Roadside Drug Testing: The Results Of The ROSITA Project.

A.G. Verstraete for the Rosita consortium

Laboratory of Clinical Biology– Toxicology, Ghent University Hospital, Belgium

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Abstract
BACKGROUND: Better enforcement of the drugs and driving legislation requires training of the police officers in drug recognition and the availability of reliable roadside drug tests.
MATERIALS AND METHODS: Onsite immunoassays were used for the detection of drugs in urine, oral fluid (saliva) and/or sweat in 2968 subjects in 8 countries. In Belgium, Finland, Germany, Italy, Norway and Spain the tests were evaluated at the roadside or in a police station. Confirmation analyses on blood, urine, oral fluid and/or sweat (GC/MS, but in some cases GC/ECD and HPLC-DAD) were performed.
RESULTS: Police officers liked having the tools to detect drugged drivers, and they were creative in finding solutions to the practical and operational problems. Onsite drug testing gave police confidence, saved time and money.
Police officers had no major objections to collecting specimens. Oral fluid was the preferred specimen. Obtaining a urine specimen was no problem if the necessary facilities (e.g. a sanitary van) were available.
Some onsite urine tests (Rapid Drug Screen, SYVA Rapidtest, Dipro Drugscreen 5, Triage) yielded good results (accuracy >95%, sensitivity and specificity >90%), but none gave a good result for all assays.
Oral fluid and sweat are promising specimens, sometimes better than urine, but more development of the onsite tests is needed. Sampling of these specimens was well accepted by drivers. Drugwipe, Cozart Rapiscan and Avitar Oralscreen were not sufficiently reliable (accuracy between 50 and 81%). Progress is needed for sampling, duration of the test, sample volume, reliability and sensitivity for cannabis and benzodiazepines.
CONCLUSION: Roadside drug tests were considered to be very useful. In the future, oral fluid seems the most promising, but the presently available tests are not satisfactory. Urine tests can be an acceptable alternative.

Introduction
In the last few years, driving under the influence of drugs is recognized more and more as a problem for traffic safety in Europe. There is a universally recognized need for the development of a valid, rapid and affordable roadside test for the major drugs (1). In countries with impairment-type laws, roadside analysis can confirm the suspicion of the police officer and focus the attention on drugs. In countries with per se legislation, screening devices are crucial for the detection of driving under the influence of drugs, before further measures (e.g. blood
sampling, temporary driving prohibition, …) can be taken. Only a few studies have evaluated roadside drug tests (2-8).

This work was performed as a part of the Rosita (Roadside testing assessment) project and consisted of the evaluation of the on-site devices for urine, oral fluid and/or sweat in 8 countries.

Materials and methods

Because of different legislation, the circumstances under which the tests were performed varied among the countries:

- Spain: The on-site tests were performed by the agents of the Traffic Police. Reading and interpretation of the results were done together by the members of the Institute of Legal Medicine present during the control and by traffic police officers trained in the use of the devices. With one exception, the tests were performed at the roadside.
- Belgium: the samples collected at the roadside were first screened by the Police with the Dipro Drugscreen 5 and then by lab technicians with the other devices.
- Norway: the on-site urine tests were performed by the police officers in the laboratory at National Institute for Forensic Toxicology, in collaboration with representatives from some manufacturers as assistants. The oral fluid tests (Cozart Rapiscan and Drugwipe) were performed at the police station.
- Italy: The on-site tests were performed at the roadside by police personnel or ambulance volunteers or in the lab by trained technicians. Roadside collection of blood, urine and oral fluid samples was made by medical personnel.
- Finland: Urine was collected under police supervision in the hospital and not at the roadside. Police and laboratory staff mainly performed the urine tests at the laboratory of drug abuse. The oral fluid tests were performed roadside by trained police officers.
- Germany: The test was performed by police officers during police controls. Oral fluid and sweat samples were collected and tested directly at the roadside, whereas urine samples were normally collected and tested at police stations or at public lavatories. The control actions were performed during the night, so the reading of the results occurred in more difficult circumstances than in a police station, hospital or laboratory.
- France: the on-site tests were evaluated in the lab.
- Scotland: The subjects were prisoners. The on-site tests were performed by at least two members of the research team, either within the prison or in the laboratory.

