Transdermal Alcohol Monitors: Research, Applications, and Future Directions

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This research was supported by grant R01AA025969 to Catharine Fairbairn.

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Chapter to appear in D. Frings & I. Albery (Eds). *The Handbook of Alcohol Use and Abuse*. Elsevier

Chapter Summary

A reliable alcohol biosensor has the potential to increase awareness of problematic drinking and so reduce alcohol-related morbidity and mortality. At the present time, transdermal alcohol monitors—which measure alcohol consumption by assessing the alcohol content of sweat and insensible perspiration—represent the technology that offers the greatest promise for a wearable alcohol biosensor. Transdermal alcohol sensors are currently used mainly as abstinence monitors, in which capacity they have proven useful within the criminal justice system, alcohol intervention programs, and also within some basic alcohol research. However, the relationship between transdermal alcohol concentration (TAC), as measured by these devices, and continuous blood alcohol concentration (BAC) is complex, likely varying based on individual and also contextual factors and also involving some degree of lag. We provide a brief review of the human subjects studies conducted to date examining the BAC-TAC relationship, provide directions for future research, and also consider future applications of transdermal alcohol monitors.

Keywords: Alcohol, measurement, biosensors, transdermal, BAC

Developing a reliable alcohol biosensor has become a major public health priority (Leffingwell et al., 2013). Approximately 4.5% of the global burden of disease and injury is attributable to alcohol (WHO, 2018) with alcohol-related traffic accidents taking approximately 10,000 lives each year in the U.S. alone (National Highway Traffic Safety Administration, 2017). An alcohol biosensor could represent a tremendous advance towards helping people make informed decisions about their drinking and, ultimately, towards curbing alcohol-related mortality.

Devices for the objective quantification of behaviors have long been of interest to researchers and consumers across health domains (e.g., wearable exercise trackers such as 'fitbit'), but, due to alcohol's neurocognitive effects and also cultural conventions surrounding drinking, the need for a biosensor to measure drinking behavior has loomed particularly large. More specifically, heavy alcohol consumption is associated with profound memory and cognitive disruptions that impair awareness of consumption (Weissenborn & Duka, 2003; White, 2003). Further, standard drink sizes and quantities can vary widely so that the consumer is not always conscious of the quantity of alcohol consumed (Barnett, Wei, & Czachowski, 2009; Kerr, Greenfield, Tujague, & Brown, 2005; Kerr, Patterson, Koenen, & Greenfield, 2008). Finally, substantial societal stigma can accompany alcohol consumption for many individuals (e.g., women, underaged individuals, members of certain religious and ethnic groups) such that, even given an awareness of their own drinking practices, some might be reluctant to share information about their drinking with others (Davis, Thake, & Vilhena, 2010; George, Gournic, & McAfee, 1988; Zapolski, Pedersen, McCarthy, & Smith, 2014). Continuous objective monitoring of alcohol consumption is likely to prove a valuable tool for prevention and intervention, where awareness of problematic behavior has been identified as a key factor in behavioral change (C.

C. DiClemente & Prochaska, 1998; Miller, Zweben, DiClimente, & Rychtarik, 1994), and could also help us move towards a better understanding of drinking behaviors by improving the measurement of alcohol consumption in empirical research studies (Leffingwell et al., 2013). Thus, the development of a reliable alcohol biosensor could represent a major advance in our ability to understand, prevent, and treat problem drinking.

In pursuit of a reliable alcohol biosensor, researchers have explored a variety of different methods, each of which has presented with its own distinct set of strengths and limitations. Breathalyzers are a reliable method for estimating BAC that will doubtless continue to be valuable moving forward (Jones, 1996). But breathalyzers require a motivated episode by the user, may be inconvenient/embarrassing to use in some settings, and further can be contaminated by mouth alcohol when used in close proximity to drinking. Techniques assessing alcohol use indirectly through metabolites may involve a significant delay and/or be alcohol nonspecific (Dougherty et al., 2014; Swift, 2003). Finally, it is possible that future biosensors will have the capability of directly assessing alcohol in tissue using optics (e.g., Near-infrared spectroscopy). However, such devices currently take the form of large tabletop machines, and the sensors they require to detect alcohol put them out of the price range of most consumers. Currently, transdermal devices are the technology with the most promise for the continuous, noninvasive assessment of alcohol consumption.

