

A Phase III Study of Belatacept-based Immunosuppression Regimens versus Cyclosporine in Renal Transplant Recipients (BENEFIT Study)

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Belatacept, a costimulation blocker, may preserve renal function and improve long-term outcomes versus calcineurin inhibitors in kidney transplantation. This Phase III study (Belatacept Evaluation of Nephroprotection and Efficacy as First-line Immunosuppression Trial) assessed a more intensive (MI) or less intensive (LI) regimen of belatacept versus cyclosporine in adults receiving a kidney transplant from living or standard criteria deceased donors. The coprimary endpoints at 12 months were patient/graft survival, a composite renal impairment endpoint (percent with a measured glomerular filtration rate (mGFR) <60 mL/min/1.73 m² at Month 12 or a decrease in mGFR ≥ 10 mL/min/1.73 m² Month 3–Month 12) and the incidence of acute rejection. At Month 12, both belatacept regimens had similar patient/graft survival versus cyclosporine (MI: 95%, LI: 97% and cyclosporine: 93%), and were associated with superior renal function as measured by the composite renal impairment endpoint (MI: 55%, LI: 54% and cyclosporine: 78%; $p \leq 0.001$ MI or LI versus cyclosporine) and by the mGFR (65, 63 and 50 mL/min for MI, LI and cyclosporine; $p \leq 0.001$ MI or LI versus cyclosporine). Belatacept patients experienced a higher incidence (MI: 22%, LI: 17% and cyclosporine: 7%) and grade of acute rejection episodes. Safety was generally

similar between groups, but posttransplant lymphoproliferative disorder was more common in the belatacept groups. Belatacept was associated with superior renal function and similar patient/graft survival versus cyclosporine at 1 year posttransplant, despite a higher rate of early acute rejection.

Key words: Belatacept, cyclosporine, kidney, renal function

Received 08 July 2009, revised 01 December 2009 and accepted for publication 04 December 2009

Introduction

Although advances in posttransplantation immunosuppressive management have reduced rates of acute rejection and improved 1-year outcomes, commensurate improvements in long-term renal allograft survival rates have not been observed (1). The kidney allograft survival rate is 95% for transplants from living donors and 89% for transplants from deceased donors during the first year, with rates decreasing to 80% and 67%, respectively, at 5 years posttransplantation (2). The leading causes of death and graft loss are cardiovascular disease and chronic allograft nephropathy, respectively (3). Among the reasons for diminished long-term graft survival may be the chronic toxicities associated with calcineurin inhibitors, the current immunosuppression standard of care. Calcineurin inhibitors may contribute to diminished long-term allograft survival rates through nephrotoxicity, which can lead to chronic allograft nephropathy, continued decline in renal function and, ultimately, graft failure (4).

In addition, since calcineurin inhibitors affect a broad range of nonimmunologic targets, they are associated with worsening hypertension (5), diabetes (6,7) and dyslipidemia (8), which can contribute to increased cardiovascular morbidity and mortality (9–12)—the most common cause of death among transplant recipients 1 year posttransplant (13,14). The current long-term outcomes in renal transplant recipients indicate a need for selective immunosuppressants that may improve long-term patient and allograft survival by avoiding the chronic toxicities of nonselective immunosuppressive therapies.

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