Field-Test of a Date-Rape Drug Detection Device

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Abstract
Drink Safe Technology Version 1.2 is an inexpensive color-change reagent test marketed internationally for use by consumers in settings such as a nightclub to detect potentially incapacitating concentrations of γ-hydroxybutyric acid (GHB) and ketamine in beverages. The objective of this study was to compare product performance in the laboratory and performance in the hands of consumers in the field. Product performance in the laboratory adhered to the protocol defined by the manufacturer. Product performance in the hands of consumers in field settings allowed browsing participants to pipette an aliquot of their own drinks into randomly coded vials containing authentic drugs, or pure water, so as to yield the same concentrations of GHB or ketamine specified in the manufacturer-defined protocol, or blanks. Consumers were to proceed according to the directions printed on the product, and to record their results on a card with a code corresponding with the vial to which they had added an aliquot of their beverage. Diagnostic performance was calculated using two-way analysis. In the laboratory, Drink Safe Technology Version 1.2 reliably detected GHB and ketamine at concentrations specified by the manufacturer's protocol. The reactive color change denoting a positive test for GHB was rapid, but a positive test for ketamine required substantially more time to resolve. Nonetheless, test accuracy following the manufacturer's protocol in the laboratory was 100%. In the field, based on 101 paired-test results recorded by consumers, the test efficiency was 65.1%, sensitivity 50%, and specificity 91.6%. The product performed much better in the laboratory than it did in the hands of consumers in the field. There seems to be considerable potential for consumers to misinterpret a test result. The potential for consumers to record a false-negative test result for a spiked drink is cause for concern.

Introduction
The Society of Forensic Toxicologists' Drug-Facilitated Sexual Assault Committee defines drug-facilitated sexual assault as an offense whereby a person is subjected to non-consensual sexual acts while he/she is incapacitated or unconscious due to the effects of alcohol and/or drugs and therefore prevented from resisting and/or unable to consent. It is not a legal definition; there is no clear legal standard for incapacitation (2). The extent that drug-facilitated sexual assault constitutes a public health problem remains poorly resolved. The uncertainty is due in large part to the want of reliable estimates of the incidence of this crime and the prevalence of its sequelae (3). There is evidence to suggest that the incidence of drug-facilitated sexual assault has increased in one Canadian locale (4). Estimates based on interviews, surveys, and statistics suggest gross underreporting of sexual assaults in general and drug-facilitated sexual assaults in particular (5-7). The nature of the crime is such that amnesic properties of the drugs attenuate assault victims' recollection of the assault, their propensity to report and their reliability as witnesses. Case reports suggest that the risk is real and that this crime can have a profound negative impact on the lives of victims (8-14). Public awareness and education initiatives have potential to reduce drug-facilitated assault if they inspire potential victims to take rational, effective precautions to lower personal risk. A caveat, described as the Melbourne effect, is the potential for widespread media attention to embolden an increase in drug-facilitated sexual assaults (4).

Fear of drug-facilitated sexual assault has generated a market for inventions that claim to reduce potential victims' vulnerability. These include tamper-resistant serving containers to prevent drinks from being surreptitiously spiked (15,16) and direct-to-consumer in vitro screening tests for beverages suspected of being drugged. Drink Safe Technology Version 1.2 is an inexpensive color-change reagent test marketed internationally and in Canada for use by consumers in settings such as a nightclub or house party. It purports to detect potentially incapacitating concentrations of γ-hydroxybutyric acid (GHB) and/or ketamine, on suspicion that one of those drugs has been surreptitiously added to the consumer's beverage. The performance of Drink Safe Technology Version 1.2 under laboratory conditions has been reported by the manufacturer (17). An independent laboratory evaluation has also been published (18). The objective of this study was to compare product performance in the laboratory, to performance in the hands of consumers in the field.
consumers in the field. The field testing component was imbedded in a university campus date-rape information campaign called “It's All About Awareness”.