Transdermal Alcohol Sensors

Three decades ago, scientists produced some of the first evidence that transdermally detected alcohol, measured by a device that rested on the surface of the skin, was highly correlated with Blood Alcohol Concentration (r's .94-.99; Giles et al., 1987; Swift, Martin, Swette, Laconti, & Kackley, 1992). Approximately 1% of alcohol consumed is diffused

transdermally in the form of sweat and insensible perspiration. So, similar to the manner in which a breathalyzer estimates BAC by measuring the quantity of alcohol in expired air, transdermal sensors estimate drinking by examining the content of alcohol in water vapor emitted from the skin's surface.

Several transdermal devices have been developed, and these devices vary substantially in their features and design. Currently, the most widely used transdermal device is the Secure Remote Alcohol Monitoring System (AMS SCRAM) transdermal bracelet. SCRAM is a relatively large/bulky device (164.4g/5.8oz) that is worn around the ankle, employing fuel cell technology to detect alcohol in insensible perspiration. SCRAM incorporates technology within the sensor itself, as well as within the sensor strap, that detects when the bracelet has been tampered with or removed—technology that is necessary given the SCRAM's use within criminal justice-involved populations (see below).

Transdermal sensors have also taken more compact forms. The WrisTAS—which was among the first of the transdermal monitors—is a relatively compact watch-like device warn around the wrist. SCRAM and WrisTAS are the devices that have most commonly been examined in research to date. More recent devices, all of which are currently under development, include the BACtrack Skyn, Milo Proof, and Quantac Tally. Similar in size/appearance to a fitbit, these devices feature smartphone/smartwatch integration, allowing users to examine real-time estimates of their blood alcohol concentration (BAC) directly from their phones/watches. However, although several transdermal monitors are under development and/or have been made available to researchers, none are currently available to consumers.

Research and Treatment Applications of Transdermal Monitors

A range of potential applications have been proposed for transdermal alcohol monitors.

Conversion factors for translating transdermal alcohol concentration (TAC) into precise estimates of BAC are still currently under development (see below), and so transdermal devices are used primarily as abstinence monitors (i.e., to detect whether any alcohol consumption has occurred), and not as a means for estimating the quantity of alcohol consumed or of quantifying BAC. Nonetheless, even as abstinence monitors, these sensors have proven useful across several domains, including within the criminal justice system, alcohol interventions, and also more basic alcohol research.

At the present time, the criminal justice system offers one of the largest markets for transdermal sensors. Individuals who have committed alcohol-related offenses (e.g., driving while intoxicated, etc.) may be assigned a transdermal alcohol monitor with the requirement that they abstain from alcohol as a condition of probation or parole. SCRAM is currently the most widely used transdermal monitor in such contexts. The SCRAM system issues "alcohol alerts," employing formulas that examine the precise rate of TAC increase and decrease to distinguish environmental alcohol (e.g., alcohol-based perfume applied to the skin) from ingested alcohol. SCRAM has been shown to detect approximately 57% of episodes of true alcohol consumption, with the rate of alcohol detection increasing with the amount of alcohol ingested, and research further indicates that rates of false positives using SCRAM are likely to be quite low (Marques & McKnight, 2009). Criminal justice applications of SCRAM have now spread across 6 countries and over 600,000 users (Alcohol Monitoring Services, 2018)

Transdermal monitors are also now beginning to be applied within intervention programs aimed at helping individuals with alcohol use disorder (AUD) achieve abstinence. Transdermal sensors have proven particularly useful within the context of contingency management programs, approaches in which patients have the opportunity to gain incentives—e.g., food items, gift

vouchers, or other items consistent with a drug-free lifestyle—in exchange for proof of abstinence from substances (Prendergast, Podus, Finney, Greenwell, & Roll, 2006). Contingency management interventions have proven highly effective when applied to illicit substances such as cocaine or opiates, but, in applications to AUD, some researchers have pointed to challenges associated with the measurement of alcohol biomarkers including a short half-life and, in the case of indirect alcohol metabolites, non-specificity to alcohol (Dougherty et al., 2014). The use of transdermal alcohol sensors within contingency management interventions appears to be effective, with initial research indicating that participants assigned to wear transdermal ankle monitors, and receiving incentives on the basis of transdermal data, significantly reduce their alcohol consumption compared with control participants (Barnett, 2015; Barnett, Tidey, Murphy, Swift, & Colby, 2011; Dougherty et al., 2014, 2015).

