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Driving under the influence of drugs — evaluation of analytical data of drugs in oral fluid, serum and urine, and correlation with impairment symptoms

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Abstract

A study was performed to acquire urine, serum and oral fluid samples in cases of suspected driving under the influence of drugs of abuse. Oral fluid was collected using a novel sampling/testing device (Dräger DrugTest® System). The aim of the study was to evaluate oral fluid and urine as a predictor of blood samples positive for drugs and impairment symptoms. Analysis for cannabinoids, amphetamine and its derivatives, opiates and cocaine was performed in urine using the Mahsan Kombi/DOA4-test, in serum using immunoassay and gas chromatography–mass spectrometry (GC–MS) confirmation and in oral fluid by GC–MS. Police and medical officer observations of impairment symptoms were rated and evaluated using a threshold value for the classification of driving inability. Accuracy in correlating drug detection in oral fluid and serum were >90% for all substances and also >90% in urine and serum except for THC (71.0%). Of the cases with oral fluid positive for any drug 97.1% of corresponding serum samples were also positive for at least one drug; of drug-positive urine samples this were only 82.4%. In 119 of 146 cases, impairment symptoms above threshold were observed (81.5%). Of the cases with drugs detected in serum, 19.1% appeared not impaired which were the same with drug-positive oral fluid while more persons with drug-positive urine samples appeared uninfluenced (32.7%). The data demonstrate that oral fluid is superior to urine in correlating with serum analytical data and impairment symptoms of drivers under the influence of drugs of abuse.

Keywords: Saliva/oral fluid; Serum; Urine; Driving under the influence; Drugs of abuse; Impairment symptoms

1. Introduction

A wide variety of illicit drugs can be found in blood samples of drivers [1] where cannabis, cocaine, opiates, amphetamine and its derivatives are those with the highest prevalence as shown in the EU-project Rosita (www.rosita.org). An efficient and reliable on-site test for drugs of abuse may enable police officers to identify drivers under the influence of drugs. Roadside urine testing is usually performed but it is time-consuming and has the risk of infections and potential disease transmission. Oral fluid testing has been proposed as an alternative [2] and has shown its usability in roadside studies [3–7]. Results can be obtained within a few minutes and sample contacts can be minimized by special sampling devices. It is assumed that drug detection in oral fluid is based on drug diffusion from blood and/or

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contamination of the oral cavity with drug substance [8] reflecting an actual drug influence [4,9] while urine provides a wider window for drug detection and is not correlated with blood levels. A reliable correlation of pharmacologic effects can only be based on blood/serum concentrations as oral fluid concentrations are elevated shortly after drug-use because of a contamination of the oral cavity [10,11]. In Germany, legal consequences for drivers depend upon the detection of drugs of abuse in blood. Blood sampling and consecutive toxicological analysis is mandatory in all cases where the driver shows signs of drug-use (e.g. blood-shot eyes or a delay in pupil reaction to light) and/or a drugs of abuse screening test is positive. Therefore, the application of easy-to-use roadside tests has gained increasing interest in Germany. The presence of any of the substances amphetamine, 3,4-methylenedioxymethamphetamine (MDMA), 3,4-methylenedioxyethylamphetamine (MDEA), morphine, benzoylecgonine or Δ^9-tetrahydrocannabinol (THC) in blood is prosecuted as an administrative offence (zero tolerance). The detection of any centrally active substance in blood in addition to signs of impairment represents a criminal offence. Administrative offences lead to lower sanctions (driving ban for 1–3 months) than criminal offences (driver's license revocation for at least 6 months). Police officers are advised to start investigation according to a criminal offence in cases where impaired driving or more severe psycho-physical disturbances are observed, e.g. motor dysfunctions, sleepiness, markedly dilated or constricted pupils with no or only weak reactions to light. In these cases, the results of a medical examination provide the primary evidence of the driver fitness [12–14] but with an increasing efficiency of trained police officers their testimony is also regarded as important evidence [15–19].

