FENPROPOREX AND AMPHETAMINE LEVELS IN ORAL FLUID FOLLOWING ADMINISTRATION OF DESOBESI-M®

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INTRODUCTION
Fenproporex (FEN) is an anorectic drug used in the treatment of moderate to severe obesity and its biotransformation originates mainly amphetamine (AMP), another potent CNS stimulant. (1) FEN is one of the three most widely used anorectic in world (2), and in Brazil it’s highly misused, especially as stimulant for professional drivers. On the other hand, AMP is not marketed as a medicine in the country. The detection and time/concentration profile of FEN together with his major metabolite AMP has been described in classical biological matrices,(1-3-4) however, there are no reports of such data in oral fluid. Oral fluid is a mixture of saliva (secretion of three main salivary glands, parotis, submandibularis and sublingualis) and other constituents present in the mouth, like water, enzymes, glycoproteins and electrolytes. (5) The aim of this work is to estimate the pharmacokinetic profile of FEN and AMP in oral fluid, in order to assist in the development, application and interpretation of positive saliva tests applied to monitor the consumption of stimulants on roads.

MATERIALS AND METHODS
Were administered orally 25 mg of FEN (one capsule of Desobesi®) to three volunteers and oral fluid samples collected with Quantisal® device during 24 hours, one before drug administration and the others in periods of 0.5, 1, 1.5, 2, 4, 6, 8, 12 and 24 hours after the drug ingestion. FEN and AMP extraction was performed by solid phase microextraction (SPME) and the analysis carried out on a gas chromatography-mass spectrometry detector (GC-MS), using selected ion monitoring (SIM) and methamphetamine as internal standard.

RESULTS
With the obtained data was established a preliminary pharmacokinetic profile of FEN and AMP in oral fluid. After FEN administration, both analytes could be detected in oral fluid of all volunteers with an initial detection time varying from 0.5 to 1 hour. FEN peak concentration occurred in samples collected between 0.5-2 hours after administration, with maximum between 72.58 and 192.27 ng/mL. For AMP, peak concentration occurred between 1-6 hours, reaching 35.22 to 156.32 ng/mL.

CONCLUSION
It was observed that oral administration of FEN results in significant amounts of FEN and AMP in oral fluid, showing that saliva can be a biological matrix suitable for pharmacokinetic studies of these substances, and be able to infer the pharmacokinetic models for both analytes. According to the data obtained, the FEM and its metabolite AMP follow different pharmacokinetic models. FEN follows one-compartment model, while its major metabolite AMP obeys two-compartment model.

REFERENCES


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