat analysis, 16 of the 71 patients (22.5 percent) receiving **mycophenolate mofetil** and 4 of the 69 patients receiving cyclophosphamide (5.8 percent) had complete remission, for an absolute difference of 16.7 percentage points (95 percent confidence interval, 5.6 to 27.9 percentage points; P=0.005), meeting the prespecified criteria for noninferiority and demonstrating the superiority of **mycophenolate mofetil** to cyclophosphamide. Partial remission occurred in 21 of the 71 patients (29.6 percent) and 17 of the 69 patients (24.6 percent), respectively (P=0.51). Three patients assigned to cyclophosphamide died, two during protocol therapy. Fewer severe infections and hospitalizations but more diarrhea occurred among those receiving **mycophenolate**.
CONCLUSIONS: In this 24-week **trial**, **mycophenolate mofetil** was more effective than intravenous cyclophosphamide in inducing remission of **lupus nephritis** and had a more favorable safety profile.

Fulltext Information

13/68 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Lenz O; Fornoni A; Contreras G

TI: Defining the role of **mycophenolate mofetil** in the treatment of proliferative **lupus nephritis**.

SO: Drugs; VOL: 65 (17); p. 2429-36 /2005/

AB: Systemic **lupus** erythematosus, which predominantly affects young women, is frequently complicated by renal involvement. The presence of acute glomerulonephritis significantly adds to morbidity and mortality. Cyclophosphamide has become the mainstay of treatment in patients with proliferative forms of **lupus nephritis**. However, adverse events such as severe infections and infertility have spurred the search for novel treatment regimens and agents. Sequential therapy has significantly reduced adverse events. In several pilot studies, **mycophenolate mofetil** (MMF) has emerged as a promising therapeutic approach for both the induction and maintenance phase in patients with **lupus nephritis**, delivering equal efficacy and a better adverse effect profile; however, these studies had a limited power, and a large, multicentre and probably multinational **clinical trial** will be needed to discern the optimal therapeutic approach. On the basis of the currently available literature, sequential therapy with cyclophosphamide induction followed by azathioprine or MMF maintenance can be recommended for most patients. In selected populations, induction with MMF is a reasonable option to reduce adverse events.

Fulltext Information

13/69 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Ong LM; Hooi LS; Lim TO; Goh BL; Ahmad G; Ghazalli R; Teo SM; Wong HS; Tan SY; Shaariah W; Tan CC; Morad Z

TI: **Randomized controlled trial** of pulse intravenous cyclophosphamide versus **mycophenolate mofetil** in the induction therapy of proliferative **lupus nephritis**.

SO: Nephrology (Carlton, Vic.); VOL: 10 (5); p. 504-10 /200510/

AB: BACKGROUND: The aim of the present **study** was to evaluate the efficacy of **mycophenolate mofetil** in the induction therapy of proliferative **lupus nephritis**.
METHODS: Forty-four patients from eight centres with newly diagnosed **lupus nephritis** World Health Organization class III or IV were randomly assigned to either **mycophenolate mofetil** (MMF) 2 g/day for 6 months or intravenous

cyclophosphamide (IVC) 0.75-1 g/m(2) monthly for 6 months in addition to corticosteroids.
RESULTS: Remission occurred in 13 out of 25 patients (52%) in the IVC group and 11 out of 19 patients (58%) in the MMF group (P = 0.70). There were 12% in the IVC group and 26% in the MMF group that achieved complete remission (P = 0.22). Improvements in haemoglobin, the erythrocyte sedimentation rate, serum albumin, serum complement, proteinuria, urinary activity, renal function and the Systemic **Lupus** Erythematosus Disease Activity Index score were similar in both groups. Twenty-four follow-up renal biopsies at the end of therapy showed a significant reduction in the activity score in both groups. The chronicity index increased in both groups but was only significant in the IVC group. Adverse events were similar. Major infections occurred in three patients in each group. There was no difference in gastrointestinal side-effects.
CONCLUSIONS: MMF in combination with corticosteroids is an effective induction therapy for moderately severe proliferative **lupus nephritis**.

Fulltext Information

13/70 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Benenson E; Fries JW; Heilig B; Pollok M; Rubbert A

TI: High-dose azathioprine pulse therapy as a new treatment option in patients with active Wegener's granulomatosis and **lupus nephritis** refractory or intolerant to cyclophosphamide.

