Poster

[P26-10] P26-10: Assay of toxicants

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[P26-10-4] Evaluation of two fully automated immunoassay based tests for the measurement of Ketamine in human urine and comparison with LC-MS/MS

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Background

In recent years, ketamine (KT), with its dissociative and hallucinogenic effects, has been abused in all over the world and major users are young people. KT use is commonly part of polysubstance use, and it’s often taken together with other club drugs. Therefore, the urine toxicology screening remain an important tool in the management of this growing social problem. We evaluated performance of two automated immunoassay recently introduced in the market in comparison with a HPLC-MS/MS and a laboratory routine on-site drug-testing device (Instalert One Step Ketamine) in order to replace it in our practice.

Methods

Immunalysis Ketamine Urine EIA (Assay 1) was applied on Dimension Vista 1500 (Siemens Healthcare Diagnostics Inc.) that used polyclonal antibodies against KT in human urine. QuantILab DRI Ketamine (Assay 2) was tested on Cobas 6000 c501 (Roche Diagnostics GmbH) that exploited a highly specific monoclonal antibody that detect both KT and nor-KT in human urine. Assessment of precision was carried out according to the reduced (n=10) CLSI-EP5A2 protocol. A total of 101 consecutive urine specimens were tested to evaluate the diagnostic efficiency calculating the relative sensitivity (RSn), relative specificity (RSp) and relative accuracy (RAc) for each assays in comparison to HPLC-MS/MS.

Results

Within-assay reproducibility (CV%, n=40) of QCs at 75-125 ng/mL were 4.4% and 3.5%, respectively, for Assay 1. Within-assay reproducibility obtained for Assay 2 using QCs at 236-400 ng/mL were 2.7% and 3.3%, respectively.

For both, laboratory routine method and Assay 1 (manufacturer's cut-off 100 ng/mL), RSn, RSp and RAc were 80% (2 false negative results), 100% and 98%, respectively. For Assay 2 (manufacturer's cut-off 300 ng/mL), RSn, Rsp and RAc were 100%, 93% (6 false positive results) and 94%, respectively. In addition, a LC-MS/MS target screening was performed on all FP samples. The following compounds were found: diazepam, nordiazepam, 7-aminoclonazepam, lamotrigine, trimipramine and levomepromazine, as possible interferences.

Conclusions

Both assays exhibit good diagnostic efficiency, but Assay 2 was chosen to replace those used in our laboratory as it does not present any FN results. From clinical point of view, reporting a false negative results is a severe oversight.