In the present study, analytical data of serum, oral fluid, and urine drug detection is correlated with impairment symptoms as an extension of previous evaluations [11,20].

2. Experimental

2.1. Study design and biological samples

A pilot study was organized to evaluate the prototype of the new Dräger DrugTest® system. Saarland State Police Officers collected samples of oral fluid in 168 cases of suspected driving under the influence of drugs at actual roadside conditions using the Dräger DrugTest® oral fluid collection device between August and November 2001. Informed consent was obtained from the offenders. The Dräger on-site test was performed preliminarily without further evaluation of the results and the collection device was saved for confirmation analysis using gas chromatography–mass spectrometry (GC–MS). In 131 cases, a urine sample was obtained and a Mahsan-Kombi/DOA4-test (Mahsan Diagnostika, Reinbeck, Germany) was performed on-site for cannabinoids, amphetamine and derivatives, opiates and cocaine–metabolite without a further confirmation analysis. In addition, a blood sample was taken by a physician about 1 h later (0.1–3.0 h, median 0.9 h) which was also submitted for toxicological analysis.

2.2. Analysis of oral fluid and blood samples

Toxicological analysis of blood samples was performed as described elsewhere [20]. After centrifugation of blood, serum was tested using the Bio-Rad CODA system and respective Pyxis 24 Serum Drug Screening tests (Bio-Rad, Munich, Germany). Cut-off values used were 2.0 μg/L for cannabinoids, 10 μg/L for opiates, 10 μg/L for cocaine–metabolite, 20 μg/L for amphetamine and derivatives. Confirmation analysis was performed in positive cases using established GC–MS procedures [20] for the following analytes using the given limits of detection: cocaine (8 μg/L), benzoylecgonine (BZE, 8 μg/L), ecgonine methyl ester (8 μg/L), morphine (MOR, 5 μg/L), 6-acetylmorphine (2 μg/L), dihydrocodeine (2 μg/L), codeine (2 μg/L), methadone (MTDN, 15 μg/L), amphetamine (AMP, 3 μg/L), methamphetamine (MAMP, 5 μg/L), 3,4-methylenedioxymethamphetamine (4 μg/L), 3,4-methylenedioxyamphetamine (2 μg/L), 3,4-methylenedioxyethylamphetamine (1 μg/L), 3,4-methylenedioxy-*N*-methylbutanamine, Δ^9-tetrahydrocannabinol (THC, 0.5 μg/L), 11-hydroxy-THC (0.5 μg/L), 11-nor-9-carboxy-THC (THCA, 1 μg/L). Blood alcohol was assayed using the routine headspace–gas chromatography–flame ionization detection procedure, only values above 0.05 g/L were considered positive.

The analysis of oral fluid samples was performed as described previously [20] consisting essentially of an elution of the DrugTest® collection device with 1 ml of a buffer–methanol mixture of which 0.5 ml were analyzed using mixed-mode solid-phase extraction in two fractions, trimethylsilylation as derivatization and GC–MS in the selected ion monitoring (SIM) mode for the analytes listed above with limits of detection between 5 and 20 μg/L [20]. For quality assurance within analytical series, the successful detection of 50 μg/L AMP, 20 μg/L MAMP, 5.0 μg/L MOR, 2.5 μg/L MTDN and 2.5 μg/L BZE in 0.5 ml of OraSure DOA Oral Negative Control Intercept® (Bethlehem, PA, USA) was used.