SO: Clinical rheumatology; VOL: 24 (3); p. 251-7 /200506/

AB: The objective of this **study** was to evaluate the feasibility and safety of high-dose azathioprine pulse (HAP) therapy in the induction of remission in patients with active Wegener's granulomatosis (WG) or progressive **lupus nephritis** (LN) refractory to or intolerant of cyclophosphamide. Four patients with antineutrophil cytoplasmic antibody (ANCA)-associated WG and two patients with progressive LN were treated with HAP (1200-1800 mg) applied monthly as continuous intravenous infusions at 50 mg/h. Patients received a total of 50 courses of intravenous azathioprine (AZA) therapy. Disease activity was assessed using the Birmingham Vasculitis Activity Score (BVAS) and the Systemic **Lupus** Erythematosus Activity Index (SLEDAI). As only partial remission was induced in patients with progressive LN on this regimen, an additional 18 cycles were applied in these patients in which oral AZA at 100 mg/day in weeks 2 and 3 was added between two intravenous courses. A hereditary defect in thiopurine methyltransferase activity was excluded before initiation of treatment. High-dose azathioprine pulse and the intensified HAP treatment were well tolerated. Complete remission was achieved in two patients with WG suffering from three relapses of disease on application of 2-6 courses of HAP. Remission was maintained for 16-24 months. The remaining two patients with WG were withdrawn after 2-3 courses due to unchanged disease activity. In two patients with LN, partial remission was noted on 6-9 courses of HAP; however, the patients relapsed despite therapy with methotrexate and **mycophenolate mofetil**. The intensified HAP regimen led to partial or complete remission in both LN patients which was confirmed by sequential renal biopsies. Our results suggest that HAP therapy represents a well-tolerated regimen in patients with active WG and LN intolerant of or refractory to cyclophosphamide. As partial or complete remission was observed in four of six patients, further studies seem warranted to assess **clinical** efficacy in these patients.

Fulltext Information

13/71 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Contreras G; Tozman E; Nahar N; Metz D

TI: Maintenance therapies for proliferative **lupus nephritis**: **mycophenolate mofetil**, azathioprine and intravenous cyclophosphamide.

SO: Lupus; VOL: 14 Suppl 1; p. s33-8 /2005/

AB: For the treatment of proliferative **lupus nephritis**, long-term cyclophosphamide (CY) regimens are efficacious, however, at the expense of substantial toxicity. In

the last decade, sequential regimens of short-term CY induction followed by either **mycophenolate mofetil** (MMF) or azathioprine (AZA) maintenance have shown to be efficacious and safe reducing the long-term exposure to CY. In a maintenance **study** including predominantly Hispanics and African-Americans, the patients who received MMF and AZA maintenance had a higher cumulative probability of remaining free of the composite of death or chronic renal failure (CRF) compared to quarterly intravenous CY (IVCY) maintenance (89% in MMF, 80%, in AZA and 45% in IVCY). Likewise, MMF and AZA maintenance were associated with significantly lower incidence of severe infections (2% in each MMF or AZA, and 25% in IVCY), sustained amenorrhea (6% in MMF, 8% in AZA, and 32% in IVCY), and hospitalizations (one hospital-days per patient-year in each MMF or AZA, and 10 in IVCY). In a European induction **study** including predominantly Caucasians, patients who received any of two sequential regimens, low dose versus high dose IVCY induction both followed by AZA maintenance, had a high cumulative probability of remaining free of treatment failure (84% in low dose IVCY and 80% in high dose IVCY; treatment failure defined as a composite of free of corticosteroid resistant flare, nephrotic syndrome, doubling creatinine, and persistent elevated creatinine). Low dose IVCY and high dose IVCY induction were associated with low incidence of sustained amenorrhea (4% in each group) and severe infections (11% in low dose and 22% in high dose IVCY induction). Of interest, most of the severe infection episodes occurred while patients were receiving IVCY induction. Finally an Asian **study** demonstrated that patients with proliferative **lupus nephritis** could be effectively treated with short-term oral CY induction followed by AZA maintenance. The cumulative probability of complete remission was 76%. The relapse rate was only 11%. The incidence of permanent amenorrhea and infection were 8% and 33%, respectively. None of the Asian patients had an increase in serum creatinine level to double the baseline value. Maintenance therapies with MMF or AZA following short-term CY induction in a sequential regimen are efficacious and safe for the treatment of high-risk patients with proliferative **lupus nephritis**.

13/72 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Chan TM; Tse KC; Tang CS; Mok MY; Li FK

TI: Long-term **study** of **mycophenolate mofetil** as continuous induction and maintenance treatment for diffuse proliferative **lupus nephritis**.

SO: Journal of the American Society of Nephrology : JASN; VOL: 16 (4); p. 1076-84 /200504/

AB: **Mycophenolate mofetil** (MMF) and the sequential use of cyclophosphamide followed by azathioprine (CTX-AZA) demonstrate similar short-term efficacy in the treatment of diffuse proliferative **lupus nephritis** (DPLN), but MMF is associated with less drug toxicity. Results from an extended long-term **study**, with median follow-up of 63 mo, that investigated the role of MMF as continuous induction-maintenance treatment for DPLN are presented. Thirty-three patients were **randomized** to receive MMF, and 31 were **randomized** to the CTX-AZA treatment arm, both in combination with prednisolone. More than 90% in each group responded favorably (complete or partial remission) to induction treatment. Serum creatinine in both groups remained stable and comparable over time. Creatinine clearance increased significantly in the MMF group, but the between-group difference was insignificant. Improvements in serology and proteinuria were comparable between the two groups. A total of 6.3% in the MMF group and 10.0% of CTX-AZA-treated patients showed doubling of baseline creatinine during follow-up (P = 0.667). Both the relapse-free survival and the hazard ratio for relapse were similar between MMF- and CTX-AZA-treated patients (11 and nine patients relapsed, respectively) and between those with MMF treatment for 12 or > /=24 mo. MMF treatment was associated with fewer infections and infections that required hospitalization (P = 0.013 and 0.014, respectively). Four patients in the CTX-AZA group but none in the MMF group reached the composite end point of end-stage renal failure or death (P = 0.062 by survival analysis). It is concluded that MMF and prednisolone constitute an effective continuous induction-

maintenance treatment for DPLN in Chinese patients.