Experimental

Materials

Drink Safe Technologies™ Version 1.2 Date Rape Drug Test Strips [UPC lots: 5534500001 (4 packages of 2 strips), 5534500002 (1 package of 10 strips), 5534500005 (1 package of 20 strips)] were provided as a gift by Drink Safe Technologies, Inc. (Wellington, FL). Drink Safe Technologies Version 1.2 customized coasters (UPC lot: 5534500029) were purchased from Drink Safe Canada, Inc. (Calgary, AB, Canada). The following drugs were used in this study: GHB sodium (Cat# H3635, Sigma-Aldrich Chemical Company, Inc., St. Louis, MO, Health Canada authorization #10258.05.05); ketamine hydrochloride (Cat# K2753, Sigma Aldrich Canada Ltd., Oakville, ON, Canada); flunitrazepam (Cat# F9261, Sigma-Aldrich Chemical, Health Canada authorization # 10257.05.03); 1,4-butanediol (Cat#18960, Sigma-Aldrich Canada); and γ-butyrolactone (Cat# 20740, Sigma-Aldrich Canada). The Milli-Q purification system for ultra-pure water was from Millipore Canada, Ltd. (Mississauga, ON, Canada). The analytical balance (d = 0.1 mg, model BL120S) was from Sartorius (Edgewood, NV). Digital camera (5.0 megapixel resolution, images stored as JPEG 2592 × 1944) was a PowerShot A95 (Canon Canada, Mississauga, ON, Canada).

Methods

This project, which doubled as an educational event and an independent consumer product field-test, underwent expedited review by the University of Saskatchewan Biomedical Research Ethics Board. Product performance was assessed in the laboratory according to the manufacturer-defined protocol (17). The laboratory readings were performed within an 80-cm diameter workspace illuminated 555.4 ± 35.6 Lux by two overhead fixtures, 120 cm apart, each with two 32 W Sylvania E2y Octron fluorescent tubes. This lighting configuration provides a color rendering index (CRI) of 82 and a color temperature of 4100 Kelvin. Drug dilutions: 3.6339 g of GHB sodium salt yields 3.0 g of γ-hydroxybutyric free acid, which, dissolved in an 8-oz drink, will yield a 115.3 mmol/L concentration (the concentration used for testing the Drink Safe Technologies product both in the laboratory and also the resulting concentration after consumers added a standard 1000-μL aliquot of their beverage to a vial that happened to contain a concentrated GHB solution) and 1.1536 g of ketamine hydrochloride yields 1 g of ketamine, and a 16.8 mmol/L concentration equates to 1.0 g of the free base in an 8-oz drink (the concentration used for testing the Drink Safe Technologies product, both in the laboratory and as the resulting concentration after consumers added a standard 1000-μL aliquot of their beverage to a vial that happened to contain a concentrated ketamine solution). A 133 mmol/L 1,4-butanediol concentration, a 127 mmol/L γ-butyrolactone concentration, and a 0.1 mmol/L flunitraze-pam concentration were used in the laboratory to determine whether those agents reacted with either of the Drink Safe Technology Version 1.2 chromogenic reagents. Diagnostic efficacy was calculated using conventional two-way (Bayesian) analysis. Relative resolution times were compared by one way analysis of variance. Product evaluation in field settings allowed browsing participants to pipette an aliquot of their own drink into any of 101 coded vials containing authentic drug standards or pure water so as to yield the same concentrations of γ-hydroxybutyric acid or ketamine specified in the manufacturer-defined protocol, or blanks. Consumers were advised to proceed according to the directions printed on the product and to record their results on a card with a code sticker corresponding to the vial to which they had added an aliquot of their beverage. Diagnostic efficacy was calculated using a two-way analysis.

Results

In the laboratory, Drink Safe Technology Version 1.2 reliably detected the concentrations of γ-hydroxybutyrate and ketamine specified by the protocol proposed by the manufacturer. The product reliably excluded pure water samples. The volume spotted on the test area influenced drying time, which affected resolution time. Spotting 25-μL samples, the reactive color change from green to blue, denoting a positive test for γ-hydroxybutyrate, resolved in 21 ± 3 s; but a definitive color change from pink to blue to denote a positive test for ketamine required substantially more time to resolve (95% CI: 5.5, 6.5 min). Resolution times are somewhat subjective. Spotting larger volumes or a lack of familiarity for recognizing a positive or negative reaction are likely to delay a confident test determination (Figure 1, see page 11A). There were no significant differences in resolution times or accuracy between lots. About 12,000 of the Drink Safe Technologies customized coasters were purchased for the “It’s All About Awareness” campaign. A stack of 250 coasters was removed for use in this project from the partial supply remaining. We found that 0.48% of the stack was defective, having no reagent present on any of the four spots of the two test areas (Figure 2, see page 11A). Excluding defective coasters, the test efficiency in the laboratory following the manufacturer’s protocol was 100% (Table 1). Although 1,4-butanediol and γ-butyrolactone are biotransformed to GHB following ingestion, neither agent at the tested concentrations reacted with either of the Drink Safe Technology Version 1.2 test reagent spots to elicit a blue color change, nor did the test concentration of flunitrazepam result in a positive color change.

