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Mycophenolate Mofetil; A Review of Indications and Use in a Large Tertiary Hospital

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ABSTRACT

Mycophenolate Mofetil (MMF) has been registered for use in Australia since 1997 for prophylaxis of solid organ allograft rejection. MMF is now increasingly used for indications outside solid organ allograft rejection, often with limited supporting efficacy data. The purpose of this audit was to examine the patterns of use, reported side effects and cost impact of the drug in the Clinical and Immunology and Allergy (CIA) unit of Australia's largest teaching hospital.

Prescription patterns for MMF by consultant immunologists at Westmead hospital between 2000 and 2004 were obtained from the pharmacy. These data were sorted for non-S100 indications. A single immunologist then reviewed the patient files. We also reviewed the literature on the use of this promising immunosuppressant.

There has been a marked increase in use of MMF since year 2000 by the Department of CIA. A total of 75 patients were prescribed MMF for non-S100 indications. Common indications were systemic lupus erythematosus, pemphigus vulgaris, chronic idiopathic urticaria, myasthenia gravis, polymyositis, atopic dermatitis, Sjögren's disease, uveitis and vasculitis.

It is clear that MMF has potential for use in a number of immunological disorders because of its relatively benign side effect profile and observed efficacy. Double blinded, placebo-controlled, multicentre trials are necessary to establish its therapeutic role. Our study highlights some of the conditions for which this agent is useful.

Key words: Immunological diseases; Immunology; Immunosuppressants; Mycophenolic acid; Mycophenolate mofetil

INTRODUCTION

Mycophenolate Mofetil (MMF) is approved in Australia for the prophylaxis and treatment of acute solid organ allograft rejection in adults receiving allogeneic organ transplantation, and in paediatric patients (2 to 18 years) receiving renal transplants. The full potential and indications of MMF are relatively unknown, as this drug is a relatively new agent worldwide. As such MMF is now being increasingly used for indications outside solid organ allograft rejection, often with supporting efficacy data from small case series or anecdotal publications. Very little information is available in the form of randomized controlled trials for the use of MMF outside solid organ allograft rejection. The purpose of this audit was to establish the current indications for the use of MMF within the Department of CIA at one of Australia's

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largest teaching hospitals, and to identify any indications which may have on treated patient population of sufficient size to enable further research.

MATERIALS AND METHODS

Westmead Hospital is a 975 bed tertiary referral hospital, which serves a population of approximately 1.5 million. It is the largest teaching hospital in Australia. The CIA department at Westmead hospital employs a total of 4 full time immunologists and one half time immunologist. MMF prescription patterns in both inpatient and outpatient settings between 2000 and 2004 were obtained from the Westmead Hospital pharmacy. These data were examined for non-transplant indications of MMF (all transplant prescriptions of MMF were excluded from study) as prescribed by the Department of CIA.

A single immunologist reviewed all patient files (including lab results, physician letters) to identify how patients responded to MMF. The responses were classified as efficacious, not efficacious, unknown or inadequate trial. It was decided not to objectively classify efficacy due to the heterogeneity of the clinical disorders.

Mechanism of Action

Mycophenolate mofetil is an ester pro-drug which is rapidly converted *in vivo* to the active metabolite mycophenolic acid, a potent immunosuppressive agent. Mycophenolic acid acts as a selective and reversible inhibitor of the enzyme, inosine monophosphate dehydrogenase (IMPDH), a key enzyme in the *de novo* pathway for purine biosynthesis. It has relative specificity for cells types which rely predominantly on *de novo* purine biosynthesis, such as T and B lymphocytes and monocytes.[1] Furthermore, its specificity for the inducible form of IMPDH renders activated lymphocytes more susceptible to its effects than resting cells, and this may improve the therapeutic ratio of MMF.[2]

Review of the Literature: Clinical Indications

Initial indications for use of MMF were in the arena of solid organ transplantation, and transplant-related MMF use continues to predominate. More recently, however it has also been used to treat other immunological disorders.