Fulltext Information

13/73 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Zhao M; Chen X; Chen Y; Liu Z; Liu Y; Lu F; Zhang Y; Wang H

TI: **Clinical** observations of **mycophenolate mofetil** therapy in refractory primary nephrotic syndrome.

SO: Nephrology (Carlton, Vic.); VOL: 8 (3); p. 105-9 /200306/

AB: **Mycophenolate mofetil** (MMF) is an effective immunosuppressive agent in renal transplantation, and preliminary studies suggest that it may also be effective in the treatment of **lupus nephritis**. This **study** investigated the efficacy and safety of MMF therapy in patients with refractory primary nephrotic syndrome in a prospective multicentre **clinical** observation. Nineteen refractory nephrotic patients with minimal change disease or mesangial proliferative glomerulonephritis were enrolled in this **study**. Combined MMF and prednisone therapy was used for 6 months with an initial MMF dose of 1.0-2.0 g/day and a prednisone dose of 20-60 mg/day; both drugs were tapered gradually. It was found that all patients achieved **clinical** remission and 11 of 19 responded within 4 weeks, and 12 of 19 patients entered complete **clinical** remission. The prednisone dose in those patients who were previously steroid dependent could be successfully tapered. During follow up, three patients experienced transient increasing of proteinuria associated with infections and recovered without an adjustment of therapy. One patient was withdrawn from the **study** because of a fall in haemoglobin levels; other adverse effects did not necessitate withdrawal. Follow-up renal biopsies in two patients found no alteration in renal pathology. **Mycophenolate mofetil** is an effective and well-tolerated immunosuppressive agent for patients with refractory nephrotic syndrome.

Fulltext Information

13/74 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Spetie DN; Tang Y; Rovin BH; Nadasdy T; Nadasdy G; Pesavento TE; Hebert LA

TI: **Mycophenolate** therapy of SLE membranous nephropathy.

SO: Kidney international; VOL: 66 (6); p. 2411-5 /200412/

AB: BACKGROUND: The immunosuppressant **mycophenolic acid** (MMF) has been used successfully to manage proliferative forms of systemic **lupus** erythematosus (SLE) glomerulonephritis (GN) World Health Organization (WHO) Classes III and IV. Less is known about MMF treatment of membranous SLE GN (WHO Class V, SLE MN).
METHODS: We report our experience with MMF therapy in 13 consecutive SLE MN patients participating in a prospective **study** of risk factors for SLE flare.
RESULTS: Baseline characteristics were: mean age 33 +/- 14 SD years, female/male ratio 11/2, Caucasians 7, African Americans 5, Oriental 1, serum creatinine 1.02 +/- 0.41, and mean 24-hour urine protein (P)/creatinine (C), ratio 5.1 +/- 4.1. Initial therapy was prednisone mean dose 31 +/- 17 mg/day, and MMF mean dose 1173 +/- 746 mg/day. Therapy also featured interventions to achieve renoprotection and proteinuria reduction. At 6 months of therapy, complete or partial remission was achieved in 10 of 13 patients. At most recent follow-up visit (mean follow-up 16 +/- 8 months), 9 of 13 patients were in complete remission, and in 11 of 13 patients, urine P/C ratio was < 0.8. During follow-up, serum creatinine either stabilized or was improved. The only serious complication during 208 patient months of follow-up was histoplasma pneumonia in 1 patient.
CONCLUSIONS: These promising results suggest that moderate dose MMF in combination with renoprotective/antiproteinuria therapy warrants further **study** in the management of SLE MN.

Fulltext Information

13/75 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Contreras G; Pardo V; Leclercq B; Lenz O; Tozman E; O'Nan P; Roth D

TI: Sequential therapies for proliferative **lupus nephritis**.

SO: The New England journal of medicine; VOL: 350 (10); p. 971-80 /20040304/

AB: BACKGROUND: Long-term therapy with cyclophosphamide enhances renal survival in patients with proliferative **lupus nephritis**; however, the beneficial effect of cyclophosphamide must be weighed against its considerable toxic effects.
METHODS: Fifty-nine patients with **lupus nephritis** (12 in World Health Organization class III, 46 in class IV, and 1 in class Vb) received induction therapy consisting of a maximum of seven monthly boluses of intravenous cyclophosphamide (0.5 to 1.0 g per square meter of body-surface area) plus corticosteroids. Subsequently, the patients were randomly assigned to one of three maintenance therapies: quarterly intravenous injections of cyclophosphamide, oral azathioprine (1 to 3 mg per kilogram of body weight per day), or oral **mycophenolate mofetil** (500 to 3000 mg per day) for one to three years. The base-line characteristics of the three groups were similar, with the exception that the chronicity index was 1.9 points lower in the cyclophosphamide group than in the **mycophenolate mofetil** group (P=0.009).
RESULTS: During maintenance therapy, five patients died (four in the cyclophosphamide group and one in the **mycophenolate mofetil** group), and chronic renal failure developed in five (three in the cyclophosphamide group and one each in the azathioprine and **mycophenolate mofetil** groups). The 72-month event-free survival rate for the composite end point of death or chronic renal failure was higher in the **mycophenolate mofetil** and azathioprine groups than in the cyclophosphamide group (P=0.05 and P=0.009, respectively). The rate of relapse-free survival was higher in the **mycophenolate mofetil** group than in the cyclophosphamide group (P=0.02). The incidence of hospitalization, amenorrhea, infections, nausea, and vomiting was significantly lower in the **mycophenolate mofetil** and azathioprine groups than in the cyclophosphamide group.
CONCLUSIONS: For patients with proliferative **lupus nephritis**, short-term therapy with intravenous cyclophosphamide followed by maintenance therapy with **mycophenolate mofetil** or azathioprine appears to be more efficacious and safer than long-term therapy with intravenous cyclophosphamide.