2.3. Reports of police observations and medical examination reports

In each case, a report of the police officers on observations of driving performance and impairment symptoms was available. In Table 1, the reported observations and possible choices are given. A report was also available from the medical examination (Table 2) which was performed prior to blood sampling. To enable assessment of an actual impairment the choices of the behavioral criteria tested were rated from 0 (normal) to 3 (strongly impaired). For the evaluation of the ratings of the police officer's observations, a score was

Table 1
Items of the police observation report

Observations on driving performance and driving circumstances	No observations, normal, impaired (1), swerving line (2), vehicle faults, vehicle operation, light conditions, weather, road conditions
Stopping reaction	Normal, delayed (0.5), extremely delayed (1)
Getting out of the car	Normal, unbalanced (1), has to hold onto vehicle (2)
Appearance	Clean and tidy, unkempt, neglected
Smell of alcohol	Yes, no
Physical signs	None, sweating, shaking/trembling (0.5), vomiting, restlessness (1)
Speech	Clear, stuttering, slurred (1), mumbling (3)
Response/orientation	Sedated (1), sleeping/unconscious (3), oriented, awakable (2), disoriented (2)
Mood/behavior	Quiet, excited, strangely cheerful (0.5), impassive (1), does not keep distance (0.5), aggressive (1), provocative (0.5), tearful (0.5)
Walking performance	Normal, dragging, swaying (1), staggering (3)
Eyes	Normal, red conjunctiva, watery/shiny, agitated
Pupils	Width right/left, prompt or delayed reaction to light
Light conditions at place of examination	Daylight, dusk, night/street lighting, night/interior lighting
Behavior during official interview	Stayed the same, increasingly strange, became more normal

Numbers in parentheses after a certain symptom indicate the impairment rating degree.

calculated being the sum of all ratings. Similarly, the criteria of the medical examination were evaluated. Subjects with values of 1 or more in the police officer's and/or the medical officer's score were classified as impaired.

3. Results and discussion

In 168 cases of suspected driving under the influence of drugs, blood and oral fluid were obtained. Because urine tests were refused by 37 subjects, in only 131 cases analytical data in serum, oral fluid and urine were evaluated. The urine samples were analyzed using the on-site Mahsan test which has been demonstrated to provide reliable results [21–23]. For the evaluation of impairment symptoms with respect to drugs detected in serum or oral fluid 22 of the 168 cases were excluded due to the presence of ethanol in excess of 0.05 g/L (n = 146).

3.1. Comparison of analytical data in oral fluid, serum and urine

For the comparison of serum (S), oral fluid (OF) and urine (U), the data were grouped according to the presence (indicated as ''+'') or absence (indicated as ''−'') of a certain drug. Evaluation of correlations was performed in terms of accuracy and positive or negative predictive values (cf. Table 3). Accuracy expresses the number of matching results (positive or negative) versus the total number of cases. The positive predictive value represents the probability of

Table 2
Items of the medical examination

Findings	Blood pressure, heartbeat, body weight and height, constitution, breath alcohol, lesions, injection marks
Walking performance	Normal, dragging (0.5), swaying (1), staggering (3), impaired turning after walking (1)
Nystagmus	Subtle movement, coarse movement, small/great amplitude, duration while fixing
Romberg test	Normal, minimal staggering, shaking/trembling (0.5), heavy staggering (1)
Speech	Normal, slurred or garbled speech, slurred (1), mumbling (3)
Tonus enhancement	In the face, trembling hands (0.5), rapid lid movement
Sclera	Clear, reddened, swollen
Pupils	Normal, dilated, constricted, width right/left, prompt or delayed reaction to light
Coordination	Impairment of finger to finger (0.5) or finger to nose (0.5) movement
Consciousness	Normal, sedated (1), unconscious (3), disoriented (2)
Memory	Normal, impaired
Mood/behavior	Calm, talkative, tearful (0.5), provocative (0.5), fluttering, somnolent (1), does not keep distance (0.5), decelerated (1), dull (1), abrasive (0.5), clumsy (0.5), strangely cheerful, aggressive (1), lethargic (0.5)
Condition	Normal, sweating, dry mouth, shivering, pain, itching, yawning
Thinking	Normal, erratic (1), stereotype (1), confused (2), decelerated (1)
Rating of drug/alcohol influence	Imperceptible, slight, marked (1), strong (2), very strong (3)

Numbers in parentheses after a certain symptom indicate the impairment rating degree.