Systemic Lupus Erythematosus (SLE)

Several studies have shown that MMF is effective in disease suppression and attenuation of nephritis and other autoimmune manifestations in animal models of SLE.[1,3,4] There have now been a number of reports of efficacy for management of SLE from human studies.[5-7] One study looked at the objective decrease in monthly anti-double stranded (ds) DNA monitoring after a clinical relapse and subsequent initiation of MMF,[5] while the other two studies looked at the effect of MMF in lupus nephritis.[6,7]

In a study by Bijl *et al.,*[5] 10/36 had a rise in the anti-(ds) DNA when they were prospectively followed in time. These patients were subsequently treated with a 2g/day dose of MMF for six months. In all patients anti-(ds) DNA decreased during treatment ($P < 0.001$), and no clinical relapse was reported. In a randomized controlled trial by Chan et al.[6] 46 patients with proliferative lupus nephritis were studied. Patients either received MMF [1g/twice daily (bd) for 6 months, then 0.5 bd for 6 months] or prednisolone with cyclophosphamide (2.5mg/kg orally daily for 6 months) followed by azathioprine (91.5mg/kg daily) and prednisolone. Both studies had similar rates of remission (MMF 81%, cyclophosphamide 76%), partial remission (MMF 14%, cyclophosphamide 14%), deaths (MMF 0%, cyclophosphamide 10%) and relapse (MMF 15%, cyclophosphamide 11%). In another study by Burrati et al.[7] MMF was used (22mg/kg/day for 3-17 months) in 11 children with various form of therapy-resistant (corticosteroid, azathioprine, cyclophosphamide) lupus nephritis. Of these patients MMF had a greater effect on membranous lupus nephritis, where all 4 patients had normalized creatinine, while it had little effect on the proliferative forms of lupus nephritis.

In addition to these trials, anecdotal reports of efficacy of MMF for management of refractory features of SLE in both children and adults have also been published.[8-11]

Idiopathic Thrombocytopenic Purpura (ITP)

MMF has been successfully used in 21 patients with refractory ITP.[12] Patients were treated with MMF in dosages of 1.5-2.0 g/daily, this resulted in an overall response rate of 62%, with a 24% complete response rate and a parallel decrease in platelet-associated auto-antibodies. MMF has also been successfully used in treatment of SLE-associated immune thrombocytopenia.[10]

Large Vessel Vasculitis

In a study by Daina et al.,[13] MMF (2 g/daily orally in two divided doses) was evaluated in three patients with severe Takayasu's arteritis. Patients were assessed by Doppler ultrasonography as well as clinical factors. Clinically all patients showed improvements, with all 3 patients able to discontinue steroids, 2 of the workers were able to return to work following months of inactivity.

Small Vessel Vasculitis

In patients with positive anti-neutrophil cytoplasmic antibody (ANCA)-associated vasculitis, MMF has been used with some success for induction and maintenance therapy (14-19). From 3 scientific meeting abstracts, in 13/20 patients remission was induced, 4 patients had to have the MMF stopped due to gastrointestinal side effects and in 3/20 patients MMF was not effective.[15-17] In a series by Norwack et al, MMF along with a combination of low dose steroids was used as maintenance therapy on 11 patients with ANCA-associated vasculitis after remission induced by cyclophosphamide.[18] In the study by Stegeman et al, 12 patients were treated with a combination of MMF (2 g/day) and prednisone (0.5–1.0 mg/kg per day with successive tapering).[19] All the patients responded to the treatment, with complete remission in 10 patients (median follow up 14 months) and the remaining 3 relapsing after 5-10 months.

