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The Accuracy of Self-Reported Drug Ingestion Histories In Emergency Department Patients

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Abstract

Inaccuracies in self-reports may lead to duplication of therapy, failure to appreciate non-compliance leading to exacerbation of chronic medical conditions, or inaccurate research conclusions. Our objective is to determine the accuracy of self-reported drug ingestion histories in patients presenting to an urban academic emergency department (ED). We conducted a prospective cohort study in ED patients presenting for pain or nausea. We obtained a structured drug ingestion history including all prescription drugs, OTC drugs, and illicit drugs for the 48 hours prior to ED presentation. We obtained urine comprehensive drug screens (CDS) and determined self-report/CDS concordance. Fifty-five patients were enrolled. Self-reported drug ingestion histories were poor in these patients; only 17 (30.9%) of histories were concordant with the CDS. For the individual drug classes, prescription drug-CDS was concordant in 32 (58.2%), OTC-CDS was concordant in 33 (60%), and illicit drug-CDS was concordant in 45 (81.8%) of subjects. No demographic factors predicted an accurate self-reported drug history. Sixteen patients had drugs detected by CDS that were unreported by history. Nine of these 16 included an unreported opioid. In conclusion, self-reported drug ingestion histories are often inaccurate and resources are needed to confirm compliance and ensure unreported drugs are not overlooked.

Keywords

compliance; comprehensive urine toxicology screen; medication reconciliation; opioid abuse

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Introduction

Drug adherence, including prescription and over-the counter medications (OTC), is a key element in patient treatment. While long-term drug therapy compliance has been estimated to be less than 50%[1-4] it is difficult to confirm the accuracy of self-reported drug ingestion histories. Self-reported therapeutic drug ingestion histories are notoriously inaccurate but remain the most commonly utilized method to measure adherence in both the clinical and research environments.[5, 6] Inaccuracies in self-reported ingestion has been demonstrated to be poor in overdose populations by comprehensive drug screens (CDS).[7-9] It is unclear if this discordance between self-reported history and actual drug ingestion also occurs for therapeutic ingestions.

Patients who over-report use of medications are likely at increased risk for premature abandonment of treatments, up-titration leading to potentially dangerous dosing, and wasting of medication. Conversely, failure of patients to report ingested drugs during reconciliation can lead to unintended drug-drug interactions, failure to identify adverse drug events (ADEs), and redundant therapy. Failure to report illicit drug use hinders physicians' ability to counsel patients about associated health risks, blinds physicians to the need for detoxification programs, and can lead to life threatening drug interactions, such as serotonin syndrome in patients taking cocaine in combination with serotonergic prescription drugs. All of these consequences ultimately increase health care costs.[10, 11] Pharmacy claim data have demonstrated discrepancies in patient reported medication history and pharmacy records[12] but these data cannot account for transient periods of non-compliance that may alter the timing of obtaining refills and doesn't capture OTC drugs. Medicaid and pharmacy claim data does not confirm ingestion of drugs in question, they fail to capture non-prescription drugs, and they do not account for the diversion and black market drug marketplace.[13, 14]

While the clinical implications of inaccurate medication histories are clear, there are also significant research implications for inaccurate medication histories. Research studies rely heavily on self-reporting for capturing drug ingestion histories. Even when trials monitor compliance with the study drug, they rarely confirm the accuracy of other drugs reported by the subject. Misclassification of these variables would impair investigators' ability to accurately attribute clinical effects to the drugs in question. Specifically, interpretation of drug efficacy and safety is altered by the poor quality of self-reported histories.[15] Clearly poor drug compliance and inaccurate self-reporting can affect patient health and research results.

Given the clinical and research implications of discordance between self-reported drug ingestion histories and what is actually taken by patients, the objective of this study was to determine the accuracy of self-reported drug ingestion histories in patients presenting to the emergency department (ED).

Methods

This is a prospective observational cohort study in an academic US ED with approximately 72,000 patient visits per year. This is a secondary analysis of a subset that was randomized

to provide a CDS from a larger cohort that included subjects presenting with self-reported pain or nausea identified during the initial nursing assessment.[16] The local institutional review board approved the study and all subjects provided written informed consent.

Patients

We enrolled a convenience sample of ED patients between June 4th, 2012 and January 25th 2013. We performed enrollment between the hours of 9am and 5pm. Subjects recruited during this timeframe are demographically indistinguishable, in terms of sex and race, from the overall ED population.[17] We approached patients after triage and after initial stabilization when the patient arrived by ambulance. In patients with dementia or critical illness, the drug ingestion history was reconciled with the healthcare proxy. Patients were excluded if they were unable to speak English, <18 y.o, if they had liver failure, or previously diagnosed with chronic pain (including those that took opioid medications daily) or cyclic vomiting. Patients with a measured or known glomerular filtration rate of < 60 ml/min/1.73 m^2 were excluded. Ten percent of the cohort was randomized to provide a urine sample for comprehensive urine drug screening (CDS) to confirm self-reported drug ingestion histories. Randomization was accomplished using a random number generator. The subjects that provided a CDS are the focus of this study.

