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A multicenter, open-label, randomized, parallel study to evaluate the prevention of New Onset of Diabetes Mellitus after Renal Transplantation following Everolimus therapy with co-administration of low-dose Tacrolimus (PROTECT)

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Objectives: Tacrolimus-based immunosuppression is most popular maintenance immunosuppressive regimen in kidney transplant recipients but new onset diabetes after transplantation (NODAT) is a serious side effect. The objective of this randomized controlled study is to investigate the effect of everolimus (EVL) with low dose tacrolimus (Tac) on the development of NODAT and allograft function.

Methods: Total 77 kidney transplant patients from 4 transplant centers were included. Six months after kidney transplantation (KT), patients were randomized to “EVL group” (EVL with low dose Tac) (n=38) and “TAC group” (standard Tac with MMF) (n=39) and followed for one year. The target trough level of Tac was 2~5 ng/mL in the EVL group, and 5~10 ng/mL in the TAC group. The primary outcome was the incidence of NODAT. Secondary outcomes included the change of insulin resistance indexes, allograft function assessed by estimated glomerular filtration rate (eGFR), incidence of biopsy proven acute rejection.

Results: The one year cumulative incidence of NODAT in total patients was 7.8% and no difference was shown between the two groups (4 patients in EVL group and 1 patient in TAC group, p=0.0819). In comparison of change in insulin resistance, the TAC group showed significant increase of HOMA-IR (1.11 to 1.30, p=0.0492 in PP population), but the EVL group did not (1.13 to 1.26, p=0.7792 in PP population). In the aspect of the allograft function, the one-year allograft rejection rate and eGFR at every 3 months follow-up did not showed differences between the two groups. But EVL group showed a significant increase in eGFR at 9 months and 12 months after KT compared to that of baseline (eGFR; baseline, 60.84 mL/min/1.73m^2; 9 months, 64.94 mL/min/1.73m^2, p=0.0242; 12 months, 64.90 mL/min/1.73m^2, p=0.0491)

Conclusions: The EVL-based treatment with lowering Tac dose may be safe alternative maintenance immunosuppression in terms of protective effect on nephrotoxicity and insulin resistance.