Myositis Syndromes

Anecdotal reports of efficacy of MMF for treatment of Polymyositis (PM)[20,21] and dermatomyositis (DM) refractory to traditional therapy have been published.[22,23] There has also been a report of successful treatment of inclusion body myositis with MMF.[21] In the study by Tausche et al, 4 patients were initiated on an open trial of MMF, in these patients the addition of MMF had enabled the reduction of concurrent corticosteroid or intravenous immunoglobulins.[23] All patients tolerated the drug well, and had improvement of muscle strength and resolution of cutaneous erythema. In a larger more recent study of 4 patients with DM and 3 patients with PM who were initiated on treatment resistant inflammatory myopathies, 6 patients responded markedly while only one patient was treatment intolerant.[24]

Mysthenia Gravis (MG)

There has been some promising use of MMF in severe MG.[21,25-27] Two large studies[25,26] have highlighted the use of MMF in MG. In the retrospective analysis in 85 patients by Meroggioli et al, 73% achieved an improvement as graded by The Myasthenia Gravis Foundation of America postintervention status score.[25] Side effects were noted in 27% of patients but only 6% required discontinuation. In the study by Chaudhry et al, 32 patients with MG were initiated with the intent of primary treatment in 29/32 cases and as a steroid sparer in 25/32 of cases.[26] The mean duration of therapy of 11 months was associated with an improvement in strength in 19/32 of patients and resulted in steroid reduction in 16/32 patients.

Dermatological Conditions

MMF has been successfully used in patients suffering from severe psoriasis. In 11 patients treated with MMF (1 g/daily for 3 weeks, 0,5g/daily for 3 weeks afterwards), 10 patients showed some improvement as measured by the psoriasis area and severity score.[28] The only patient that showed side effects was withdrawn from the study (muscle pain).

MMF has also shown promise in pemphigus vulgaris (PV). In 12 patients who were initiated on MMF following relapse after treatment with azathioprine, 11 patients responded to the therapy and did not show any relapse after follow up at 9-12 months.[29] In some patients this allowed the tapering of the steroid dose.

Ten patients with moderate-severe atopic dermatitis who did not respond to conventional treatment (topical/systemic) were initiated on MMF.[30] All 10 had improvement as measured by the Scoring Atopic Dermatitis index within 4 weeks. After 4 weeks in 7/10 patients there was clear resolution of the disease. In other 3 patients, 2 responded primarily well and then relapsed and 1 had to discontinue due to the development of herpes retinitis.

A literature review of Medline, Pubmed, and Embase revealed that MMF has also been used in several other conditions with some success, including; chronic inflammatory demyelinating neuropathy, adult onset still's disease, bullous pemphigoid, cicatricial pemphigoid, epidermis bullosa acquista, pyoderma gangrenosum, pfeifer-weber-christian disease, dyshidrotic eczema, scleritis, Bechet's disease, idiopathic panuveitis.

RESULTS

From our study we identified a total of 75 patients treated with MMF (Table 1). There were 36 conditions, with the most common being SLE,[23] MG,[4] PV,[4] uveitis,[4] PM,[3] atopic dermatitis,[3] urticaria[3] and Sjögren's syndrome.[3]

Of these 75 patients, efficacy was noted in 46, non-efficacy in 20, inadequate trial in 5 and unknown outcome in 4. In larger patient groups, efficacy was noted in 17/22 patients with SLE, 4/4 patients with PV, 4/4 in patients with MG, in 2/3 patients with atopic dermatitis and 1/3 patients with PM.

The side effect profile of MMF in our patients was minimal in severity, with minimal side effects noted only in 13/72 patients with unknown side effect profiles noted in the remaining 3 patients. The most common complaint was gastrointestinal disturbance, noted in 10, cytopenia in 2 and abnormal liver function tests in 2.

The most commonly used dosage in the various conditions was 2000mg/day (range 500-3000mg/day). The duration of therapy varied among the patient group, hence is displayed individually as opposed to mean/median. In many of the patients MMF was used with other immunomodulators, including azathioprine, cyclophosphamide, methotrexate, corticosteroids, intravenous immunogloubulins and cyclosporin.