The reference method (gold standard) was gas chromatography-mass spectrometry (GC-MS) or, in some cases, high pressure liquid chromatography with diode array detection (HPLC-DAD) or gas chromatography with electron capture detection (GC-ECD).

The data from the evaluations in the eight countries were obtained in Microsoft Excel format. For the evaluation of opiates, we have considered positive the specimens which contained morphine, 6-acetylmorphine, or codeine. It should be noted that other substances may give positive results with on-site tests, for example dihydrocodeine or pholcodine. We used the following analytical criteria for a good test: accuracy > 95%, sensitivity > 90%, specificity > 90%, when compared with a reference method in urine. Statistical analysis of the data was performed using Microsoft Excel, Medcalc (MedCalc Software, Mariakerke, Belgium) and SPSS (SPSS Inc. Chicago, IL).

Several comparisons were made between the different methods (on-site tests or reference methods) and matrices (blood, urine, oral fluid or sweat). For each drug class, the following comparisons are made:

- A comparison between the reference method in blood and the other biological fluids, in order to assess if findings in each matrix correspond well to those in blood. There is
general consensus that blood is the reference sample, as impairment (or recent exposure to drugs) corresponds best to presence of drugs in blood;
- A comparison of on-site results with the reference method for the same matrix;
- the validity of the roadside test for predicting blood positives by comparison with the blood reference method.

For the determination of the optimal cut-off in oral fluid, we used receiver operating characteristic curves (ROC curves).

Results
The study was performed on 2968 subjects, 92 % of them male.

Analytical aspects
For amphetamines, with the reference methods, all fluids could be used to detect or exclude the presence of amphetamines in blood (see table 1). Both urine and oral fluid have good accuracy and predictive values. Eighteen different on-site tests for amphetamine or methamphetamine were evaluated. Only one test (Syva Rapid Cup, SRC) satisfied the analytical criteria, but it was tested only on a low number of samples. Three other tests came close to satisfying the analytical criteria (Mahsan, SYVA rapid test SRT amphetamine, and Triage).

Most methamphetamine tests succeed better in detecting samples that contain MDMA (ecstasy) or related compounds.

If the results of amphetamines and methamphetamine are considered jointly (i.e. if one considers the test to be positive if either the amphetamine or the methamphetamine test is positive), Rapid Drug Screen (RDS), Dipro and SRT satisfy the analytical criteria. This strategy seems to be an good way of obtaining excellent sensitivity and specificity.

Tests for oral fluid have much lower accuracy (80 % or less in all cases). For sweat, the low number of samples (nearly all positive) does not permit definite conclusions, but use of sweat seems promising. The optimal cut-off for amphetamines in oral fluid is in the range of 70-90 ng/mL.

Table 1: Comparison of the accuracy, sensitivity and specificity of the qualitative results by GC-MS in urine, oral fluid and sweat versus GC-MS in blood for the different drugs.

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Accuracy</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Urine</td>
<td>Oral fluids</td>
<td>Sweat</td>
</tr>
<tr>
<td>Amphetamine</td>
<td>94%</td>
<td>95%</td>
<td>97%</td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>89%</td>
<td>29%</td>
<td>NA</td>
</tr>
<tr>
<td>Cannabinoids</td>
<td>86%</td>
<td>89%</td>
<td>78%</td>
</tr>
<tr>
<td>Cocaine</td>
<td>97%</td>
<td>99%</td>
<td>89%</td>
</tr>
<tr>
<td>Opiates</td>
<td>86%</td>
<td>91%</td>
<td>80%</td>
</tr>
</tbody>
</table>

For benzodiazepines, with the methods used, urine seems to be a better fluid to detect benzodiazepines at the roadside (table 1). Out of the tested on-site urine tests, Triage and RDS were the only that met our analytical criteria. This is explained by the extremely low concentrations of benzodiazepines in oral fluid (often less than 1 ng/mL). The sensitivity of the on-site test and of some confirmation methods seems insufficient at present. This is even more so for the low dose benzodiazepines like flunitrazepam.

