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COMPARISON BETWEEN ASSAYS ON THE THERAPEUTIC DRUG MONITORIN OF EVEROLIMUS

M.C. Donoso Rengifo[1], J. López-Santamaria Donoso[2], M.D. Aumente[2].
[1]Hospital Universitario Virgen Macarena, Pharmacy, Seville, Spain.
[2]Hospital Universitario Reina Sofia, Hospital Pharmacy, Córdoba, Spain.

Background

The strong degree of structural similarity between Everolimus and Sirolimus causes cross-reactivity between them. The understimation observed with the Everolimus Quantitative Microsphere System (QMS) led in many centers to opt for the sirolimus chemiluminescence magnetic microparticle immunoassay (CMIA) on the therapeutic drug monitoring of everolimus

Purpose

The aim of this study was to compare the QMS assay both with CMIA and HPLC/MS assay (reference method).

Material and methods

Blood samples of patients treated with everolimus from November/14 to March/15 were used on the correlation study between QMS and CMIA. Correlation between QMS and HPLC/MS and CMIA and HPLC/MS was carried out using data reported by the External Quality Control Program, NEKAS,*International ProficiencyTesting Scheme.*(St George's University of London), from October/10 to March/15, testing target samples (blood to which a known amount of everolimus is added) and pool samples (blood of patients). Passing-Bablock regression method, Bland-Altman plot, and concordance correlation coefficient (CCC) were used in the statistical analysis.

Results

Bland-Altman plot showed that on target samples (n=60) there was an understimation of real value.

Target-QMS= 2.8ng/ml(1.96SD: -0.1 to 5.6),

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Target-CMIA=-0.08 (1.96 SD: -1.41 to 1.24)
Target-HPLC/MS=0.12 (1.96SD: -0.92 to 1.17)

different from that observed in the two other assays

In the pool samples (n=20) results by QMS were closer to those reported by HPLC-MS than CMIA:

HPLC/MS-QMS=0.06 (1.96SD: -1.6 to 1.71)
HPLC/MS-CMIA=-1.9(1.96SD: -4.3 to 0.5)

Correlation between the two methods in 75 patient samples showed that both were equivalent

QMS=-0.32 + 0.94CMIA, r=0.9054, CCC=0.8726(95% CI=0.8095 to 0.9158)

Conclusion

QMS tends to underestimate real value and the CMIA to overestimate it. It is possible that changing analytical method generates a significant decrease from the previous values but CMIA determined with better accuracy target simples than QMS, therefore it is preferable to use CMIA to determine everolimus.

References and/or Acknowledgements
External Quality Control Program, NEKAS, *International Proficiency Testing Scheme*