Of 101 paired field test results recorded by consumers, there were three instances in which paired tests of the same drink did not concur; this was perhaps due to uneven carryover of reagent between spots in one but not both test areas, but more likely due to applying different volumes of the drink sample to the two test areas, such that the areas did not resolve at the same rate. Noting that all five pairs of false-positive responses were associated with Bombay Sapphire London Dry Gin, the
potential for that spirit to react with the GHB reagent spot was confirmed in the laboratory to elicit a distinct but transient bluish color change. The proportion of vials that actually contained ketamine or GHB (i.e., prevalence) was 40.2%. On the basis of theoretical results in relation to results recorded by consumers, the test efficiency was 65.1%, sensitivity 50%, specificity 91.6%, and Likelihood Ratios: (+) 5.950, (-) 0.546 (Table II).

Discussion

The product performed substantially better in the laboratory than it did in the hands of consumers in the field. There is considerable potential for consumers to misinterpret a test result. This field test supported what Meyers and Almirall had predicted: that the time it takes for the color reaction to occur could hinder the proper interpretation of the test (18). They anticipated that if the reaction is expected within a few minutes, a person might prematurely interpret the test to be negative when, in reality, a positive reaction had not yet resolved. Compared to laboratory conditions, the lighting available to read a test strip in a typical nightclub would be less optimal. Lack of experience or visual reference to aid interpretation of a positive color change may further compromise the performance of Drink Safe Technology Version 1.2 in the hands of consumers. There were few false positives. The consequence of a false positive is to compel disposal of an unadulterated beverage. A false positive could also trigger false accusations. The greater probability for a largely university student population to falsely conclude a negative test on a spiked drink is a safety concern for those who would rely on this product to reduce their risk.

Table I. Performance Characteristics of Drink Safe Technologies Version 1.2 Test Strips and Coasters in the Laboratory following the Protocol Specified by the Manufacturer*

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Sensitivity = TP/(TP + FN) 0.997 0.968, 1.000  
Specificity = TN/(TN + FP) 0.997 0.968, 1.000  
Likelihood Ratio (+) = Sens / (1 − Spec)  
Likelihood Ratio (−) = (1 − Sens)/Spec  
Efficiency = (TP + TN)/(TP + TN + FP + FN) 100%  
95% CI

Table II. Performance Characteristics of Drink Safe Technologies Version 1.2 Custom Coasters in the Hands of Consumers in the Field*

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Specificity = TN/(TN + FP) 0.918 0.822, 0.964  
Likelihood Ratio (+) = Sens / (1 − Spec) 6.100  
Likelihood Ratio (−) = (1 − Sens)/Spec 0.545  
Efficiency = (TP + TN)/(TP + TN + FP + FN) 0.651 0.553, 0.748  
95% CI

* Pooled results from four different UPC lots comprising 146 units, 2 tests per unit, 1 card or coaster from each lot provided a wet and a dry control.

Implications for Clinical Practice

At best, the Drink Safe Technology Version 1.2 product is capable of detecting only 2 of the over 50 parent drugs listed by the Society of Forensic Toxicologists (SOFT) Drug-Facilitated Sexual Assault Committee website (19). Perhaps no technology will protect those who venture into nightclubs and private parties better than being aware of the risk, being selective about the places they party and the people with whom they party. There is safety in the company of conscientious friends who know what to watch for and can be trusted to watch out for each other. A supplementary role for the Drink Safe Technology Version 1.2 test kit to enhance personal safety is questionable.

Acknowledgments

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References


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