Data collection

The principle investigator or a trained professional research assistant obtained drug ingestion histories for the 48 hours preceding the ED visit. All prescription, OTC, and drugs of abuse were captured along with the dose and time since the patient's last dose. Drug ingestion histories were gathered in a structured format. Initially, we asked, “What medications have you taken in the last 48 hours?” We then asked specifically about the use of prescription, non-prescription, and drugs of abuse. All reported drugs were recorded. The electronic medical record was then reconciled to ensure capture of drugs listed in the record. If the patient had any difficulty recalling the prescription name, their pharmacy was contacted to ensure accuracy of the obtained history. OTC drug combination formulations were reconciled using internet pictures to verify the specific product ingested.

Classification of drugs

A prescription medication was considered any drug that could only be obtained with a physician prescription. OTC drugs were classified as any medication available in any form not requiring a prescription. For instance, while ibuprofen is available as a prescription, it was classified as an OTC drug. Cocaine, heroin, ketamine, methamphetamine, 3,4-methylenedioxy-methamphetamine (MDMA), phencyclidine, and marijuana were considered illicit drugs. Herbal treatments, supplements, and vitamins were excluded from this analysis since they are not detectable by the CDS.

Comprehensive drug ingestion evaluation

Urine was obtained within 4 hours of patient consent in those randomized to urine testing. Urine was frozen at -80° C and CDS was performed by Quest Diagnostics™ utilizing liquid chromatography tandem mass spectrophotometry (LC MS/MS). This general drug screen

detects 142 prescriptions, over-the-counter (OTC) drugs, drugs of abuse (DOA) and their metabolites.[18] We determined if each individual subject's self report was concordant with the CDS. A report of drug ingestion within 2 half-lives of urine sampling was considered accurate if it was detected by the CDS. If the ingestion was reported more than 2 half-lives from the time of CDS, it was considered undetectable and not included in the self report-CDS concordance analysis. This timing was chosen to ensure an adequate concentration would be present in the urine based upon CDS detection limits. This eliminates the possibility of false negative due to low concentration despite an accurate history within the 48 hours reported. If a drug was not reported by a subject but was detected by the CDS, it was not considered inaccurate if 5 half lives of the drug totaled more than 48 hours, the time period for which each patient reported drug ingestion prior to ED arrival. This ensured that at least 97% of the drug was eliminated and we were unlikely to misclassify the history as inaccurate due to a false positive CDS.

Statistics

A logistic regression model including age, male sex, and drug class was used to predict a concordant CDS with the patient reported ingestion history. Odds ratios (OR) were calculated for patients that reported taking a drug class and those that had an accurate CDS for that class.

Results

502 patients were enrolled and 55 were randomly selected to provide a urinalysis for drug ingestion confirmation. The median age was 50 years (IQR: 32, 63) and 25 were males (45.5%) (Table 1). The median number of drugs taken in the prior 48 hours was 4 (IQR: 3, 8) and the median number of detectable drugs by CDS was 2 (IQR: 1, 4). The accuracy of self-reported ingestion histories was poor when compared with CDS confirmatory testing; only 17 of 55 (30.9%) were concordant. 29 (52.7%) patients had 1 or more drugs detected but not reported (range: 0-7 drugs). The median number of total drugs detected by CDS but not reported was 1 per subject (IQR: 0, 2). Sixteen (29.1%) had drugs reported but not detected (range: 0-3 drugs) and the median number of drugs deleted from the self reported list following CDS was 0 (IQR: 0, 1). The range of drugs detected by CDS but not reported by patients for each drug class was 0-11 for Rx drugs, 0-5 for OTCs, and 0-1 for illicit drugs. The range of the number of drugs reported but not confirmed by CDS for each individual drug class was 0-8 for Rx, 0-2 for OTCs and 0-1 for illicit drugs. See Table 2.

There were no factors associated with an accurate self-reported ingestion history (Wald test *p* values: age=0.73, male gender=0.44, reported taking Rx=0.85, reported taking OTC=0.065, and reported taking illicit drugs=0.46). Report of taking the drug class was not associated with an accurate CDS for that class (Rx OR: 0.51 [0.09-2.92]

OTC OR: 0.32 [0.09-1.15), illicit drug OR: 0.19 [0.02-1.52]). While not statistically significant, there is a troubling trend toward an increase in history-CDS discordance when patients report taking any class of drugs.