13/76 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Kapitsinou PP; Boletis JN; Skopouli FN; Boki KA; Moutsopoulos HM

TI: **Lupus nephritis**: treatment with **mycophenolate mofetil**.

SO: Rheumatology (Oxford, England); VOL: 43 (3); p. 377-80 /200403/

AB: OBJECTIVE: To evaluate the safety and efficacy of **mycophenolate mofetil** (MMF) treatment in patients with **lupus nephritis**.
METHODS: Eighteen patients with biopsy-proven **lupus nephritis** (17 females, one male; mean age 31.6 yr; mean **lupus** duration 92 months; mean duration of **nephritis** 57 months; nine with focal proliferative glomerulonephritis, three with diffuse proliferative glomerulonephritis, six with membranous nephropathy) were included. With five exceptions, all patients had been treated previously with cyclophosphamide and were selected because of either toxicity or inadequate **clinical** response to treatment. MMF was given at 2 g daily in combination with steroids for up to 31 months (mean 15.3 months). The side-effects of MMF were recorded and efficacy was assessed as the renal function profile.
RESULTS: Complete remission was observed in 10/18 patients and another 4/18 went into partial remission. Both creatinine clearance and proteinuria were significantly improved during MMF treatment in patients with the proliferative forms of **nephritis**. MMF demonstrated a steroid-sparing effect in the whole population. Treatment failure was recorded in 4/18 patients, all with membranous nephropathy. Two patients developed gastrointestinal complaints and infectious meningitis occurred in one patient.
CONCLUSIONS: MMF appears to be an efficacious and safe treatment in patients with proliferative forms of **lupus nephritis** who do not respond to or cannot tolerate conventional treatment. The efficacy of MMF in **lupus** membranous

nephropathy remains unclear.

Fulltext Information

13/77 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Hu W; Liu Z; Chen H; Tang Z; Wang Q; Shen K; Li L

TI: **Mycophenolate mofetil** vs cyclophosphamide therapy for patients with diffuse proliferative **lupus nephritis**.

SO: Chinese medical journal; VOL: 115 (5); p. 705-9 /200205/

AB: OBJECTIVE: To make an open label prospective **trial** for comparing the therapeutic effects of **mycophenolate mofetil** (MMF) vs cyclophosphamide (CYC) pulse therapy on patients with diffuse proliferative **lupus nephritis** (DPLN).
METHODS: Forty-six patients with biopsy proven active DPLN were enrolled in this **study**. Twenty-three patients were given MMF orally at a dosage of 1.0 - 1.5 g/d (MMF Group). Another 23 cases received conventional intermittent CYC pulse therapy (CYC Group). Supplemental steroid treatment was offered in the same manner to both groups. The age, sex distribution and severity of renal damage were matched in two groups. Therapeutic effects were evaluated at the end of six-month treatment. Fifteen patients in the MMF Group and 12 patients in the CYC Group had repeated renal biopsy at that time.
RESULTS: MMF therapy was more effective in reducing proteinuria and hematuria. A 50% reduction of urinary protein and urinary red blood cell excretion from baseline value in 69.6% and 91.3% patients in the MMF Group, while only 47.8% and 65.2% in the CYC Group. MMF was more effective in inhibiting autoantibody production (especially anti-dsDNA antibody) and in decreasing serum cryoglobulin levels. Pathologically, the MMF group showed more markedly reduction in glomerular immune deposits with less glomerular necrosis, and less microthrombi, less crescent formation and vascular changes in the repeated renal biopsy as compared with the CYC group. Adverse reactions related to the treatment included gastrointestinal symptoms 26.1% and 43.5% in the MMF and CYC Groups respectively, infection 17.4% in the MMF group and 30.4% in the CYC group.
CONCLUSIONS: MMF was more effective in controlling the **clinical** activity of DPLN and renal vascular lesions as compared with CYC pulse therapy in a 6 month follow-up **study**.

Fulltext Information

13/78 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Contreras G; Roth D; Pardo V; Striker LG; Schultz DR

TI: **Lupus nephritis**: a **clinical** review for practicing nephrologists.