More recently, scientists have begun using transdermal alcohol sensors within basic alcohol research, including studies seeking to understand contexts and correlates of acute alcohol reinforcement as a means of understanding the roots of problematic drinking. For example, our team employed transdermal sensors to better understand the role of social factors in the emotional rewards that heavy drinkers gain from alcohol (Fairbairn et al., 2018). Participants in this study wore the SCRAM transdermal sensor in their daily lives over the course of a week while self-reporting on their mood and also taking photographs of their social surroundings. Since the relationship between TAC and BAC is thought to be moderated in part by individual difference factors, each participant in the study attended an alcohol-administration session, the data from which was used to convert that individual's TAC collected outside the laboratory into estimates of BAC (see below). Using these individualized equations to estimate the timing of alcohol episodes, we found that individuals gained more emotional reward from drinking alcohol

in social settings than when drinking alone and, further, that alcohol boosted mood to a greater extent when individuals drank among strangers vs. among friends. We also conducted analyses using calibrated transdermal sensors to show that estimated BAC's were significantly higher when individuals were drinking with strangers vs. friends although, given complexities associated with creating continuous estimates of BAC from transdermal data, these results should be considered preliminary.

In sum, use of transdermal sensors is increasing across domains, with the most widespread current application of these sensors being within the criminal justice system. Other more recent applications include contingency-management alcohol interventions and also basic alcohol research. The current primary function of transdermal sensors as abstinence monitors, rather than as devices permitting the continuous estimation of BAC, lends itself mainly to applications within non-voluntary populations and/or those whose motivation for abstention might vary over time (i.e., those in treatment for AUD). Studies are also being conducted that seek to convert transdermal alcohol data into continuous, real-time estimates of BAC—a field of research that, if successful in its aims, would greatly expand the range of potential applications for transdermal technology.

Converting TAC into Estimates of BAC

Unlike the relationship between BAC and the alcohol content of expired air, which can be characterized by a relatively straightforward conversion factor (Jones, 1996), the relationship between BAC and transdermal alcohol concentration (TAC) is believed to be complex (Anderson & Hlastala, 2006; Brown, 1985; Fairbairn, Rosen, Luczak, & Venerable, in press). In particular, researchers have pointed to the following factors that complicate the transdermal estimation of alcohol consumption: 1) The relationship between BAC and TAC may vary

depending on individual difference factors that covary with physical properties of the skin (e.g., gender; Hill-Kapturczak et al., 2015; Marques & McKnight, 2009). 2) The TAC-BAC relationship may vary depending on within-person/contextual factors (e.g., the temperature of the skin, the amount of sensible perspiration; Anderson & Hlastala, 2006); and finally 3) Some studies suggest TAC lags behind BAC by as much as 3-4 hours, a lag that would impact the utility of TAC as a proxy for BAC in real time (vs. as a record of past drinking; Swift, 2003).

Several groups have conducted research aimed at creating formulas that account for these complexities and so allow for the conversion of TAC into estimates of BAC. For example, studies conducted by researchers Dougherty and colleagues employ laboratory drinking paradigms and relatively straightforward regression models to predict BAC from TAC (Dougherty et al., 2012; Hill-Kapturczak et al., 2014, 2015). Note, however, that these regressions include parameters as predictors that are typically only known post-hoc (e.g., time to peak TAC) and so are not appropriate for the conversion of real time TAC data. Researchers Rosen and Luczak have created a sophisticated model for the estimation of BAC from TAC data via formulas reflecting the physiological process through which alcohol is transported from the blood through the skin and then measured by the transdermal sensor. While earlier applications of these formulas required individual calibration of transdermal sensors to each participant via a laboratory alcohol-administration (Luczak & Rosen, 2014)—thereby allowing for adjustment for individual differences (e.g., skin thickness; see Fairbairn et al., 2018 for example application)—recent work by this group indicates that estimates of BAC may be created using non-calibrated, generic models as well (Fairbairn et al., in press; Sirlanci et al., 2018). Various research groups are also exploring the utility of machine learning algorithms—methods that use artificial intelligence to learn complex patterns in data—for translating TAC into BAC estimates.

In sum, several statistical/computational frameworks have been proposed for the conversion of TAC into estimates of BAC, and so the field is not lacking potential analytic methods that might be used to convert data from transdermal monitors. While rich in analytic theory, however, the field has tended to be poor in data, as there has been a relative paucity of human subjects research that examines the TAC-BAC relationship using empirical methods.

