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Hair analysis and its concordance with self-report for drug users presenting in emergency department

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ABSTRACT

Background: Secondary analysis using data from the National Drug Abuse Treatment Clinical Trials Network randomized trial (NCT # 01207791), in which 1285 adult ED patients endorsing moderate to severe problems related to drug use were recruited from 6 US academic hospitals. Objective: To investigate the utility of hair analysis in drug use disorder trials with infrequent visits, and its concordance with Timeline Follow Back (TLFB). Methods: This study compared the self-reported drug use on the TLFB instrument with the biological measure of drug use from hair analysis for four major drug classes (Cannabis, Cocaine, Prescribed Opioids and Street Opioids). Both hair analysis and TLFB were conducted at 3, 6 and 12 month follow-up visit and each covered a 90-day recall period prior to the visit. Results: The concordance between the hair sample results and the TLFB was high for cannabis and street opioids, but was low to moderate for cocaine and prescribed opioids. Under-reporting of drug use given the positive hair sample was always significantly lower for the drug the study participant noted as their primary drug of choice compared with other drugs the participant reported taking, irrespective of whether the drug of choice was cannabis, cocaine, street opioids and prescribed opioids. Over-reporting of drug use given the negative hair sample was always significantly higher for the drug of choice, except for cocaine. Conclusions: This study extends the literature on hair analysis supporting its use as a secondary outcome measure in clinical trials.

1. Introduction

In clinical trials, a common way to collect illicit drug use information is self-report, yet accuracy of self-reported drug use is highly controversial (Donovan et al., 2012). Some studies have shown good concordance of self-report with biological measures of drug use (Fals-Stewart et al., 2000; Hersh et al., 1999; Napper et al., 2010), while others have shown poor concordance (Ehrman and Robbins, 1994; Winhusen et al., 2003). The reliability and validity of self-report are limited by the veracity and recall ability of research participants.

Often self-report is used in conjunction with a biological measure such as urine drug screen (UDS; Winhusen et al., 2014a,b; Campbell et al., 2014). UDS typically enables the detection of drug use only for a short recent period, usually 1.5–4 days. In chronic users, drug use can be detected approximately 1 week after last use (Verstraete, 2004). However, moderate drug use during a longer window of time cannot be detected using urine drug screen. Frequent UDS testing (e.g., 3 times per week in many cocaine treatment trials) is expensive and can affect validity by restricting the study sample to those who will comply with such a regimen, and confound treatment effects with the effects of frequent monitoring. Also, considerable amounts of missing data are inevitable with such designs, complicating the analysis and its interpretation.

Hair testing enables detection of drug use over a significantly longer window of time (Caplan and Goldberger, 2001; Gallardo and Queiroz, 2008) and is increasingly being used as a biological measure to complement self-reported drug use outcomes in clinical trials (Ondersma et al., 2014; Schwartz et al., 2014). Extended detection window of approximately 1 month per half inch of hair allowing 1.5 in. section (3.9 cm) of hair captures a 90-day window of drug use (Gryczynski et al., 2014). A significant benefit of this approach is the non-intrusive nature of collecting a hair sample from the scalp (Kintz et al., 2006). When comparing hair analysis to other methods, Pelander et al. (2008) reported that in 72% of the cases examined, sample compounds that were not present in other

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matrices were detected in hair, suggesting the increased sensitivity of this approach relative to other biomarkers.

Under-reporting of drug use, defined as a negative self-report when a biological measure indicates drug use, may differ according to drug class. For example, under-reporting for cannabis may be less compared with cocaine, as cannabis is more socially acceptable compared to cocaine and other drugs. Also, there may be factors associated with under-reporting, e.g., pregnant women would tend to under-report drug use due to fear of losing custody or criminal retribution (Kline et al., 1997). Over-reporting of drug use, defined as a positive self-report when a biological measure does not indicate drug use may also occur, but likely less frequent than under-reporting. One possible explanation for over-reporting is inaccuracy of the assay procedure.

This current study compares hair sample results to self-report collected via Time-Line Follow-Back (TLFB; Sobell and Sobell, 1992, 1996) based on an algorithm developed to map drug classes encountered in hair analyses with drug classes collected on the TLFB. With this algorithm, we investigate concordance between hair sample outcomes and TLFB for the four most prevalent drugs: cannabis, cocaine, street opioids (heroin, opium) and prescribed opioids. We also explore the association between study participant characteristics and under-reporting and over-reporting.

2. Methods

2.1. Primary study

This study is a secondary analysis using data from a randomized trial to contrast the effects of a brief intervention with telephone boosters (BI-B) with those of screening, assessment, and referral to treatment (SAR) and minimal screening only (MSO) among patients presenting at an Emergency Department and screened positive for drug use. Both the design of the study and the results of the primary outcome and key secondary outcomes, including the hair sample analysis, are discussed elsewhere (Bogenschutz et al., 2011, 2014).

