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Case report

Comparison of urine to sweat patch test results in court ordered testing

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Abstract

A former cocaine and methamphetamine abuser was continuously monitored with both sweat patch and urine testing for approximately 6 months. Thirteen sweat patches were applied and collected, five were positive for cocaine and/or methamphetamine, but all the urine specimens collected were negative at the analytical cut-off levels. The high incidence of false positive sweat patch tests in relation to the sensitivity, specificity, and efficiency of the sweat patch assay is discussed. Possible mechanisms, which can lead to false positive results, are presented. The results of our study raise further questions about the preferential use of the sweat patch in detecting new episodes of drug use in formerly chronic drug users.
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1. Introduction

Two recent studies from the Addiction Research Center assessed the sensitivity, specificity, and efficiency of sweat patch versus urine testing in a group of 44 methadone maintenance patients. For the sweat patch detection of concurrent cocaine use, the sensitivity was 97.6%, specificity 60.5%, and efficiency 77.7%; and, for opiate use, the corresponding values were 68.6, 86.1, and 78.6% [1,2]. The relatively low values for specificity and efficiency raise concerns about whether sweat patch testing is the appropriate methodology to be used when false positives can lead to serious or adverse action against the test subject. We recently had the opportunity to compare test results of a sequential series of urine specimens and sweat patches of a probationer, which were collected continuously over a 6 month period. Our findings confirm the low specificity and efficiency values reported in the earlier studies.

2. Case study

A 35-year-old woman with a history of chronic methamphetamine and cocaine abuse was ordered by the courts to undergo drug monitoring. She reported using both drugs interchangeably. When abusing methamphetamine, she consumed, on average, a gram a day. When abusing cocaine, she consumed 2–4 g per day. Her period of heaviest drug use occurred during the 3 months just prior to the commencement of drug monitoring. The court ordered that she submit to sweat patch monitoring. However, she also elected to have observed urine specimens collected and analyzed for comparison. Fig. 1 displays the inclusive dates the sweat patch was worn with test results along with the dates and results of the urine collections.

Over a period of 170 days, 104 urine specimens were collected and analyzed. All specimens were negative for benzoylecgonine and methamphetamine at 300 and 1000 ng/ml cut-off values, respectively. With the exception of 1 day during this period, the subject was continuously monitored. A total of 13 sweat patches were applied. Each patch was worn a minimum of 10 days, and several as long as 14 days.

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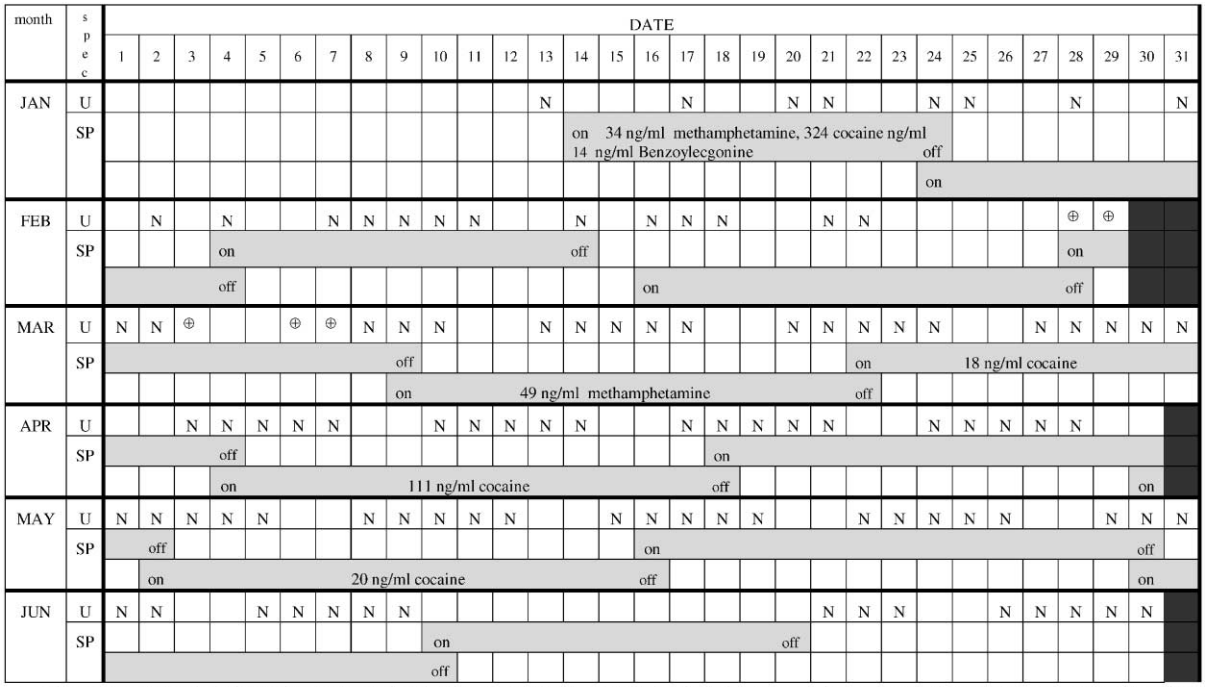