DISCUSSION

Our case series represent the departmental uses of MMF at a large tertiary hospital in Australia. As such it highlights the use of MMF in a wide variety of cases, in some instances our series included conditions that have not been previously reported. Interpretation of the results of our study must be viewed with the caution that efficacy was recorded subjectively by one Immunologist by review of the patient clinical notes as opposed to objective laboratory markers. However due to the vast heterogeneity of the conditions treated, there was no common marker that could be measured retrospectively. In an attempt to decrease the variability of efficacy, only one immunologist reviewed the patients. The findings from our case series encourage other researchers to evaluate the role of this medication in randomized controlled studies. The results from our study along with the building evidence base for MMF suggest that this useful immunosuppressant has a role in non-transplant patients. Results from our study may prompt other centres in Asia and around the world to evaluate the non-transplant use of MMF in randomized controlled trials. Emerging evidence suggests that it may have a role to play in induction and maintenance therapy, steroid reduction therapy and sole therapy in resistant immunological conditions. However this agent is new and expensive and is not routinely used as 1st line treatment in many conditions.

Adverse Reactions

The safety profile of MMF compares favourably with those of alternative immunosuppressive agents which are less specific for activated lymphocytes.[31] In contrast to the other agents, side effects such as neurotoxicity, nephrotoxicity, infertility, hypertension and hyperglycemia are rarely seen with MMF. Much of the data on the side effect profile of MMF is derived from studies in transplant recipients who display an increased risk of infections, especially from cyto-megalovirus. Furthermore these data are derived from studies where transplant recipients were receiving MMF as part of a potent combination immuno-suppressive regime. In addition, doses of MMF used in allograft recipients tend to be higher (commonly 3g/day) compared to those used for management of immunological disorders (usually 1-2g/day).

Previous Drugs Tried

The majority of publications describing therapeutic use of MMF for non-transplant-related immunological disorders describe its use in refractory cases. At present, MMF is not commonly used as first line therapy, due, at least in part, to its high cost and limited efficacy data. The majority of treated patients have previously received one or more additional immunosuppressive agents, including intravenous and oral corticosteroids, methotrexate, azathioprine, alky-lating agents and cyclosporin. This was especially true among our patients, in the majority of our patients MMF was only initiated after non-responsiveness to other immunosuppressive agents.

Departmental Costs

The use of MMF has increased since 2000-2004. With the ever increasing non-S100 indications for MMF, this trend is like to continue. However, the cost of MMF is considerable in comparison to traditional immunosuppressive agents, and this may limit increasing use in the current economic climate.

Table 1. Patients' characteristics, clinical manifestations and responses to mycophenolate mofetil.

Disease manifestations	Total number	Efficacy	Duration of therapy, (individually expressed in months)	Dosage (mg)	Side effects	Previous treatment tried
Systemic immune-mediated inflammatory disorders						
Systemic lupus erythematosus	23	17/22 (1 inadequate trial)	26 (mean), 1-84 (range)	1000-3000	GIT in 5	hydroxycholorquine, penicillamine, AZA, CPH, CYC, MTX, STR
Sjögren's syndrome	3	1/1 (2 unknown)	3, 7, 49	2000	GIT in 1	plasmaphoresis, AZA, STR
Adult-onset Still's disease	1	0/1	6	2000	nil	AZA, STR
Behcet's disease	1	1/1	unknown	2000	unknown	STR
Sarcoidosis with uveitis	1	0/1	6	2000		AZA, MTX, STR, CYC
Rheumatoid overlap syndrome	1	1/1	29	2000	nil	infliximab, lefunomide, AZA, MTX, STR
Seronegative arthritis with uveitis	1	1/1	7	2000	nil	AZA, CYC, STR
Systemic vasculitis syndromes						
Chürg Strauss syndrome	1	1/1	15	1000-2000	cytopenia in 1	CPH, STR
Cryoglobulinaemic-vasculitis, HCV-related	1	0/1	<1	1000	nil	CPH, IVIg, STR
Temporal arteritis	1	1/1	58	1000-2000	nil	AZA, CYC, MTX, STR
Leukocytoclastic vasculitis and ulceration	1	0/1	23	2000	nil	thalidomide, AZA, CYC, IVIg, MTX, STR
Nodular vasculitis and ulceration	1	1/1	18	1000-2000	nil	AZA, STR
Cutaneous vasculitis and ulceration	1	1/1	7	2000	nil	STR
Neuroimmunological disorders						
Myasthenia gravis	4	4/4	14, 20, 21, 39	1000-2500	abnormal LFT's in 1	plasmaphoresis, AZA, STR, IVIg
Demyelinating polyneuropathy	1	1/1	19	2000	nil	plasmaphoresis, AZA, STR
Myositis syndromes						
Polymyositis	3	1/3	12,12, 20	1500-2000	GIT, cytopenia, abnormal LFT's in 1	AZA, MTX, STR
Dermatomyositis	1	1/1	10	2000	nil	AZA, CYC, IVIg, STR