SO: Clinical nephrology; VOL: 57 (2); p. 95-107 /200202/

AB: The renal manifestations in systemic **lupus** erythematosus (SLE) are protean and difficult to categorize into **clinical** syndromes and histologic classes. **Lupus nephritis** is frequently unrecognized until full-blown nephritic and/or nephrotic syndrome with renal failure emerge. Epidemiologically, approximately one third of SLE patients from unselected populations have renal involvement early during the disease. Most renal abnormalities emerge within the first few years of SLE diagnosis. Currently, most nephrologists agree that an early renal biopsy is worthwhile in those SLE patients with abnormal urinalysis and/or reduced renal function. First, it provides a histologic categorization of the glomerulonephritis as well as an assessment of the degree of activity and chronicity. Second, it provides vital prognostic information. Third, it is beneficial in planning a more rational therapy with or without potentially toxic immunosuppressive agents. Over the last 3 decades, many **controlled clinical** trials for treatment of **lupus nephritis** have been completed with a few therapeutic immunosuppressive regimens. Among those agents used. cyclophosphamide and azathioprine provide a reduction of morbidity in those patients afflicted with proliferative forms of **lupus** glomerulonephritis. A new immunosuppressive agent, **mycophenolate mofetil**, is being studied for treatment of proliferative forms of **lupus** glomerulonephritis in a **controlled clinical trial** at our institution. Immunosuppressive agents and the availability of dialysis and transplantation have improved the survival of patients

with **lupus nephritis**, in particular those with proliferative forms.

Fulltext Information

13/79 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Kingdon EJ; McLean AG; Psimenou E; Davenport A; Powis SH; Sweny P; Burns A

TI: The safety and efficacy of MMF in **lupus nephritis**: a pilot **study**.

SO: Lupus; VOL: 10 (9); p. 606-11 /2001/

AB: Inducing and maintaining remission in patients with **lupus nephritis** may be difficult. Current treatments have significant toxicity. **Mycophenolate mofetil** (MMF) limits damage in murine models of **lupus nephritis**. We have assessed the efficacy and tolerability of MMF in the treatment of patients with long-standing or resistant **lupus nephritis**. We have treated 13 patients with biopsy proven **lupus nephritis** (two membranous nephropathy, four membranous nephropathy with superimposed proliferative changes, seven with proliferative glomerulonephritis). All patients had relapsed on conventional treatment or there were pressing indications to minimise steroid dosage or avoid alkylating agents. Nine out of 13 were treated with MMF and prednisolone, 3/10 with MMF alone and 1/10 with MMF, prednisolone and cyclosporine. Thirteen patients were treated with MMF for up to 37 months (median 25 months). Three patients were withdrawn from MMF during the first 8 months of treatment. The remainder tolerated MMF (median dose 1 g/day). Serological improvements were observed in 9/13 and steroid dosage was reduced in 8/10 patients. Infections occurred in 3/13. One patient relapsed. MMF significantly reduced the rate of decline of renal function. MMF should be considered in the treatment of long-standing or resistant **lupus nephritis**. **Controlled clinical** trials are required to confirm these findings.

Fulltext Information

13/80 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Buratti S; Szer IS; Spencer CH; Bartosh S; Reiff A

TI: **Mycophenolate mofetil** treatment of severe renal disease in pediatric onset systemic **lupus** erythematosus.

SO: The Journal of rheumatology; VOL: 28 (9); p. 2103-8 /200109/

AB: OBJECTIVE: To report the first **clinical** experience with **mycophenolate mofetil** (MMF, CellCept) in: children with **lupus nephritis**.
METHODS: Eleven children with various forms of **lupus nephritis** were treated with oral MMF at a mean dose of 22 mg/kg/day (range 17-42) for a mean of 9.8 months (range 3-17). All children received concomitant prednisone and 7/11 were taking concomitant hydroxychloroquine. Indications for MMF included treatment refractory **nephritis** despite high dose oral or IV prednisone, azathioprine, and/or cyclophosphamide. Treatment outcome was monitored through assessment of Systemic **Lupus** Erythematosus Disease Activity Index (SLEDAI) score, renal function, and serologic markers such as complement and anti dsDNA antibodies.
RESULTS: While renal function normalized in 4/4 patients with membranous glomerulonephritis, little effect was observed in children with proliferative glomerulonephritis. Ten children experienced a marked reduction in SLEDAI score. Anti-dsDNA antibody and serum complement levels improved or remained stable in 80% of the children. Concomitant prednisone was decreased in 6/11 patients (55%) without deterioration of renal function. Adverse events, observed in 8 patients (73%), were not dose dependent, and included infections, leukopenia, nausea, pruritus, headache, and fatigue.
CONCLUSIONS: MMF may represent a valuable alternative to traditional cytotoxic agents for children with class V **lupus nephritis**, but was less effective in attenuating disease progression in class IV glomerulonephritis. MMF had a steroid sparing effect and appeared to be effective in controlling serologic disease activity in pediatric onset SLE. Adverse events such as infections may limit its use and remain a concern.

Fulltext Information

13/81 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Chan TM; Li FK; Tang CS; Wong RW; Fang GX; Ji YL; Lau CS; Wong AK; Tong MK; Chan KW; Lai KN

TI: Efficacy of **mycophenolate mofetil** in patients with diffuse proliferative **lupus nephritis**. Hong Kong-Guangzhou Nephrology **Study** Group.

