

ANALYSIS OF INTRA-PATIENT VARIABILITY OF PLASMATIC LEVELS OF TACROLIMUS IN EARLY MAINTENANCE OF RENAL POST-TRANSPLANT

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Purpose

Tacrolimus is a calcineurinic inhibitor characterized by narrow therapeutic window and high variability of plasmatic levels.

To assess the intra-patient variability of tacrolimus plasmatic levels in kidney transplanted patients during the early maintenance period, 3-6 months after surgery. In the early maintenance period begins a progressive reduction of immunization to establish the future immunosuppressant dosage.

Material and Methods

Observational retrospective study: January 2015- January 2017

 Kidney transplanted patients > 18 years old



Analyzed variables

- Mean and standard deviation of plasma concentrations
- Number of blood determinations
- Coefficient of variation
- Proportion of values lower than 5 and 7 ng/ml (P5 and P7)
- Area under the concentration-estimated time

* To describe the intra-patient variability was used the coefficient of variation

Range of therapeutic tacrolimus plasmatic levels values is established between 5-20 ng/ml

Therapeutic control is considered inadequate if intra-patient variability is superior to 30 % or the P7 or P5 is superior to 20 %.

Results



211 patients and 996 tacrolimus blood determinations

Mean tacrolimus plasmatic levels	8.57 ng/ml	IC95%: 8.26 - 8.88
Mean blood determinations	4.72	IC95%: 4.17 - 5.26
Coefficient of variation	25.41 %	IC95%: 23.09 - 27.74 %
Coefficient of variation > 30%	31.75 %	IC95%: 25.42 - 38.09 %
Area under the concentration-estimated time	7.61 ng/mL/día	IC95%: 7.2 - 8.0 %
P5	9.28 %	IC95%: 6.49 - 12.06 %
P5 > 20%	17.2 %	IC95%: 12.3 - 21.8 %
P7	27.20 %	IC95%: 23.16 - 31.24 %
P7 > 20%	52.3 %	IC95%: 45.6 - 58.8 %

The intra-patient variability of tacrolimus plasmatic levels during the early maintenance period was higher than recommended in 31.75% of cases; similarly, 27.2% of the determinations were lower than 7ng/ml.

Conclusion

The early detection of patients with high intra-patient variability, or analytical values lower than 7 ng/ml in the early maintenance period is essential, since these are associated in the long term with a worse prognosis, leading to chronic rejection of the graft and/or greater pharmacological toxicity.