Table 1. (continued)

Disease manifestations	Total number	Efficacy	Duration of therapy, (individually expressed in months)	Dosage (mg)	Side effects	Previous treatment tried
Ocular inflammatory disorders						
Uveitis	4	2/3 (1 inadequate trial)	8, 8, 15, 32	2000-3000	nil	AZA, CYC, STR
Birdshot chorioretinopathy	1	1/1				CYC, STR
Vogt-Koyanagi-Harada syndrome	1	0/1	28	2000	nil	CYC, STR
Grave's opthalmopathy	1	0/1	12	2000	GIT	plasmaphoresis, CYC,STR
Orbital myositis	1	1/1	40	2000	nil	STR, AZA
Serpiginous choroidopathy	1	1/1	19	2000	nil	CYC, STR
Cutaneous disorders						
Pemphigus vulgaris	4	4/4	21, 24, 36, 69	1000-3000	nil	AZA, CPH, STR
Atopic dermatitis	3	2/3	5, 9, 24	2000	GIT in 1 , headache and alopecia in 1	topical tacrolimus, AZA, CYC,STR,
Cicatricial pemphigoid	1	1/1	61	2000-2500	nil	dapsone, AZA, STR
Pyoderma gangrenosum	1	0/1	2	2000	nil	thalidomide
Urticaria	3	2 inadequate trial, 1 unknown	1, 3, 6	500-2000	GIT and renal impairment in 1	hydroxychloroquine, AZA, CPH, CYC, MTX, STR
Discoid lupus	1	0/1	3	2000	nil	tacrolimus, AZA, STR
Miscellaneous						
Autoimmune hepatitis	1	1/1	48	1500	nil	CYC, STR
Sweets syndrome	1	unknown	24	1000	unknown	MTX, STR
Autoimmune inner ear disease	1	0/1	25	2000	nil	MTX, STR
Pulmonary fibrosis	1	1/1	24	500	nil	STR
Steroid dependent asthma	1	0/1	12	2500	nil	MTX, STR
Crohn's disease/panuveitis/ mononeuritis multiplex	1	Inadequate trial	1 week	2000	GIT in 1	STR
Sarcoidosis	1	0/1	6	2000	unknown	

AZA– azathioprine; CPH– cyclophosphamide; CYC– cyclosporin A; GIT– gastrointestinal disturbance; IVIg– intravenous immunoglobulin; LFT– liver function test; MTX– methotrexate; STR– corticosteroids

SUMMARY

This study illustrates some of the current non-transplant-related indications for this promising new immunosuppressive agent, as well as documenting its increasing non S-100 use for immunological indications. MMF has a low incidence of serious adverse effects as evident from published literature and from the analysis of our patients. Further research could involve performance of randomized controlled trials to look at the efficacy of this agent in the indications reported in this study. The high cost of MMF may constrain more widespread use.

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