SO: The New England journal of medicine; VOL: 343 (16); p. 1156-62 /20001019/

AB: BACKGROUND: The combination of cyclophosphamide and prednisolone is effective for the treatment of severe **lupus nephritis** but has serious adverse effects. Whether **mycophenolate mofetil** can be substituted for cyclophosphamide is not known.
METHODS: In 42 patients with diffuse proliferative **lupus nephritis** we compared the efficacy and side effects of a regimen of prednisolone and **mycophenolate mofetil** given for 12 months with those of a regimen of prednisolone and cyclophosphamide given for 6 months, followed by prednisolone and azathioprine for 6 months. Complete remission was defined as a value for urinary protein excretion that was less than 0.3 g per 24 hours, with normal urinary sediment, a normal serum albumin concentration, and values for serum creatinine and creatinine clearance that were no more than 15 percent above the base-line values. Partial remission was defined as a value for urinary protein excretion that was between 0.3 and 2.9 g per 24 hours, with a serum albumin concentration of at least 30 g per liter.
RESULTS: Eighty-one percent of the 21 patients treated with **mycophenolate mofetil** and prednisolone (group 1) had a complete remission, and 14 percent had a partial remission, as compared with 76 percent and 14 percent, respectively, of the 21 patients treated with cyclophosphamide and prednisolone followed by azathioprine and prednisolone (group 2). The improvements in the degree of proteinuria and the serum albumin and creatinine concentrations were similar in the two groups. One patient in each group discontinued treatment because of side effects. Infections were noted in 19 percent of the patients in group 1 and in 33 percent of those in group 2 (P = 0.29). Other adverse effects occurred only in group 2; they included amenorrhea (in 23 percent of the patients), hair loss (19 percent), leukopenia (10 percent), and death (10 percent). The rates of relapse were 15 percent and 11 percent, respectively.
CONCLUSIONS: For the treatment of diffuse proliferative **lupus nephritis**, the combination of **mycophenolate mofetil** and prednisolone is as effective as a regimen of cyclophosphamide and prednisolone followed by azathioprine and prednisolone but is less toxic.

Fulltext Information

13/82 of 87 DIMDI: MEDLINE (ME90) © NLM - Document Price: 0.25 €

AU: Dooley MA; Cosio FG; Nachman PH; Falkenhain ME; Hogan SL; Falk RJ; Hebert LA

TI: **Mycophenolate mofetil** therapy in **lupus nephritis**: **clinical** observations.

SO: Journal of the American Society of Nephrology : JASN; VOL: 10 (4); p. 833-9 /199904/

AB: **Controlled clinical** trials in renal transplantation have demonstrated that **mycophenolate mofetil** is well tolerated and has lower renal transplant rejection rates than azathioprine regimens. This **study** reports on the **clinical** experiences at two institutions with **mycophenolate mofetil** (MMF) for severe **lupus nephritis**. Twelve patients with relapsing or resistant **nephritis** previously treated with cyclophosphamide therapy and one patient who refused cyclophosphamide as initial therapy for diffuse proliferative **nephritis** but accepted MMF were included. During combined MMF/prednisone therapy, serum creatinine values remained normal or declined from elevated values: mean change in serum creatinine was -0.26+/-0.46 microM/L, P = 0.039. Proteinuria significantly decreased: mean change in urine protein-to-creatinine ratios was -2.53+/-3.76, P = 0.039. Decreased serum complement component C3 and elevated anti-double-stranded DNA antibody levels at baseline improved in some, but not all, patients. The mean initial dose of MMF was 0.92 g/d (range, 0.5 to 2 g/d). The mean duration of therapy was 12.9 mo (range, 3 to 24 mo). Adverse

events included herpes simplex stomatitis associated with severe leukopenia (n = 1), asymptomatic leukopenia (n = 2), nausea/ diarrhea (n = 2), thinning of scalp hair (n = 1), pancreatitis (n = 1), and pneumonia without leukopenia (n = 1). Recurrence of the pancreatitis led to discontinuation of MMF in this patient; all other adverse events resolved with dose reduction. It is concluded that MMF is well tolerated and has possible efficacy in controlling major renal manifestations of systemic **lupus** erythematosus. **Controlled clinical** trials are needed to define the role of MMF in the management of **lupus nephritis**.

Fulltext Information

13/83 of 87 DIMDI: EMBASE (EM90) © 2016 Elsevier B.V. - Document Price: 1.36 €

AU: Hahn BH; Wong M; Lourenco E; Skaggs B

TI: Laquinimod (LAQ) is equivalent to **mycophenolate mofetil** (MMF) in preventing and suppressing murine **lupus nephritis** and has greater effects on myeloid/monocyte/macrophage cells

