INTRODUCTION

Corticosteroids have been a cornerstone of immunosuppression in organ transplantation for 40 years and are currently the standard in all renal transplant programs. The burden of steroid use is multi-systemic and the adverse consequences have been greatest among pediatric transplant recipients. Despite diligent effort, transplant physicians have, for the most part, struggled unsuccessfully to eliminate the well-recognized steroid complications such as infection, hypertension, hyperlipidemia, growth suppression during crucial growth years, glucose intolerance and diabetes mellitus, bone loss, cataracts, acne, cushinoid appearance and changes in mood and behavior ***(Sarwal et al., 2001).***

Various attempts have been made to reduce or eliminate steroid use ***(Hericik et al., 1994).*** Alternate day steroid dosing in selected patients has been shown to achieve same improvement in growth velocity in children ***(Borger et al., 1992; Jabs et al., 1996)*** but has failed to gain wide spread acceptance because of a higher incidence of acute rejection after conversion to alternate day therapy ***(Roberti et al., 1994)***.

In the last few years there have been significant advances in immunosuppression, including the introduction of well tolerated interleukin-2 receptor inhibitors (daclizumab and basiliximab), mycophenolate mofetil (MMF), Sirolimus, and a new formulation of cyclosporine (Neoral). In addition, the calcineurin inhibitor; Tacrolimus has found increasing use in kidney transplantation. Given these recent advances, complete steroid avoidance in renal transplantation may be achievable with a well-balanced use of these newer agents ***(Sarwal et al., 2001).***

A combined tacrolimus / MMF regimen was viewed by many as the current best therapy in kidney transplantation (voted best therapy at the 1999

AST congress) and therefore the evaluation of anti-IL-2 monoclonal antibodies in this setting would be most appropriate.

Withdrawal of steroids is desirable because it may prolong graft survival and through improvements in cardiovascular fitness increase patient quality of life and long-term survival.

The efficacy of basiliximab in the prevention of acute rejection has been evaluated in two multicentre, double-blind, randomised, placebo-controlled trials in Europe, Canada ***(Kavarik et al., 1996; Nashan et al., 1997)*** and U.S. ***(Kovarik et al., 1997; Nashan et al., 1997; Kahan, 1998).*** The incidence of acute rejection episodes can be significantly lowered by basiliximab, without increasing the incidence of infections ***(Kovarik et al., 1996; Nashan et al., 1997)*** post-transplant lymphoproliferative disorders ***(Gunnarson et al., 1984)*** or other malignancies ***(Kovarik et al., 1996; Nashan et al., 1997).***

It has been shown in a study (n=27) with tacrolimus/ MMF triple regimen that it is possible to withdraw steroids in some patients as early as 7 days post transplant ***(Jindal et al., 1999).*** In this study there was an overall 27% acute rejection incidence (mean follow-up 6 months) but only 17% experienced rejection after withdrawal of steroids. It was suggested in this study that the early rejection episodes were as result of a delay in attaining therapeutic MPA levels. Immunosuppressive coverage during this period using monoclonal antibody, such as basiliximab, may facilitate early steroid withdrawal at an acceptable acute rejection incidence.

There were two trials had already investigated early steroid withdrawal or no steroid regimes. The first was a Canadian study in which anti-IL2R mAB, daclizumab, in a MMF/ciclosporin regimen, totally without steroids, have being tested ***Grewal, 1998).*** The other is a US-European study

in which basiliximab, was used in a regimen includes MMF and ciclosporin with steroids given only pre-operatively and for the first 4 days post transplant ***Vincenti et al., 1999).***