Buprenorphine and norbuprenorphine concentrations in human breast milk samples determined by liquid chromatography-tandem mass spectrometry.

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Abstract
Buprenorphine (BUP) is considered to be safe during pregnancy. However, the extent of BUP transfer into breast milk has not been investigated thoroughly. Because the drug concentration in the milk is 1 of the determinants in the assessment of the exposure risk, a rapid and sensitive LC-MS/MS method has been developed and evaluated to measure BUP and norbuprenorphine (norBUP) concentrations in milk. A solid-phase and 2 liquid-liquid extraction procedures have been compared. The lower limits of detection and quantification were 0.05 ng/mL and 0.18 ng/mL for BUP and 0.05 ng/mL and 0.20 ng/mL for norBUP, respectively, using a sample volume of 0.5 mL milk. BUP and norBUP concentrations determined from 10 random breast milk samples collected over 4 successive days from a lactating woman during buprenorphine maintenance therapy ranged from 1.0 to 14.7 and 0.6 to 6.3 ng/mL, respectively. Drug exposure of the infant may be considered to be low. Further investigations may seek to extend these preliminary findings to evaluate an infant's level of BUP exposure through breast milk.

PMID: 16044112

[PubMed - indexed for MEDLINE]