SO: Arthritis and Rheumatism; VOL: 64; p. s1032 /October 2012/

AB: Background/Purpose: **Lupus nephritis** (LN) depends on autoAb deposition and activation of multiple cell types that infiltrate kidneys and promote inflammation-monocytes/macrophages (MM), DCs, T and B cells. Laquinimod (LAQ) administered to **humans** downregulates Ag presentation, decreases chemokine production, decreases MHC expression on MM, and induces apoptotic pathways in PBMC (Gurevich M et al 2010). LAQ reduces progression of relapsing remitting multiple sclerosis (Comi G et al NEJM 2012); it is currently in **clinical** trials in SLE. MMF targets primarily lymphocytes; it is effective in many LN patients. Methods: We compared **clinical** and immune cell changes in groups of 10-12 BWF1 female mice treated orally 3 times a week for 24 weeks with a) water; b) LAQ 1 mg/kg; c) LAQ 25 mg/kg; d) MMF 30 mg/kg; e) MMF100 mg/kg. Results: Survival was better in both LAQ groups and the MMF100 group vs controls (p=0.028). LAQ at both doses was equivalent to MMF100 in preventing proteinuria in mice treated before disease appeared. At 32 wks of age 50% of mice on water had proteinuria vs zero in LAQ and MMF100 groups (p< 0.0001) Renal histology mirrored proteinuria: mean total histologic scores were 7.8 on water, 1.0 on LAQ and 0.9 on MMF100 (p< 0.01 both treatment groups compared to controls). Glomerular deposition of Ig and C3 were in the normal range in LAQ and MMF, but significantly increased in the water group (p< 0.001). Mice treated after **clinical nephritis** appeared (> =3+proteinuria) improved on LAQ: after 3 wks of treatment proteinuria was present in 100% on water vs 25% on LAQ (p< 0.001). Survival was also better in mice treated with LAQ (p< 0.0001). Effects on splenic PBMC differed between LAQ and MMF. Neither treatment changed total numbers of B cells. MMF decreased CD4+ and CD8+ T cell percents; LAQ did not. LAQ compared to MMF increased numbers of two putative regulatory cells, CD4+CD25+Foxp3+ Treg and CD11b+Ly6intGR-1+ myeloid MM. Most interesting was the observation that LAQ, but not MMF, significantly reduced numbers of MM. Conclusion: LAQ was highly effective in preventing and suppressing proteinuria and glomerular immune disease in BWF1 mice. Responses to MMF in high dose were similarly good. However, LAQ reduced numbers of MM, and MMF did not. In addition, LAQ induced different types of regulatory cells, distinguishing it from MMF. Since suppression of MM is likely to reduce renal inflammation and damage, future development of LAQ as a therapeutic for **lupus nephritis** is especially promising. .

Fulltext Information

13/84 of 87 DIMDI: EMBASE (EM90) © 2016 Elsevier B.V. - Document Price: 1.36 €

AU: Liu L-L; Jiang Y; Wang L-N; Yao L; Li Z-L

TI: Efficacy and safety of **mycophenolate mofetil** versus cyclophosphamide for induction therapy of **lupus nephritis**: A meta-analysis of **randomized controlled** trials

SO: Drugs; VOL: 72 (11); p. 1521-1533 /2012/

AB: Introduction: Whether **mycophenolate mofetil** is superior to cyclophosphamide

as induction therapy for **lupus nephritis** (LN) remains controversial. Objective: Our objective was to investigate the efficacy and safety of **mycophenolate mofetil** compared with cyclophosphamide as induction therapy for LN patients. Methods: **Randomized controlled** trials (RCTs) on **humans** were identified in searches of PubMed/MEDLINE,EMBASE and theCochraneCentralRegister of **Controlled** Trials (all to 1 December 2011). Studies that compared the efficacy and safety between **mycophenolate mofetil** and cyclophosphamide as induction therapy in LN patients were selected. Methodological quality of the included trials was assessed according to Cochrane criteria and Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines. The fixed effects model was applied for pooling where there was no significant heterogeneity, otherwise the random effects model (Dersimonian and Laird method) was performed. Results: Seven trials were identified, including 725 patients. The Dersimonian and Laird method was applied for renal remission in the presence of significant heterogeneity, and no statistically significant differences were distinguished between **mycophenolate mofetil** and cyclophosphamide. To explore the possible source of heterogeneity, meta-regression was performed. It was suggested that no obvious **study**- or patient-level factors could explain interstudy heterogeneity with statistical significance. Among all these factors, the mode of administration of cyclophosphamide could explain most of the heterogeneity, although the coefficient was insignificant. Therefore, we performed a sensitivity analysis by excluding the **trial** in which cyclophosphamide was administered orally instead of intravenously, which suggested that mycophenolatemofetil was more effective than intravenous cyclophosphamide for inducing complete remission (relative risk [RR] 1.72; 95% CI 1.17, 2.55; p = 0.006) and complete or partial remission (RR 1.18; 95% CI 1.04, 1.35; p = 0.01). In addition, **mycophenolate mofetil** was superior to cyclophosphamide for significantly reducing end-stage renal disease (ESRD) or death (RR 0.64; 95% CI 0.41, 0.98; p = 0.04). For the safety comparison, lower risks of leukopenia, amenorrhoea and alopecia, and a higher risk of diarrhoea were found with **mycophenolate mofetil**. No statistical differences in infection and gastrointestinal symptoms were distinguished between **mycophenolate mofetil** and cyclophosphamide. The relatively small number and the open-label fashion of eligible RCTs may limit the value of our meta-analysis. Conclusions: **Mycophenolate mofetil** is superior to intravenous cyclophosphamide for inducing renal remission, and has a significant advantage over cyclophosphamide for reducing ESRD or death. Furthermore, **mycophenolate mofetil** has lower risks of leukopenia, amenorrhoea and alopecia, but a higher risk of diarrhoea than cyclophosphamide. However, our conclusions need to be proved further in larger well designed trials. Adis © 2012 Springer International Publishing AG. All rights reserved.