ng/ml = ng drug per ml elution solvent; U = Urine drug screen; SP = Sweat Patch; Shaded areas = period sweat patch was worn; N = Negative urine drug screen; + = Positive opiate screen.

Fig. 1. Schedule and results of sweat patch and urine testing.

Of the 13 patches, five were considered positive: three for cocaine, one for methamphetamine, and one for cocaine, benzoylecgonine, and methamphetamine. Excluding the period from 14 to 24 January, urine samples were collected and tested on the day before and the day after each patch was placed plus all weekdays while the patch was worn. The overlay presented in Fig. 2 compares the protocol used to test this subject and the protocols used in previous clinical studies.

DRUG PATCH AND URINE TOXICOLOGY TEST SCHEDULE

	Days of Week	M	T	W	Th	F	S	S	M	T	W	Th	F	S	S	M	T	W	Th	F
Reference protocol [1,2]	SWEAT PATCH									ON							OFF			
	URINE COLLECTION								X		X		X			X		X		
Court subject	SWEAT PATCH		ON*	ON**													OFF			
	URINE COLLECTION	X	X	X	X	X			X	X	X	X	X			X	X	X	X	X

COURT SUBJECT TEST RESULTS

TESTING DATES	RESULTS		COURT CONCLUSIONS	Using Guidelines in ref [1,2]***
**March 22 (Wed) – April 4 (Tues)	patch	18 ng/ml Cocaine	positive drug use	false positive patch test
	all urines	Negative		
*April 4 (Tues)– April 18 (Tues)	patch	111 ng/ml Cocaine	positive drug use	false positive patch test
	all urines	Negative		
*May 2 (Tues)– May 16 (Tues)	patch	20 ng/ml Cocaine	positive drug use	false positive patch test
	all urines	negative		

ng/ml = concentration of drug in sweat patch eluate
*** A positive patch test with concurrent negative urine tests is defined as a False Positive

Fig. 2. Comparison of testing protocol of court subject to reference protocol.

3. Discussion

The concepts of sensitivity, specificity, and efficiency are widely used in clinical medicine to estimate how accurately a test result will predict the presence or absence of disease [3]. When these terms are applied to forensic drug testing, the definitions remain the same, but the implications are very different, and these differences have led to some confusion in the courts, even among toxicologists.

3.1. Sensitivity

The term sensitivity is defined as the incidence of true positive results obtained when a test is applied to patients known to have the disease, or

$$\text{Sensitivity} = \left(\frac{\text{TP}}{\text{TP} + \text{FN}}\right) \times 100$$

where TP is true positive, and FN is false negative.

In previous publications on sweat patch testing [2], the term false negative was used to indicate that a negative sweat patch test result had been obtained, even though a urine specimen tested positive while the patch was being worn. Thus, during the period of 28 February–9 March, a false negative patch test result was recorded when the subject was given opiates during oral surgery. She did have a positive urine test, but her sweat patch test result was negative, consistent with the low sensitivity of the sweat patch test for opiates. A sensitivity of 100% means that if drugs are used while the patch is being worn, a positive sweat patch test is always accompanied by at least, one positive urine test. The higher the sensitivity, the more likely it is that drug use will be detected. By definition, a False Positive Test result does not alter the sensitivity value of a test. That means then, that a test with a very high degree of sensitivity is not always desirable, especially when a false positive may result in incarceration or loss of child custody for the person being tested.