2.2. Assessments

The Time-Line Follow-Back (TLFB) procedure was used to assess drug use behavior at baseline and follow-up visits. The TLFB is a semi-structured interview that provides estimates of the daily quantity, frequency, and pattern of drug use during a specified time period. This method uses a calendar prompt and a number of other memory aids (e.g., holidays, payday, and other personally relevant dates) to facilitate accurate recall of drug use during the target period. The procedure has been used in numerous clinical and research contexts and has demonstrated adequate levels of reliability and validity when administered as an in-person interview, over the telephone, and by computer (Sobell et al., 1988, 1996; Sobell and Sobell, 1996). In this study, daily use self-report data were collected for cannabis, cocaine, methamphetamine and prescription stimulants, street opioids (primarily heroin) and prescription opioids, inhalants, sedatives, hallucinogens, alcohol, and other drugs. The TLFB interview was conducted at baseline to assess the past 30 days of drug use, and then at each of the 3, 6 and 12 month follow-up visits to assess drug use over the past 90 days before these visits.

Hair sample analyses were conducted at baseline, 3, 6 and 12 month visits. A standard test of one hundred milligrams of head hair cut close to the scalp provides a several-month window to detect drug ingestion. Hair grows at a rate of 0.6–1.4 cm per month (Saitoh et al., 1969), thus the first 3.9 cm of hair corresponds to an average of three-month hair growth. Approximately 90–120 strands of hair were required from study participant, and only if head hair was not available, body hair from the leg, chest or underarm was collected as an alternative. Since body hair exhibits longer periods of dormancy than head hair, the timeframe of drug use derived from body hair testing is more difficult to establish than head hair because it spans several months. Head hair and body hair were not mixed in a sample for analysis. Once a hair sample was cut from the participant, the sample was secured in aluminum foil with root ends marked and protruding from the edge of the foil. The sample was then shipped to the central lab. An extensive wash procedure on test samples was employed to ensure that any potential contamination has been removed or taken into account. The wash procedure minimizes the potential effect of environmental contamination (Gallardo and Queiroz, 2008).

The lab uses a digestion method to liquefy the hair, thereby effectively releasing essentially all the drugs present for analysis, and increasing detection capabilities. Screening cut-off levels followed the laboratory's standard practices for the 5-panel test: 1 ng/gm for marijuana, 5 ng/10 mg for cocaine and amphetamines and 2 ng/10 mg for opioids; GC/MS confirmation cut-offs were: 0.20 pg/10 mg for carboxy-tetrahydrocannabinol (THC) metabolite, 0.2 ng/10 mg for cocaine and its metabolites (benzoylecgonine; norcocaine; cocaethylene), 0.25 ng/10 mg for amphetamines, 0.2 ng/10 mg for MDA, 1 ng/10 mg for MDEA, MDMA and methamphetamines, and 0.2 ng/10 mg for hydromorphone, 0.5 ng/10 mg for morphine, codeine, oxycodone, hydrocodone, and 6MAM. A sample testing positive during the preliminary screening radioimmunoassay for any of the drug classes were confirmed using gas chromatography tandem mass spectrometry (GC/MS/MS) for marijuana, liquid chromatography tandem mass spectrometry (LC/MS/MS) for opiates, cocaine, and amphetamines, and gas chromatography-mass spectrometry for PCP (Hegstad et al., 2008). If the quantity of hair sample was not sufficient to process and test for the full panel of drugs, only single drug testing was performed until the sample was used up using the following order: Drug of Choice, Opiates, Cocaine, Amphetamines, Marijuana, and PCP.

2.3. Algorithm

The central lab tested the hair sample for 5 drug classes: marijuana, cocaine, PCP, amphetamines and opiates. The TLFB instruments collect daily use for following drug classes: cannabis, cocaine, methamphetamine, prescription stimulants, street opioids, prescription opioids, inhalants, sedatives, and hallucinogens. To investigate the concordance between TLFB and hair sample results, an algorithm was developed to map the 5 drug classes from the hair sample analysis to the drug classes in the TLFB (See Supplementary Section A).

2.4. Statistical analysis

The agreement between the hair sample comparator and the TLFB for cannabis, cocaine, prescribed opioids and street opioids was calculated using the percent concordance and Cohen's kappa. In addition, for the discordance, under-reporting and over reporting percentages were calculated for self-report via TLFB compared with the hair sample analysis. We define TLFB under-reporting to be the probability of self-reporting no drug use in the past 90 days on TLFB, given the hair sample comparator was positive. We define TLFB over-reporting to be the probability of self-reporting any drug use in the past 90 days on TLFB, given the hair sample comparator was negative. (Note that is technically possible for the same person to be both over-reporting at one visit and under-reporting at another.) Sensitivity, specificity, positive predictive value and negative predictive value were also calculated. Except for concordance and kappa, all analyses implicitly assume that the hair sample results are the "gold standard".