Poster

[P26-2] P26-2: Central nervous system drugs (1)

Chair: Atsushi Yonezawa, Japan

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[P26-2-5] Evaluation of thermo scientific CEDIA Buprenorphine II assay

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Background

Buprenorphine (Suboxone®) is used increasingly in opioid substitution therapy and offers attractive advantages over methadone, including increased safety and convenience. Buprenorphine monitoring in urine is commonly conducted to assess patient compliance and guide patient management. The Thermo Scientific CEDIA® Buprenorphine assay (BUP) is a homogenous enzyme immunoassay for the semi-quantitative determination of buprenorphine and buprenorphine-glucuronide in human urine at a cutoff concentration of 5 ng/mL. The recently developed CEDIA Buprenorphine II assay (BUP II) measures buprenorphine and its metabolites (norbuprenorphine, buprenorphine-glucuronide and norbuprenorphine-glucuronide) at a cutoff concentration of 10 ng/mL.

Methods

390 urine samples from patients enrolled in opiate dependency treatment were screened on an Olympus AU 480 autoanalyzer using the Thermo Scientific CEDIA Buprenorphine Assay and CEDIA Buprenorphine II Assay. Confirmation testing for buprenorphine and the metabolite, norbuprenorphine, was performed using gas chromatography mass spectrometry and liquid chromatography tandem mass spectrometry (after hydrolysis).

Results

Comparison of the screening results from both BUP methods showed 16 urine samples were not in agreement. Confirmation testing revealed that 12 screening results were false positive or false negative results from the old BUP assay and 4 results were false positive or false negative results from the new BUP II assay. Median results (buprenorphine, norbuprenorphine and glucuronide conjugates) from the BUP II assay were approximately 2 times greater (100 ng/mL) compared to the old BUP assay (buprenorphine and glucuronide conjugates) (49 ng/mL). Calibration for the BUP II assay was stable for 5 days compared to 1 day for the old BUP assay.

Conclusions

The Thermo Scientific CEDIA Buprenorphine II assay is better able to monitor buprenorphine use through detection of both parent and metabolites. False negative results are reduced with the BUP II assay with no increase in the observed false positive results. The more stable calibration with the BUP II assay allows for significant cost savings. The BUP II assay is recommended over the former BUP assay for the monitoring of buprenorphine (Suboxone®) in urine.