3.2. Specificity

The specificity of a test characterizes the incidence of true negative results when a test is applied to subjects known to be free of disease, or

$$\text{Specificity} = \left(\frac{\text{TN}}{\text{TN} + \text{FP}}\right) \times 100$$

where TN is true negative and FP is false positive.

Unlike sensitivity, specificity is greatly influenced by the number of false positives. A positive sweat patch test in relation to all negative urine tests while the patch is being worn is defined as a false positive [1,2]. A specificity of 100% means that if drugs are not used while the sweat patch is being worn, both the sweat patch test and the urine tests will always be negative. As the number of false positives increases, the specificity of the test decreases. Compared to urine testing, the specificity of sweat patch tests for cocaine detection is reported to be between 60.5 and 62.9% [1]. A test with the highest specificity is desired when the occurrence of a single False Positive test can lead to serious and adverse action against the test subject. By this definition, all the positive sweat patches reported for this subject were not true positives, but in fact were false positives.

3.3. Efficiency

The efficiency of a test is defined as the percent of all results that are true results, whether positive or negative, or

$$\text{Efficiency} = \left(\frac{\text{TP} + \text{TN}}{N}\right) \times 100$$

where N is the total number of tests.

If a test is 100% efficient, the test represents the true condition all the time. An efficiency of <80%, as was the case in the clinical studies for cocaine and opiate detection [1,2], suggests the assay represents true results <80% of the time. A test with the highest efficiency is desired when both false positive and false negative results are equally serious and damaging. False positives and false negatives present something of a conundrum, False Positive tests damage the probationer, while False Negative tests can be said to damage the justice system by allowing drug users to go free, in spite of the courts orders.

Sweat patch proponents argue that, in the case of cocaine abuse, the test has a 97.6% sensitivity, which means that the test can be relied upon to detect drug use when drug use occurs. However, should a test for cocaine detection with a specificity of 60.5% and a 21.1% false positive rate [1] be acceptable? In monitoring opiate use, Huestis et al. [2] reported a false positive rate of as high as 7.9%. Of 44 monitored subjects, 15 subjects had positive sweat patches during weeks when all corresponding urine tests were negative. During the course of the study, one of the test subjects had six positive sweat patches associated with all negative urine tests, and >30% of the participants had at least, one false positive sweat patch at some times during the study.

There are several possible mechanisms that might explain the high incidence of false positive sweat patch tests. Licit and illicit drugs are readily identified in skin and adipose tissues of cadavers, and their presence is a function of antemortem deposition, not postmortem redistribution [4,5]. Jufer et al. [6] reported that chronic cocaine users exhibit prolonged terminal urine half-lives for cocaine and metabolites and suggested that cocaine might accumulate in the fatty tissues of the body. Slow release from these tissues might account for the prolonged elimination. Subjects who undergo court ordered drug testing undergo testing for a reason, and the reason is usually that they are chronic drug users. The time it takes to clear all residual drug from their bodies has never been studied and is not known.

There is also evidence to suggest that drugs can migrate from adipose tissues to the skin surface via extra-circulatory routes [4,7]. Others have suggested that skin-to-skin contact is another possible mechanism of drug deposition on the sweat patch. Kidwell [8] demonstrated that drugs applied to

the skin surface remain on the skin surface for days and that simple cleansing does not remove all the drug. Joseph et al. [9] showed that cocaine persists for several weeks in the stratum corneum (the outer layer of the skin) in chronic drug users. Individuals who must wear sweat patches have husbands, live-in lovers, and friends who may continue to use drugs. It is not surprising that the sweat patch wearer may unknowingly be exposed to these drug sources.

Whether one or all of these mechanisms contribute to the problem is not known, and will never be known until the appropriate studies are undertaken. Until such studies are undertaken the appropriateness of the sweat patch methodology, at least for use by the courts, remains in doubt.

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