

# Pharmacovigilance of Calcineurin Inhibitor (Tacrolimus) in Solid Organ Transplantation

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## Abstract

**INTRODUCTION:** Tacrolimus is lactones antibiotic isolated from the fermentation of streptomyces tskubaeis. This calcineurin inhibitor widely used for its immunosuppressive properties to increase patient survival and prevent graft function, organ rejection. It was first approved for use to prevent graft rejection in 1994 for liver transplantation and in 1997 for kidney transplantation. Tacrolimus, a pivotal immunosuppressant drug, acts by inhibiting calcineurin, which leads to inhibition of Tcell activation. Tacrolimus used to prevent graft rejection in solid organ transplant and graft-versus-host disease in transplant patients

**AIM:** This study was conducted to monitor the adverse drug reactions (ADRs) associated with calcineurin inhibitor (tacrolimus) to various immunosuppressant's drug regimens, its causality, severity and preventability assessment in patients receiving tacrolimus and as well as for solid organ Transplantation Observed between 2011 And 2013.

**METHOD:** In these study solid organ transplantation patients who received calcineurin inhibitor (tacrolimus) was mainly on the literature as case report and procedure of observational case series, cohort method study & analysis of the data was done. Solid organ transplantation patient's case report and characteristic summary of product characteristic were included in the study. Sources of Medical literatures published in any language on calcineurin inhibitor tacrolimus, identified using Pubmed, Medline and EMBASE, supplemented by Emtree & the ADR terms used in summary tabulation are coded as per medical dictionary for regulatory activities (MedDRA).

**RESULTS AND DISCUSSION:** As immunosuppressive drugs calcineurin inhibitors (tacrolimus) were identified 296 adverse drug reaction. all pivotal ADRs compared the investigational agent with calcineurin inhibitor (tacrolimus) 39 case reports studies was shown that 296 adverse drug reaction inclusion sources of literatures of the total 295 ADRs 81 were serious unsuspected, 138 serious listed, 19 were non serious unlisted, 58 were non serious listed. The following adverse drug reactions were reported as nervous system disorder, gastrointestinal disorder and infection & infestations, blood and lymphatic disorder renal & urinary disorder.

**Keywords:** Calcineurin-inhibitor (Tacrolimus), immunosuppressant, solid organ transplant, grafts rejection, adverse drug reaction reporting.