For cannabinoids, the comparison of the performance of the different matrices shows a small advantage for oral fluid (table 1), which is not unexpected considering the much longer window of detection of cannabis metabolites in urine compared to the presence of THC in blood. Three out of 11 on-site tests for urine met the analytical criteria: Dipro, Cortez and SRT. In comparison to blood, the accuracy of the best on-site urine tests was close to 90 %. For the
on-site oral fluid tests, the sensitivity was too low (18 to 25 % compared to blood). The required sensitivity of on-site oral fluid tests is 2 ng/mL of THC. No on-site tests were available for sweat.

There are indications that tetrahydrocannabinol (THC) binds to the material of some sampling devices. Much higher concentrations of THC can be extracted from the cotton of the Salivette, in comparison to the THC-concentrations in oral fluid. A possible explanation could be that the cotton of the Salivette absorbs the THC which has been sequestered on to teeth and gum, but this needs further confirmation. This phenomenon could be useful in order to increase the sensitivity of oral fluid analysis for THC, if a suitable extraction method can be found to release the THC trapped on the fibers of the sampling device.

For cocaine and metabolites both oral fluid and urine gave good results for the prediction of positivity in blood with the reference methods (table 1). Eight of the 11 on-site tests met the analytical criteria: Dipro, RDS, TesTcup, SRC, SRT, SureScreen, Status DS and Triage. Even compared to blood, 4 tests have an accuracy > 95 % and sensitivity and specificity > 90 %: RDS, Roche TesTcup, SRT and Triage. In oral fluid, the evaluation was hampered by the low number of positive samples. For Drugwipe the sensitivity is too low. For sweat, the number of samples that could be evaluated was also small, and the evaluation was done with positive samples only. The accuracy of Drugwipe was 77 %.

For opiates, in the comparison of the different fluids with reference methods, oral fluid has slightly better results than urine (table 1). Six of the eleven on-site tests met the analytical criteria: RDS, Cortez, SRC, SRT, Status DS and Triage. In oral fluid, the on-site tests showed less accuracy than urine tests. The sensitivity in particular, was too low. An ideal oral fluids test should have a detection limit of 2-5 ng/mL for opiates.

Practical and operational aspects:
When the necessary facilities are available (e.g. a sanitary van), urine can be obtained relatively easily at the roadside. When the facilities are not available, obtaining a urine sample is a problem and it can be time-consuming if the driver has to be brought to a suitable facility. In some cases, the volume of urine obtained is low, and tests should require a small sample volume. Some countries clearly stated that sampling urine at the roadside was unacceptable. A clear majority of countries prefer oral fluid as the matrix for roadside testing, while one country favored sweat and one favored urine. The methods for obtaining saliva need further improvements. Wiping over the tongue seems to be a well accepted technique, but in this case the analytical detection technique needs to be very sensitive. Sampling oral fluid with dedicated devices gave the following problems: it was sometimes messy; it was sometimes uncomfortable for the subject; in some cases it took a long time; the co-operation of the subject was needed (in some cases, intentionally or not, the subject swallowed the collection device); oral fluid is sometimes viscous, which can give problems with some devices.

Dry mouth is a frequently encountered problem in drug users. Sampling is then more difficult and time-consuming, but in the evaluation it was possible to obtain oral fluid in nearly all cases. In all, sweat and saliva sampling seemed very well accepted by the subjects, much better than urine or blood sampling.

Discussion
Due to the design of the study (mainly dictated by the different legal situation), some limitations must be pointed out:
- the analytical methods used in all the countries were not identical;
- the evaluation of the devices was done in different places, at the roadside, in the police station, or in the laboratory;
- the devices were evaluated by different persons, which makes the comments on the practical and operational aspects more difficult to compare;
- the prevalence of different drugs and the selection criteria of the subjects differed according to countries, which resulted in strongly different prevalences in the samples used to test with for different on-site devices, depending on the countries they were tested in.