Table 3
Comparison of the results in detecting (+) and not detecting (−) amphetamine and derivatives (AMP), cocaine and metabolites (COC), opiates (OPI), cannabinoids (CAN) or any drug (ANY) in serum (S), oral fluid (OF) and urine (U)

n = 131	CAN	CAN_{THC}	AMP	COC	OPI	ANY
S + OF + U+	69	66	31	17	21	100
S + OF + U−	1	0	4	1	0	0
S + OF − U+	36	7	1	3	4	8
S + OF − U−	0	0	0	0	0	0
S − OF + U+	0	3	1	1	2	3
S − OF + U−	1	2	7	0	0	0
S − OF − U+	6	35	4	6	8	20
S − OF − U−	18	18	83	103	96	0
Oral fluid vs. serum (reference)						
Accuracy (%)	71.8	90.8	93.1	96.9	95.4	91.6
Positive predictive value (%)	98.6	93.0	81.4	94.7	91.3	97.1
Negative predictive value (%)	40.0	88.3	98.9	97.3	96.3	71.4
Urine vs. serum (reference)						
Accuracy (%)	94.7	71.0	93.1	93.9	92.4	82.4
Positive predictive value (%)	94.6	65.8	86.5	74.1	71.4	82.4
Negative predictive value (%)	95.0	100.0	95.7	99.0	100.0	n.c.
Urine vs. oral fluid (reference)						
Accuracy (%)	66.4	66.4	87.8	92.4	90.8	78.6
Positive predictive value (%)	62.2	62.2	86.5	66.7	65.7	78.6
Negative predictive value (%)	90.0	90.0	88.3	99.0	100.0	n.c.

The column CAN_{THC} differs from CAN in so far that for serum only the active ingredient THC was considered. The correlation of results are described in terms of accuracy (e.g. oral fluid vs. serum, [“S + OF+” + “S − OF−”]/n), positive predictive value (e.g. oral fluid vs. serum, “S + OF+”/[“S + OF+” + “S − OF+”]) and negative predictive value (e.g. oral fluid vs. serum, “S − OF−”/[“S + OF−” + “S − OF−”]). n.c. = not calculated.

a matching positive result; the negative predictive value represents the probability of a matching negative result. Since only drugs present in serum exhibit pharmacological effects serum was chosen as reference in comparison to oral fluid or urine. For the comparison of oral fluid and urine, oral fluid was selected as reference. In Table 3, the results are given for amphetamine and derivatives (AMP), cocaine and metabolites (COC), opiates (OPI) and cannabinoids (CAN) as well as the detection of any of these drugs in an additional column (ANY). Cannabinoids detected in urine were inactive metabolites like THCA, in oral fluid only the psychoactive ingredient THC is present [9] and in serum both, THC and THCA were assayed. As only the presence of THC in serum is indicative of a recent cannabis-use, the analysis results of serum were differentiated for the presence of THCA (CAN) and THC (CAN_{THC}, used in ANY).

The detectability of AMP, COC or OPI in oral fluid or in urine in comparison to serum was very accurate (>90%). The accuracy by comparing urine and oral fluid was in the same range. Negative predictive values were consistently higher than the accuracy values (usually >96%) indicating a high probability that recent drug-use may be detected. On the other hand, positive predictive values were generally less than the accuracy values indicating that a certain number of positive test results in oral fluid or urine might not be confirmed in serum. Positive predictive values for oral fluid in comparison to serum were greater than 90% for CAN_{THC}, OPI and COC which has also been found by Samyn et al. [7], but only 81.4% for AMP which suggests that amphetamine and derivatives may be detectable longer in oral fluid than in serum, a finding that has been reported previously [24,25]. The observation that in seven cases amphetamine or MDMA were detected neither in serum nor in urine (S − OF + U− in Table 3) may be due to non-detectable serum levels in the terminal excretion phase and to corresponding low urine levels not detectable by immunoassay.