Of the 16 subjects that had Rx drugs detected by CDS but not reported by history, 9 included an unreported opioid and 5 included an unreported benzodiazepine or centrally acting muscle relaxant. Of the 9 that had an unreported opioid detected on CDS, 6 received a prescription for an opioid when discharged. Other unreported drugs included: 4 neurologics (all gabapentin), 2 antidepressants, 1 atypical antipsychotic, 1 anti-arrhythmic, 2 antibiotics, and 1 β-blocker. Of the 8 subjects that reported taking Rx that could not be confirmed by CDS, 5 included benzodiazepines, 2 opiates/opioids, 1 antidepressant, and 1 anticoagulant.

Eleven subjects had OTC drugs detected by CDS but not reported by history; 9 of these included an unreported antihistamine, 6 failed to report taking an NSAID, and 2 failed to report taking an anti-tussive (dextromethorphan). Reported but not detected OTC drugs were the same classes; 8 reported taking an NSAID that wasn't detected, 2 reported an antihistamine, and 2 reported an anti-tussive. 7 failed to report cocaine and 1 failed to report methamphetamine that was subsequently detected by CDS. 2 subjects reported marijuana use within 24 hours that was not detected by CDS.

Limitations

The internal validity of this study is threatened by reliance on a commercially available comprehensive drug screen. This test is Clinical Laboratory Improvement Amendment (CLIA) certified and undergoes regularly scheduled verification with positive and negative controls. Detection limits are set to ensure detection of drugs well below the therapeutic range utilizing the extremely sensitive technique of LC MS/MS. Therefore, it is unlikely that we failed to detect drugs that were actually present using this methodology. This detection technique does not employ a de-glucuronidation step therefore some drugs may not be captured when bound. However, many redundant metabolites are included to account for this limitation. For instance, oxymorphone, a metabolite of oxycodone is included as a separate metabolite in this screen. Therefore, if all the oxycodone were present in bound glucuronidated form, the oxymorphone metabolite would still demonstrate presence of oxycodone mitigating this limitation.

Drug half-lives vary between patients, and therefore it is possible that a patient with either exceptionally rapid metabolism or slow metabolism led to either a short half-life or long half-life drug, respectively. This half-life variability can affect our results by either increasing the number of drugs detected but not reported or vice versa, decreasing the number of detected drugs that were reported. This is likely to be more of a problem for long half-life drugs leading to increased detection. However, drugs detected but not reported tended not to have increased half-lives. For instance, even oxycodone extended release has a half-life of only 4.5 hours.

The research drug ingestion history tool has not been validated making it possible that this tool has its own limitations. We would argue that this technique is more sensitive than generalized questionnaire, and structured histories have been demonstrated to capture more ingested drugs than the standard nursing or physician work-flow.[19, 20] It is possible that business hour convenience sampling does not represent our overall ED population. Consecutive 24 hour, 7 day a week enrollment or true random sampling is the most

representative sampling method in our ED though this was not feasible due to resource limitations. We know that business hour sampling best represents sex and race demographics in our ED[17] and outperforms 4-hour time block sampling. Though this method does not account for variability medical co-morbidity and variation in ED arrival times based upon this factor.

External validity may be limited by the self-selected small sample size and conducting the study at a single academic center. Self-selection would likely have resulted in patients who were deliberately under-reporting refusing to participate. Therefore we would expect self-selection to under-estimate the rate of under-reporting. While the absolute rates at other centers may differ, we believe our findings demonstrate that a significant number of patients under-report opioid use. We may be limited by exclusion of non-English speaking patients may result in different levels of compliance or black market drug ingestion. More than 90% of our ED population speaks English and this exclusion may actually bias our results toward better compliance; while most pharmacies can print instructions in a limited number of languages, non-English speaking patients may not understand physician instructions as completely as native English speakers and they may not be able to ask pharmacists for clarification as easily. This data should not be applied to non-English speaking populations. In addition, this urban academic ED patient population may not be representative of smaller community hospital ED populations.

Discussion

Less than one third of patient reported drug histories were accurate when confirmed with CDS. This poor compliance is consistent with pharmacy claim data but adds unreported ingestions as another element of inaccurate self-reporting. This further decreases self-report/CDS concordance. Our liberal definition of compliance, if the drug was taken and detected within only two half-lives, may even bias the results toward compliance. The failure of patients to report taking OTC medications is not surprising. These drugs are often considered too weak to cause any problems by patients[21] and it is estimated that 50% of physicians do not inquire about OTC drugs that patients take.[22-24] However, in this study we specifically asked about non-prescription medications. Even with prompting these drugs were under-reported suggesting more community education regarding the effects of these drugs is needed. Unfortunately, we were not able to identify any demographic factors that predict accurate self-reporting. This suggests the problem is similar across demographics. However, the problem is likely multi-factorial with different etiologies more prevalent in different demographics. Potential explanations include inaccurate reporting due to fear of negative judgment in some, unintentional forgetfulness in others, and intentional misleading behavior in others. Each contributory reason requires a different intervention and educational strategy to mitigate the clinical implications of the inaccuracy.