Given the complex nature of the TAC-BAC relationship, studies employing large samples of participants as well as those examining the same participants across a range of contexts would be indicated. To date, to our knowledge, only 11 studies have examined TAC in relation to objectively assessed BAC (i.e., breathalyzer or direct blood/plasma measure). Of these studies, 7 have featured only laboratory methods (Davidson, Camara, & Swift, 1997; Dougherty et al., 2012; Giles et al., 1987; Hill-Kapturczak et al., 2014, 2015; Swift et al., 1992; Wang, Fridberg, Leeman, Cook, & Porges, in press) and 4 studies combined laboratory and ambulatory methods (Fairbairn et al., 2018; Luczak & Rosen, 2014; Marques & McKnight, 2009; Sakai, Mikulich-Gilbertson, Long, & Crowley, 2006). Of note, none of these studies were well powered to examine individual differences in the TAC-BAC relationship. The average sample size across all studies was 19, with the largest study involving just 48 participants (Fairbairn et al., 2018). Of the four studies to employ ambulatory methods (i.e., examining drinking in everyday contexts outside the lab), two focused on validating transdermal devices as abstinence monitors and so contain little information on the continuous TAC-BAC relationship (Marques & McKnight, 2009; Sakai et al., 2006) while a third featured a sample size of one expert user (Luczak & Rosen, 2014). Our own ambulatory study involved objective (breathalyzer) transdermal validation only in the lab, and not in everyday contexts (Fairbairn et al., 2018). None of these ambulatory studies have examined contextual factors (e.g., humidity level, degree of physical

exertion, etc.) as moderators of the BAC-TAC relationship.

While deficiencies in the size and quantity of prior studies (particularly ambulatory studies) is notable, also notable are the limitations of the transdermal devices employed in these studies. Studies conducted to date report lags between BAC and TAC varying from 30 minutes (Swift et al., 1992) to 270 minutes (Marques & McKnight, 2009), and correlation coefficients (*r*'s) ranging as low as .49 (Sakai et al., 2006) and as high as .99 (Giles et al., 1987). One possibility is that these results reflect true variability in the TAC-BAC relationship. However, a close look at this research suggest that at least some of this variation is likely attributable to limitations of the transdermal devices themselves. Three of these studies (Luczak & Rosen, 2014; Marques & McKnight, 2009; Swift et al., 1992) employed the WrisTAS sensor, a device that is notorious for nonresponse and extreme data noise, with the largest WrisTAS study yielding a remarkable 67% failure rate (Marques & McKnight, 2009). Of note, however, the device most commonly used in prior research is the SCRAM ankle bracelet (Dougherty et al., 2012; Fairbairn et al., 2018; Hill-Kapturczak et al., 2014, 2015; Marques & McKnight, 2009; Sakai et al., 2006). The ankle positioning of the SCRAM device is ideal for the minimization of tampering and removal among criminal-justice populations but may interfere with the measurement of BAC transdermally. Specifically, the precise positioning of the transdermal device relative to the skin has been identified as an important factor impacting the transdermal detection of alcohol (Anderson & Hlastala, 2006), and the ankle positioning of the SCRAM might introduce variability into this position (e.g., SCRAM might slip from sitting snug against the calf to hanging loose around the ankle as the user walks). Further, the relationship between TAC and BAC can vary significantly depending on the positioning of the TAC device on the body—e.g., measurement from forearm vs. forehead produce different TAC-BAC relationships

(Swift, 2000). Importantly, the notion that TAC lags behind BAC by many hours is derived primarily from studies employing the SCRAM ankle bracelet (e.g., 130 min lag in Fairbairn et al., 2018; 129 min lag in Hill-Kapturczak et al., 2015; 150 min lag in Sakai et al., 2006), with wrist-worn devices typically estimating 50%, or less, the delay of ankle worn devices (e.g., 30 min lag in Swift et al., 1992; average 65 min lag in Wang et al., in press)—see also Marques and McKnight (2009) for research capturing this lag differential within a single participant sample.

In sum, the relationship between TAC and BAC is complex, likely varying based on contextual and individual factors and also involving some degree of lag. Although a number of mathematical models have been developed to characterize the relationship between BAC and TAC, human subject studies, particularly those examining transdermal sensors in everyday contexts, have been scarce and underpowered, and the devices examined in these studies (SCRAM and WrisTAS) have been suboptimal. As a result, the precise relationship between transdermal alcohol concentration and blood alcohol concentration is unknown. Further, it is possible that the extent of the complexity of this relationship may have been overestimated on the basis of noisy and otherwise suboptimal transdermal monitoring devices employed in extant human subjects research.