In the evaluation of cannabinoid detection, it is important to differentiate between THC and the metabolite THCA. If the detection of THC in serum and oral fluid is considered, the accuracy was very good (CAN_{THC}, 90.8%) suggesting that oral fluid is a good predictor of actual cannabis influence, while this was less accurate for urine (CAN_{THC}, 71.0%) where only the inactive metabolite was measured. On the other hand, the presence of THCA in urine and in serum correlated well (CAN, accuracy 94.7%) while this was expectedly not as good for THCA in serum and THC in oral fluid (CAN, 71.8%) or for THC in oral fluid and THCA in urine (CAN, 66.4%).

Urine testing has a longer detection window in comparison to serum which explains the lower positive predictive

values of urine in comparison to serum and oral fluid in the detection of AMP, COC and OPI. This is shown in Table 3. In 20 of the 131 cases, drug-use (''ANY'') was only detected by urine analysis. This indicates that by urine testing, a larger number of persons would be suspected of driving under the influence of drugs although the serum is drug-negative.

In general, the accuracy of drug detection in oral fluid or urine in comparison to serum was excellent indicating that both samples are useful predictors of drug detection in serum. Oral fluid has the advantage over urine of a slightly better correlation with serum and of markedly higher positive predictive values.

3.2. Evaluation of impairment symptoms

In Germany, conviction of driving under the influence of drugs does not require evidence of driving faults, but it is sufficient to demonstrate severe impairment of psychophysical functions to conclude inability to drive. This can be proven by impairment symptoms observed by police officers at the time of the offence (Table 1) or by the medical officer at the time of blood sampling (Table 2). In court proceedings all facts, statements and circumstances of individual cases are considered.

In the present study, the most relevant information of the cases was evaluated consisting of police officer and medical reports as well as toxicological analysis data. In a rating scale from 0 (not impaired) to 3 (extremely impaired), marked impairment symptoms such as sedation, imbalance or restlessness were considered to produce driving inability and were rated as 1 which was therefore used as a threshold value. Some items were rated as 0.5 which might have been affected by circumstances such as trembling or slight deviations in mood or behavior. For the evaluation of the ratings of the police officer's observations, the final score was compared with the threshold value of 1. Similarly, the criteria of the medical examination were evaluated.

Subjects with values of 1 or more in at least one of the two scores were classified as impaired in 119 of the 146 cases (81.5%). Table 4 shows the ranges and medians of police officer and medical officer scores and the sum of both concerning the various drug-use patterns. Table 5 shows the frequency of the classification as impaired or not according to the threshold value. Although more items are included in the medical examination score, the police officer's scores and frequencies of impairment were in general higher than those of the medical officers. This might be due to drug effects diminishing during the time between arrest and medical examination. The highest scores and frequencies of impairment were consistently observed in the opiate users with or without other drugs. Drug users combining cocaine and opiates were predominant.

Comparing the impairment classifications of police officer's and medical officer's data, the results agreed in only 65.1% of the cases. Again, persons using opiates always showed impairments which were detected by both observer groups. Of the cannabis users with the active ingredient THC still present in serum, 31.9% were classified as impaired by both observer groups (THC concentrations in serum were 4.6 $\pm$ 4.8 μg/L, mean $\pm$ S.D.), 27.7% were classified as impaired only by police officer (THC 7.1 $\pm$ 6.9 μg/L) and 31.9% appeared not to be impaired at all (THC 5.9 $\pm$ 4.9 μg/L). The combination of amphetamine or its derivatives with THC increased the chance to be classified as being impaired by both observer groups to 50% of the cases (THC 5.0 $\pm$ 5.3 μg/L, mean $\pm$ S.D.). However, a correlation of the THC concentrations with the impairment classification was not possible. Subjects with no drugs (n = 5) or with only the inactive cannabinoid THCA (n = 15) detected in serum showed surprisingly higher scores and frequencies of impairment than observed for subjects with THC or amphetamine and its derivatives in serum. This is difficult to explain without a detailed investigation of the cases and considering the statements of the offenders.

