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Everolimus – Initial side effects of everolimus should not exclude patients from long-term therapy – observation in 63 patients after pediatric heart transplantation

Ulrich S.M. (1), Lehner A. (1), Birnbaum J. (1), Schramm R. (2), Hagl C. (2), Dalla Pozza R. (1), Haas N.A. (1)
Department of Pediatric Cardiology and Intensive Care Medicine, Ludwig-Maximilians-University, Munich, Germany (1);
Department of Heart Surgery, Ludwig-Maximilians-University, Munich, Germany (2)

Background: Everolimus, the modern mTor-inhibitor, has the potential benefit of reduced side effects such as nephrotoxicity, risk of infections and risk of secondary malignancies. As many patients suffer from relevant side effects (such as stomatitis and gastrointestinal problems) during initial treatment, many patients after pediatric heart transplantation might be excluded from the potential benefit of everolimus.
Methods: Retrospective analysis of all of our patients under immunosuppressive therapy with everolimus. We focused on the reasons for switch of the immunosuppressive therapy to everolimus and the side effects that led to an interruption or termination of the therapy with everolimus.
Results: 63 patients after pediatric heart transplantation were switched to an everolimus based immunosuppressive therapy between January 2007 and October 2015. The therapy with everolimus was started in average 5.9 years after transplantation. Only five patients were switched to calcineurin inhibitor free therapy, the remaining patients had a combination therapy with cyclosporine A (n = 2) or with tacrolimus (n =56). After 2013 everolimus was standard therapy for all patients (n = 20). Other reasons for therapy with everolimus were vasculopathy (n = 15), renal insufficiency (n = 11) and gastrointestinal problems (n = 10). There was a mild improvement of the renal function and gastrointestinal problems especially 6 months after change of the immunosuppressive medication. The majority showed a stabilisation or even a mild improvement of the vasculopathy under treatment with everolimus.
However, almost one third of the patients (n = 18) discontinued the treatment with everolimus. The most important reasons were stomatitis (n = 6), gastrointestinal (n = 5) and haematological problems (n = 3). Based on the excellent clinical effect of everolimus we could convince 14 of 18 patients to restart everolimus about one year later. Thereafter 70 percent (n = 10) tolerated everolimus without the previously reported side effects.
Conclusion: The immunosuppressive therapy with everolimus is a save possibility even in pediatric patients who do not tolerate everolimus during the initial treatment.