Future Research Directions and Applications

Moving forward, to produce a transdermal device capable of creating precise estimates of BAC, the field is in need of human subject research that is improved across several different areas. In particular, given that the relationship between TAC and BAC is theorized to vary based on individual-difference factors, research with much larger samples of participants would be required to create BAC estimates with a high likelihood of generalizing across people. Further, in light of the potential influence of contextual factors on the transdermal measurement of BAC

(e.g., humidity, temperature, etc), more research examining individuals across contexts is needed, including research in everyday drinking settings and research that attempts to explicitly measure and/or manipulate contextual factors. Finally, given the limitations of prior devices, transdermal devices for use in research that are better suited to producing precise estimates of BAC in near real time would be required. It is possible that some of the wrist-worn smartphone-integrated devices currently under development would serve this purpose, although none are currently widely available to researchers.

Current transdermal technology does appear to serve the purpose of monitoring whether or not any alcohol consumption is taking place, a purpose that serves key functions in criminal justice settings as well as abstinence-oriented alcohol interventions. Such abstinence-monitoring devices might also ultimately be useful to researchers seeking to understand frequency of drinking across longer spans of time. However, since individuals' awareness/memory for abstinence vs. non-abstinence tends to be relatively good, at least over brief time intervals, such applications are likely to be specifically useful among populations who are unmotivated and/or sporadically motivated to accurately report on their alcohol consumption. In other words, among consistently motivated, voluntary populations, abstinence monitors have limited utility above and beyond self-report.

In contrast, were alcohol biosensors to be developed with the capability of producing relatively precise estimates of BAC, a range of additional applications for these devices seem plausible. In the realm of prevention, a discreet, wearable alcohol monitor could prove attractive to individuals interested in monitoring and improving their overall health and wellbeing, as has been the case with other health biosensors such as the fitbit. This widespread use of alcohol monitoring devices among social drinkers might stem the development of alcohol use disorder as

well as various medical disorders associated with drinking (Centers for Disease Control and Prevention, 2010). In the realm of motor vehicle safety, continuous passive monitoring of BAC might reduce drunk driving fatalities, which are currently estimated at 10,000 annually (National Highway Traffic Safety Administration, 2017). Users might link transdermal sensors to automated prompts or alarms which would indicate when BAC is approaching unsafe levels, thus potentially reducing alcohol-related accidents and injuries. They might also be programmed to send alerts to notify a designated driver or ride-sharing service. In the medical realm, interventions for some of the U.S.'s most common health conditions (i.e., diabetes, high blood pressure) require that patients moderate their alcohol intake, while not necessarily requiring abstinence (Howard, Arnsten, & Gourevitch, 2004; Puddey & Beilin, 2006). A continuous BAC monitor could help patients maintain healthy levels of alcohol consumption. The information provided by these monitors might also be useful to their healthcare providers in assessment and intervention.

In the clinical realm, transdermal sensors could be integrated into the assessment phase of alcohol interventions, thereby increasing motivation for change at intake by providing patients with objective information about their current drinking patterns (Miller et al., 1994; Vasilaki, Hosier, & Cox, 2006). Furthermore, within moderation management and harm reduction approaches to treating alcohol problems, transdermal sensors might be used as a means by which to track alcohol consumption and aid in the reduction of unsafe drinking practices (Marlatt & Witkiewitz, 2002). Finally, in the realm of research, an alcohol biosensor could revolutionize alcohol studies by providing an objective means of tracking drinking over time, thus improving science aimed at examining the causes and correlates of alcohol consumption, as well as research evaluating the success of intervention and prevention programs.

Conclusions

In sum, transdermal sensors show promise for the discreet, continuous assessment of alcohol consumption in real time. Currently, these devices are well validated for use as abstinence monitors among populations likely to produce unreliable reports of drinking episodes. The human subjects literature examining the relationship between TAC and BAC is currently small, underpowered, and inadequate to modelling contextual effects, and so continuous estimates of BAC from transdermal data may be imprecise and applications of transdermal sensors are somewhat limited. However, with improved human subjects research and a more precise understanding of the TAC-BAC relationship, transdermal sensors might serve health needs across a variety of domains, including aiding prevention of alcohol-related disorders, improving outcomes in harm reduction alcohol interventions, refining outcome assessment in alcohol research, and reducing the number of alcohol-related motor vehicle fatalities.

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