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Evaluation of three rapid oral fluid test devices on the screening of multiple drugs of abuse including ketamine

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ABSTRACT

Rapid oral fluid testing (ROFT) devices have been extensively evaluated for their ability to detect common drugs of abuse; however, the performance of such devices on simultaneous screening for ketamine has been scarcely investigated. The present study evaluated three ROFT devices (DrugWipe® 6S, Ora-Check® and SalivaScreen®) on the detection of ketamine, opiates, methamphetamine, cannabis, cocaine and MDMA.

A liquid chromatography tandem mass spectrometry (LCMS) assay was firstly established and validated for confirmation analysis of the six types of drugs and/or their metabolites. In the field test, the three ROFT devices were tested on subjects recruited from substance abuse clinics/rehabilitation centre. Oral fluid was also collected using Quantisal® for confirmation analysis.

A total of 549 samples were collected in the study. LCMS analysis on 491 samples revealed the following drugs: codeine (55%), morphine (49%), heroin (40%), methamphetamine (35%), THC (8%), ketamine (4%) and cocaine (2%). No MDMA-positive cases were observed.

Results showed that the overall specificity and accuracy were satisfactory and met the DRUID standard of >80% for all 3 devices. Ora-Check® had poor sensitivities (ketamine 36%, methamphetamine 63%, opiates 53%, cocaine 60%, THC 0%). DrugWipe® 6S showed good sensitivities in the methamphetamine (83%) and opiates (93%) tests but performed relatively poorly for ketamine (41%), cocaine (43%) and THC (22%). SalivaScreen® also demonstrated good sensitivities in the methamphetamine (83%) and opiates (100%) tests, and had the highest sensitivity for ketamine (76%) and cocaine (71%); however, it failed to detect any of the 28 THC-positive cases. The test completion rate (proportion of tests completed with quality control passed) were: 52% (Ora-Check®), 78% (SalivaScreen®) and 99% (DrugWipe® 6S).

1. Introduction

Oral fluid is becoming a popular matrix for rapid screening of drugs of abuse. In contrast to blood and urine, collection of oral fluid is easy and non-invasive with minimal intrusion into personal privacy. Oral fluid can also be collected under direct observation, thus eliminating the possibility of sample substitution or adulteration as with urine. As such, oral fluid can be useful in various settings that require drug testing, for example workplace, corrections, probation or for treatment. Importantly, it is by far the most convenient biological matrix that facilitates roadside testing for driving under the influence of drugs (drugged driving) [1]. Compared with urine, oral fluid is a better reflection of blood concentrations of a drug. It indicates recent drug use and provides better correlation with pharmacological effects such as impaired driving performance [2].

Drugged driving is a major concern worldwide. In the large-scale European Union (EU) study, Driving under the Influence of Drugs, Alcohol and Medicines (DRUID), it has been reported that the detection rate of illicit drugs in the general driving population was

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1.9%. This detection rate was higher in seriously injured drivers (2.3–12.6%) [3]. In Hong Kong, a study on the prevalence of illicit drug use in non-fatal traffic accident casualties showed that 10% of the injured drivers tested positive for drugs (although it should be noted that urine rather than blood was tested). Ketamine was the most commonly detected substance found in 45% of the subjects [4].

Currently, many countries including Germany, France, Belgium, Italy, Finland and Australia routinely conduct roadside rapid oral fluid testing (ROFT) to tackle drugged driving [5]. Prior to usage, ROFT devices must undergo rigorous scientific evaluation to ensure acceptable performance in terms of their sensitivity, specificity and overall accuracy. In the early EU studies on Roadside Testing Assessment (ROSITA-1 and -2), the proposed acceptance criteria of sensitivity and specificity were >90% and accuracy >95% [6,7]. These criteria were later lowered to 80% in the subsequent DRUID study [8]. During the past two decades, ROFT devices have been extensively evaluated and the results widely published [9–14]. However, whilst the performance of ROFT devices for detecting amphetamines, opiates, cocaine and cannabis (THC) has been comprehensively investigated, there is currently minimal data for ketamine.

Although the abuse of ketamine is widespread in Hong Kong and Asia, it has not traditionally been a popular drug of abuse in Europe and North America [15]. As a result, detailed investigations of ROFT device performance on screening for ketamine have been scarce thus far. One study evaluated the performance of OratectXP solely on the detection of ketamine [13]. On the other hand, recent publications have reported an increase in the use of ketamine in Europe [9,16]. In view of this, the current study was conducted to evaluate ROFT devices suitable for simultaneous screening of ketamine as well as five other illicit substances (heroin, methamphetamine, cannabis, cocaine and MDMA). Three ROFT devices (DrugWipe® 6S, Ora-Check® and SalivaScreen®) were chosen for evaluation of their sensitivity, specificity and accuracy. Prior to conducting the ROFT field test, a liquid chromatography tandem mass spectrometry (LCMS) assay was established for confirmation analysis, the results of which will be used to assess the performance of the ROFT devices.