In several countries, the Rosita evaluations were the first experience police officers had with roadside drug tests, and, despite some problems and disappointments, police officers liked **having the tools to detect drugged drivers**. Users of on-site tests have shown great creativity in overcoming some of the encountered problems. The oral fluid devices available at the moment of the study all had some practical disadvantages, and the analytical evaluation was not satisfactory. But the need for such devices is so great that in one country, police officers prefer to use an oral fluid test that is imperfect, than no test at all (although we strongly advise against using any of the present oral fluid devices for benzodiazepines or cannabis detection). In other countries, police will rather use urine tests.

**Police did not have major objections to collecting specimens.** There was a majority of countries that favored **oral fluid** as a matrix.

**On site testing gave police confidence, saved time and money.** In general, the use of roadside tests offered the following advantages in the enforcement of drug-driving laws, both in countries with an impairment-type law and in countries with ‘per se’ laws:

- It gave confidence to the police officer. Without an on-site tool to confirm his impression, a police officer will be more reluctant to press charges. Thanks to the immediate feedback, he rapidly increases his skill at detecting drugged drivers.
- On-site tests saved time, because the subject did not need to be transported to the police station for testing.
- On-site tests saved money, because the more expensive confirmation tests were limited to cases that are much more likely to be positive. The use of on-site tests will be more targeted and economical if it is based on a suspicion by a trained police officer.
- Subjects were impressed by the result (even more so if the procedure was complex or if the result is read electronically) and often confessed when confronted with a positive result.
- The publicity that accompanied the use of roadside tests (e.g. in Finland) was considered (by the police officers) to have a preventive effect.

**Most of the urine devices worked well and generally served as good predictors of blood concentrations.** Sampling urine was no problem if appropriate facilities were present. Urine on-site tests are relatively easy to use after some training, however, appropriate training in the use and reading of on-site tests is essential. There is no clear majority for dip or pipette-type devices, but cup-type devices should require less sample. A preference exists for blue lines and multi-analyte tests. In some countries, ‘aggressive’ tests (fewer false negatives than false positives) are preferred. For the different drugs (amphetamines, benzodiazepines, cannabinoids, cocaine and opiates), several on-site devices met our analytical criteria for the reliability of analytical results.

**Oral fluid and sweat are promising specimens and in some cases are better than urine but more research and development will be needed.** Sampling of oral fluid and/or sweat were much better accepted by the drivers and the police officers. For some drugs, with reference methods, there was a better agreement between oral fluid and blood than between urine and blood. The oral fluids devices that were tested were not satisfactory for use at the roadside either in terms of ease of use, duration, sample volume needed, sensitivity and reliability (accuracy of 50-81 % for the different drugs in comparison to blood). On-site tests for oral fluid should be targeted to the parent molecule and not to the urinary metabolite, e.g. to THC, 6-acetylmorphine, cocaine. For sweat, only one device was available and relatively good re-
results were seen for some drugs, but more studies are needed to determine if external contamination and the later appearance of drugs in sweat are an issue.

**The technology is changing rapidly and more accurate, more sensitive, easier to use devices are expected in the near future.** Many development efforts are under way, and new devices and improved versions of the devices that we tested here, are expected soon. Further studies will be needed to evaluate them.

Roadside tests are, and should always remain, preliminary tests, that allow the police officer to take immediate measures on-site. A legal sanction should only be based on the result of a reference method in a certified laboratory and/or on the signs of impairment of the subject (depending on the type of legislation in force).

The ROSITA project has shown that there is a strong desire amongst forensic scientists, police officers and manufacturers in the EU to co-operate in technical developments in the field of traffic safety. It would be desirable if a move could be made within the EU to a single set of regulations for driving under the influence, given the removal of barriers to movement within the EU. We accept that this is likely to be a long-term aim, but at least the trend would be determined on a scientific rather than a political basis.

**Conclusion**

Roadside drug tests were considered to be very useful. In the future, oral fluid seems the most promising, but the presently available tests are not satisfactory. Urine tests can be an acceptable alternative.

**References**