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Induction therapy with Daclizumab in pediatric heart transplantation

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Daclizumab is a humanized monoclonal antibody which binds with high affinity to the Tac subunit of the IL-2 receptor complex. Effective immunosuppression with Daclizumab in adult patients encouraged the initiation of the administration of Daclizumab as induction therapy in pediatric heart transplantation. Sixteen patients (9 boys, 7 girls, age 8-7 yrs, BMI 1.75-0.52 m²), received Daclizumab as induction therapy in a dose of 1 mg/kg intravenously perioperatively and on day 7 and 21 after orthotopic heart transplantation. Additional immunosuppression was cyclosporine (CsA, n=14) or tacrolimus (TAC, n=2), mycophenolate mofetil (MMF) and prednisolone. Prednisolone was tapered rapidly in the first six months after heart transplantation.

The administration of Daclizumab was not associated with any side effect. Owing to the blockade of the IL-2-receptor the dosage of calcineurin inhibitors could be reduced leading to less renal and hepatic toxicity. Instead of aiming at CsA trough levels of 350-400 ng/ml/TAC trough levels of 12-15 ng/ml in the first weeks after transplantation we reduced to 250 in the CsA group and to 10 in the TAC group. CD25+ T-lymphocytes began to be re-expressed after 2-3 months after administration of Daclizumab.

In a mean follow-up time of 50.2 months no acute or chronic episode of rejection could be experienced. The incidence of opportunistic infections was not elevated (5 bacterial, 4 viral and 3 fungal infections which responded well to adequate treatment). No de novo malignancies, especially no lymphoproliferative disease (PTLD) was noticed. Actually patient and graft survival is 100%. Our results show that immunoprophylaxis with Daclizumab induction therapy in pediatric heart transplantation is safe, effective and well tolerated and does not lead to increased opportunistic infections or malignancies. The reduction of calcineurin inhibitors led to less calcineurin related side effects and raised the quality of life of transplanted patients.