2. Methods

2.1. Materials

Reference standards and deuterium internal standards (I.S.) for each analyte were purchased from Cerilliant (Round Rock, TX) or Lipomed (Arlesheim, Switzerland), including ketamine (KET), norketamine (NORKET), methamphetamine (MET), amphetamine (AMP), methylenedioxymethamphetamine (MDMA), methylenedioxyamphetamine (MDA), 6-monoacetylmorphine (6-MAM), codeine (COD), morphine (MOR), cocaine (COC), benzoylecgonine (BEG), cannabis (THC), KET-D4, NORKET-D4, MET-D5, AMP-D5, MDMA-D5, MDA-D5, 6-MAM-D3, COD-D6, MOR-D6, COC-D3, BEG-D8 and THC-D3.

Isolute® SLE+ supported-liquid extraction (SLE) 400 μL columns were obtained from Biotage (Uppsala, Sweden). Quantisal® synthetic negative oral fluid (pre-diluted in extraction buffer) and Quantisal® oral fluid collection devices were purchased from Alere (Waltham, MA).

The ROFT device DrugWipe® 6S was purchased from Securetec (Neubiberg, Germany), Ora-Check® from Safecare Biotech (Hangzhou, China) and SalivaScreen® from Ulti med Products (Ahrensburg, Germany).

2.2. ROFT field test

Subjects were recruited from the Hospital Authority substance abuse clinics at Castle Peak Hospital (CPH), Kwai Chung Hospital (KCH) and Pamela Youde Nethersole Eastern Hospital (PYNEH), as well as the Society of Rehabilitation and Crime Prevention (SRACP) in Hong Kong. Written informed consent was obtained from all subjects, who were at least 18 years of age. Repeated sampling was allowed provided that each collection was at least one week apart. The protocol had been approved by the Hospital Authority Kowloon West Cluster Research Ethics Committee.

For each subject, a confirmation sample was firstly collected using the Quantisal® oral fluid collection device. The sampling sponge was placed in the subject's oral cavity for 10 min (or when the indicator turned blue, whichever was earlier). The sponge, which was supposed to have collected 1 mL of oral fluid, was then deposited into the designated tube containing 3 mL of buffer. This sample was subsequently transported back to the laboratory and the weight of the whole tube was recorded for adjusting the volume of oral fluid collected. The sample was then stored at 4 °C for 3 days, after which a plunger separator was used to harvest all the buffered oral fluid inside the tube. The oral fluid sample was then stored in a separate container at −80 °C until analysis. Those samples with weight corresponding to less than 0.5 mL oral fluid were not subjected to confirmation analysis; whilst samples with volume between 0.5 and 1 mL were analysed for all analytes except cocaine and THC.

The ROFT devices, as shown in Fig. 1, were evaluated sequentially on each subject. Some subjects did not have sufficient oral fluid to complete all three evaluations. DrugWipe® 6S required the least amount of oral fluid (approximately 0.1 mL), thus was tested last of the three. In order to have similar number of completed tests for Ora-Check® and SalivaScreen®, these two devices were tested first on alternate days. When at least four LCMS-positive cases (with completed ROFT testing) have been achieved for all analytes on a device, the data was considered meaningful for interpretation [12,17] and thus testing on this device would be terminated.

Ora-Check® and SalivaScreen® were capable of separately testing all 6 drug classes: ketamine, methamphetamine, cannabis, cocaine, MDMA and opiates (OPI). DrugWipe® 6S only detected 5 types of drugs: ketamine, cannabis, cocaine, opiates and the amphetamines. This device was unable to differentiate among amphetamine-type drugs; this class of drugs was tested collectively by one "AMP/MET" test.

The DrugWipe® 6S device consisted of a sample collector containing 3 small sampling pads, the test cassette and an integrated liquid ampoule. Oral fluid was collected by wiping the sampling pads on the tongue several times until the pads changed colour. The collector was then placed back onto the test cassette, with the pads in contact with the test strips. The device was held vertically; the liquid ampoule was broken by compression and the buffer flowed along the test strips. After 10 s, the device was placed on a horizontal surface and the results read after 8 min. Result interpretation was performed according to the manufacturer's instructions (i.e. a visible band indicated a positive result. Faint bands were regarded as positive).

The Ora-Check® device comprised a sampling sponge, a collection chamber and the test cassette. The sponge was placed in the subject's mouth for 3 min (with occasional sweeping motion), during which supposedly 0.5 mL oral fluid would have been collected. The sponge was then firmly pushed into the collection chamber to release the oral fluid. The chamber was inverted and the oral fluid was transferred through the dropper onto the sampling area of the test cassette. After 10 min, results were interpreted according to the manufacturer's instructions (i.e. a visible band indicated a negative result. Faint bands were regarded as negative).

The SalivaScreen® device consisted of a sampling sponge with volume indicator (1 mL) and a test cassette that extracted the oral