The finding of poor self-reporting accuracy has major implications for researchers and clinicians. Clinically, non-compliance results in greatly increased risk of coronary heart disease[25], cerebrovascular accidents[25], diabetic complications[26, 27], HIV treatment failure[27], among many other chronic medical conditions. It also has been shown to increase ED visits[28, 29] likely due to decompensation of such medical conditions. Understanding this

dynamic is key to providing effective emergency care. Simply ensuring compliance can alter how emergency physicians change treatment plans. This highlights the need for on-going discussion between EM and primary care providers to augment each other's understanding of compliance issues in individual patients.

The frequent failure to report opioids and benzodiazepines is a troubling finding. While our study was not designed to determine the reasons for under-reporting, we found it interesting that the majority of under-reported medications were opioids. One explanation for this finding is that patients are deliberately not disclosing opioid use, a potential sign of opioid abuse or misuse. False reporting of opioid ingestions is a concerning given the current opioid prescription drug epidemic. Sixteen percent of subjects in this cohort failed to report ingesting an opioid despite ultimate detection by CDS and 67% of these patients were given an opioid prescription when discharged. Providers often consider prior opioid prescriptions when determining the best treatment for pain in the ED. The most common way to determine the patient's prior opioid use is by taking a medication history. Our study suggests that these histories are often inaccurate, and there is a need for alternative assessment of recent opioid use such as real-time prescription drug monitoring programs. Providers should be concerned when a patient's do not report recent opioid use, but a patient's prescription history, through hospital records or a prescription drug monitoring program, demonstrates numerous opioid prescriptions by numerous providers. Clearly larger studies are needed to determine the scope of failure to report opioid ingestions and to examine the reasons why patients omit this information.

The failure of the CDS to confirm marijuana in two subjects reporting ingestion within 24 hours may be a local phenomenon since marijuana was considered a therapeutic drug by the public during the study period. It may be that patients considered this a medication for pain when requesting an additional ED intervention for pain, similar to reporting ineffective home NSAID use. It is interesting that patients reporting using many different drugs for pain prior to an ED visit often misrepresent what they have taken, both under and over reporting what they have taken. More than half of people failing to report an ingested drug had taken an opioid and 25% of those with history-CDS discordance due to failure of the CDS to detect a reported drug, had given a history of taking an opioid that wasn't detected. This may represent different individual patient motives for misrepresenting their ingestions; some may over report to elicit a physician intervention while in the ED and others may under report for fear of judgment.

Self-reported ingestion histories should not be the standard capture method for research requiring accurate drug ingestion. The interpretation of drug safety and efficacy can be affected by drug interaction and adverse drug events. Therefore, these types of clinical studies, such as clinical drug trials, must devote resources toward, at a minimum, qualitative confirmation of ingested drugs. An argument can also be made for employing compliance screens, i.e. screens documenting self report concordance with CDS, in clinical arenas allowing physicians to target behavior rather than alteration of pharmaceutical interventions.

In conclusion, self-reported drug ingestion histories were poor when confirmed by CDS in an urban academic ED. This finding has important clinical and research implications.

Increased research resources, increased communication with primary care providers, and consideration of routine CDS utilization are needed to confirm drug ingestion histories and mitigate the clinical risks of inaccurate self-reporting.

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Table 1

Patient Demographics

Demographic Variable	Total Group n=55
Age, years (IQR)	50 (32, 63)
male n (%)	20 (45.5)
Ethnicity/Race	
Hispanic/Latino n (%)	7 (12.7)
Caucasian n (%)	40 (72.7)
African American n (%)	13 (23.6)
Asian n (%)	0 (0)
American Indian/Alaskan Native n (%)	2 (3.6)
Native Hawaiian/Pacific Islander n (%)	0 (0)
Median number of drugs taken (IQR)	6 (4, 12)
Median number of drugs detectable (IQR)	3 (2, 4)
Number of concordant self-reported ingestion histories (total drug list) with overall CDS n (%)	17 (30.9)
Number of concordant self-reported prescription drug ingestion histories with CDS n (%)	32 (58.2)
Number of concordant self-reported OTC drug ingestion histories with CDS n (%)	33 (60.0)
Number of concordant self-reported illicit drug ingestion histories with CDS n (%)	45 (81.8%)

Table 2

The number of subjects with CDS/self report concordance by drug class.

	Overall List	Rx List	OTC List	Illicit List
Subjects with drugs detected by CDS but not reported by history. n (%)	29 (52.7)	16 (29.1)	16 (19.1)	8 (14.5)
Subjects reporting ingestion of a drug that was not confirmed by CDS. n (%)	16 (29.1)	8 (14.5)	11 (20.0)	2 (3.6)