Table 6 shows the detection of any psychoactive drug in serum, oral fluid or urine with respect to the classification as

Table 4
Scores of the impairment observations by police officers (cf. Table 1) and medical officers (cf. Table 2) and the sum of both classified for the drug-use pattern

Drug-use pattern	n	Police officer's score [Min–max (median)]	Medical officer's score [Min–max (median)]	Sum of both scores [Min–max (median)]
No drugs detected	5	0.5–3.0 (2.5)	0.0–3.0 (1.0)	0.5–5.5 (3.0)
THCA only	15	0.0–8.0 (2.0)	0.0–5.5 (1.0)	0.5–13.5 (3.0)
THC	47	0.0–21.0 (1.0)	0.0–5.0 (0.0)	0.0–21.0 (1.5)
AMP	8	0.0–2.5 (0.5)	0.0–3.5 (0.5)	0.0–4.0 (1.5)
COC	0			
OPI	9	1.0–6.0 (4.0)	0.0–5.5 (2.5)	1.5–10.5 (5.5)
THC + AMP	26	0.0–6.0 (1.5)	0.0–5.5 (1.5)	0.0–8.5 (3.3)
THC + COC	6	0.0–8.0 (2.3)	0.0–2.5 (0.25)	0.0–8.0 (3.8)
THC + OPI	9	0.5–7.0 (4.0)	0.0–5.5 (1.0)	1.5–9.0 (6.0)
COC + OPI	9	2.0–12.0 (5.0)	0.0–9.0 (4.0)	3.5–21.0 (8.0)
More than two drugs	12	0.0–7.5 (2.5)	0.0–6.0 (1.0)	1.0–11.0 (4.0)

Table 5
Cases classified for drug-use pattern and impairment scores ≥1 as observed by police officers (PO+) or medical officers (ME+); scores <1 were considered not impaired (PO− or ME−)

Drug-use pattern	PO+ (%)	ME+ (%)	PO+, ME+	PO+, ME−	PO−, ME+	PO−, ME−	Accuracy (%)
No drugs detected	80.0	60.0	3	1	0	1	80.0
THCA only	80.0	60.0	8	4	1	2	66.7
THC	59.6	40.4	15	13	4	15	63.8
AMP	25.0	50.0	1	1	3	3	50.0
COC			0	0	0	0	
OPI	100.0	77.8	7	2	0	0	77.8
THC + AMP	61.5	73.1	13	3	6	4	65.4
THC + COC	66.7	33.3	2	2	0	2	66.7
THC + OPI	88.9	66.7	5	3	1	0	55.6
COC + OPI	100.0	88.9	8	1	0	0	88.9
More than two drugs	83.3	66.7	6	4	2	0	50.0
Total			68	34	17	27	65.1

The columns "PO+, ME+" to "PO−, ME− " show the comparison of police officer and medical officer classification as impaired or not impaired with accuracy giving the percentage of matching classifications (["PO+, ME+" + "PO−, ME−"]/*n*).

Table 6
Comparison of the detection of drugs in serum, oral fluid or urine and the classification as impaired or not (cf. Table 5)

n = 113	Serum	Oral fluid	Urine
Drug+, impaired	76	72	76
Drug+, not impaired	18	17	37
Drug−, impaired	0	4	0
Drug−, not impaired	19	20	0

impaired or not impaired. In this comparison, only 113 cases could be considered where the subjects had not consumed alcohol and provided a urine sample. Of these cases 76 were classified as impaired (67.3%), all were positive for drugs in serum and urine, oral fluid was negative in only four cases (5.3%). On the other hand, 18 persons exhibiting drugs in serum were not considered to be impaired (19.1% of drug-positives). For oral fluid, almost the same result was obtained but of subjects with a drug-positive urine sample a higher fraction appeared unimpaired (32.7%) which can be explained by past drug-use without an actual drug influence.

From the study, it is concluded that drug detection in oral fluid is more closely related to drugs present in serum and is superior to urine testing. Drug screening in oral fluid is an effective method to detect drug-use and to suggest an influence of psychoactive substances in drivers.

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