KSN SEOUL, KOREA 2023
April 27(Thu) - 30(Sun), 2023
Coex, Seoul, Korea

Abstract Type : Poster
Abstract Submission No. : 1281

Appropriate tacrolimus level for preventing malignancy and graft failure in kidney transplant patients

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Objectives: Too low tacrolimus levels increase risk for rejection and graft failure, whereas too high tacrolimus levels could increase risk for malignancy in kidney transplant (KT) patients. We aimed to determine balanced tacrolimus levels for preventing malignancy as well as graft failure.

Methods: We analyzed 1,616 adult KT patients in Severance hospital between 1979 and 2017. We calculated mean tacrolimus trough concentration between the first 6th month and 1 year after KT and investigated association of tacrolimus levels with malignancy and death-censored graft failure using Cox regression analysis.

Results: Overall, malignancy occurred in 120 (7.4%) KT patients. Tacrolimus levels ≥ 7.0 ng/mL had a higher risk for malignancy compared to tacrolimus level < 5.5 ng/mL (Hazard ratio [HR] 1.899, 95% confidence interval [CI] 1.015-3.517) and tacrolimus level between 5.5 and 7.0 ng/mL (HR 2.324, 95% CI 1.150-4.697). However, there was no difference between the low (<5.5) and the intermediate tacrolimus groups (5.5 ≤ < 7.0).
Graft failure occurred in 248 (15.3%) KT patients. Tacrolimus levels < 5.5 had a higher risk for graft failure compared to tacrolimus levels ≥ 7.0 (HR 2.186, 95% CI 1.422-3.361) and tacrolimus levels between 5.5 and 7.0 (HR 1.681, 95% CI 1.009-2.800). However, there was no difference between the high (≥ 7.0) and the intermediate tacrolimus groups (5.5 ≤ < 7.0).
To minimize risk of malignancy and graft failure simultaneously, the intermediate tacrolimus levels (5.5 ≤ < 7.0) seemed to be balanced target. In parallel, the intermediate tacrolimus group had a tendency of lower risk for mortality compared to both the low (HR 0.603) and the high tacrolimus groups (HR 0.596), despite no statistical significance.

Conclusions: Tacrolimus levels between 5.5 and 7.0 is the optimal level between 6 months and 1 year after KT to minimize risk of both malignancy and graft failure.

Figure2_(a) KM plot for mean TAC C0 ranges and cancer free survival