

Tacrolimus once daily – Safe and effective after pediatric heart transplantation

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Background: Tacrolimus twice daily is the commonly used tacrolimus formulation after pediatric heart transplantation. In general, decreased adherence to regular intake of medication is a huge problem in pediatrics. To improve the situation tacrolimus once daily was developed. Several studies could verify the safety and effectiveness of tacrolimus once daily in adults; however, mild increase of the daily dose is required to achieve the target levels. If these findings also apply to pediatric patients is unknown yet.

Methods: Retrospective analysis of all patients after pediatric heart transplantation treated with tacrolimus once daily, special focus on the absolute daily dose required.

Results: Between 2012 and October 2015 44 patients after pediatric heart transplantation were switched from tacrolimus twice daily (n = 42), cyclosporine A (n = 1) and everolimus monotherapy (n = 1) to tacrolimus once daily. This change of the medication was in average 6.7 years after transplantation. In 25 cases, an evaluation of the daily tacrolimus dose before, one month and six months after change of the medication was possible. These patients needed an average daily tacrolimus dose of 2.5 mg under tacrolimus twice daily. The mean daily dose increased to 2.8 mg one month and to 3.0 mg six months after switch of the medication. Altogether, the development of the daily dose of tacrolimus was quite different. Six months after switch of the medication the daily dose of tacrolimus ranged between a decrease of 38 percent and an increase of 317 percent in comparison of the daily dose of tacrolimus before switch of the medication. None of the patients suffered from new side effects. Only one patient showed fluctuating tacrolimus trough levels, so that reinstatement of tacrolimus twice daily was necessary. In addition, patient compliance to the medication and quality of life were assessed by a patient questionnaire.

Conclusion: Based on our results we can recommend tacrolimus once daily as a safe and effective regime after pediatric heart transplantation. Single daily dose improves the adherence to the medication and the quality of life. Careful evaluation of the blood levels of tacrolimus is necessary during initiation of the medication.