Fulltext Information

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AU: Rangan GK; Nguyen T; Mainra R; Succar L; Schwensen KG; Burgess JS; Ho KO

TI: Therapeutic role of sirolimus in non-transplant kidney disease

SO: Pharmacology and Therapeutics; VOL: 123 (2); p. 187-206 /August 2009/

AB: Sirolimus is a member of a novel class of immunosuppressant drug that potently suppresses T cell proliferation and expansion by inhibition of the Target of Rapamycin Complex 1 (TORC1) protein kinase. Sirolimus also has anti-proliferative effects on intrinsic cells of the kidney, and increasing evidence suggests that it may have a therapeutic role in non-transplant renal diseases. In the normal kidney, sirolimus is considered to be non-nephrotoxic. In the diseased kidney, sirolimus may be beneficial or detrimental, depending on the type of renal injury. In polycystic kidney disease, TORC1 activation mediates renal tubular epithelial cell (TEC) proliferation and cyst growth in animals, and Phase III **clinical** trials are underway to determine the effect of sirolimus in attenuating disease progression in **humans**. In contrast, in acute kidney injury, sirolimus transiently impairs proximal TEC regeneration and delays renal recovery. In animal models of **lupus nephritis** and diabetic kidney disease, sirolimus prevents

disease progression. However, the efficacy of sirolimus in human glomerulonephritis as well as in diabetic chronic kidney disease remains unclear, as it paradoxically exacerbates renal dysfunction when the baseline glomerular filtration rate is low (< 40 ml/min/1.73 m²) and there is heavy proteinuria (> 300 mg/day). This may, in part, be due to inhibition of compensatory glomerular capillary repair through the suppression of endothelial cell proliferation and angiogenic growth factor production by podocytes. Therefore, at present, polycystic kidney disease is the most promising therapeutic application for sirolimus in non-transplant renal diseases, and further studies are needed to clarify its role in other situations. Crown Copyright © 2009.

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AU: Davidson A; Aranow C

TI: Pathogenesis and treatment of systemic **lupus** erythematosus **nephritis**

SO: Current Opinion in Rheumatology; VOL: 18 (5); p. 468-475 /200609/

AB: PURPOSE OF REVIEW: Glomerulonephritis is a challenging complication of systemic **lupus** erythematosus that still results in kidney loss in up to 30% of patients. In this review we highlight the development of integrated efforts to link pathogenesis with disease definition and new therapeutics. RECENT FINDINGS: Immune complex deposition in the kidney initiates an inflammatory cascade that causes glomerular disease but there are many modulating factors including genetic predisposition, products of the innate immune system, cytokines, complement and activated cells (both renal and immune). Animal models can help dissect potential disease mechanisms but the **study** of multiple models will be required since there are multiple subsets of human disease. Recent therapeutic studies in **humans** address the distinction between therapies for remission induction and remission maintenance. Multiple studies confirm the therapeutic equivalence of **mycophenolate mofetil** and cyclophosphamide in induction of remission but results are still far from ideal. The next few years should see the testing of new biologic reagents in **humans**. Another area of interest is the search for noninvasive measures of disease and disease response. SUMMARY: Although there has been remarkable progress in our understanding of the immunology and phenotype of **lupus nephritis** current therapies have insufficient efficacy. As new therapies emerge, improved **clinical** design coupled with mechanistic studies will be needed to identify agents that may be effective only in some patient subpopulations. © 2006 Lippincott Williams & Wilkins.

Fulltext Information

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AU: Teplitsky V; Shoenfeld Y; Tanay A

TI: The renin-angiotensin system in **lupus**: Physiology, genes and practice, in animals and **humans**

SO: Lupus; VOL: 15 (6); p. 319-325 /2006/

AB: Although multiple studies suggest a potential role for angiotensin II in inflammation, most were performed either in vitro or in animals with non-immune-complex-mediated diseases. Extrapolation of these findings to **humans**, particularly patients with **lupus**, which involves multiple immunoregulatory pathways, is unclear. In autoimmune-prone MRL/lpr mice, angiotensin-converting-enzyme (ACE) inhibition improved survival although to a lesser degree than cyclophosphamide and diminished the glomerular histopathologic damage, proteinuria, lymphoid hyperplasia, dermatitis, and hypergammaglobulinemia, with a reduction in TGF-beta1 and beta 2 expression in the kidneys and renal chemokine mRNA expression. Spleen levels of IL-4 and IL-10 were also reduced. Uncontrolled studies in patients with treatment-refractory **lupus nephritis** showed a significant reduction in proteinuria with ACE-inhibitors and Angiotensin receptor blockers treatment. The 'masking' effect of ACE-inhibitors should be taken into consideration, as an exacerbation of **lupus nephritis** may be missed when estimated by the magnitude of proteinuria, which is decreased by these

treatments. No single ACE genotype was consistently associated with subsets of SLE patients. In retrospective analyses, ACE-inhibitor use predicted a favourable outcome in 94 cases of pauci-immune vasculitis. The attenuating effect of angiotensin II inhibitors on the progression of chronic renal disease is well recognized. The data on the role of this intervention in **lupus** is limited.

*** End of SHOW ***

Anlage 1b

DIMDI-Recherche in Medline und EMBASE am 11.04.2016

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3 : Number of hits is 51605
?
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4 : Number of hits is 21398
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f 3 OR 4
5 : Number of hits is 56490
?
f ft=clinical trial
6 : Number of hits is 1575604
?
f ft=multicenter study
7 : Number of hits is 336820
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8 : Number of hits is 822588
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Übersetzung der Recherche

Find (“lupus nephritis“ AND (“mycophenolic acid” OR “mycophenolate mofetil”) AND “humans“ AND (“clinical trial” OR “multicenter study“ OR “randomized controlled trial“ OR “metaanalysis“))