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Registered Report

Validation of transdermal alcohol concentration data collected using wearable alcohol monitors: A systematic review and meta-analysis

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ABSTRACT

Objective: To evaluate the diagnostic accuracy of transdermal alcohol content (TAC) data (*i.e.* index test) collected with wearable alcohol monitors for assessment of alcohol use or any other alcohol related outcome (*e.g.*, excessive alcohol use) among adults 18 and older.

Methods: We will systematically search MEDLINE, EMBASE, PsycINFO, and the Social Sciences Citation Index (SSCI, Web of Science) for TAC validation studies. The reference standards for this systematic review study are alcohol use data collected through self-reports, breathalyzers, or blood samples. If enough studies are available to conduct a meta-analysis, we will use a hierarchical regression approach to pool the results and obtain summary point estimates.

1. Background

Excessive alcohol use is a modifiable risk factor responsible for various health conditions and premature deaths (Danaei et al., 2009). Alcoholic liver disease, liver cirrhosis, alcohol use disorder, alcohol poisoning, alcohol abuse, motor-vehicle traffic crashes, suicide, homicide, fall injuries, risky sexual behaviors, and sexual assaults are only some of the harmful effects linked to excessive alcohol use (Centers for Disease Control and Prevention [CDC], 2013; CDC, 2018; Ullman, 2003). Annually, 79,000 deaths are attributable to excessive alcohol use in the United States (CDC, 2013; 2018). One in ten deaths in working-age adults is due to excessive alcohol use (Stahre et al., 2014). It is estimated that the annual average for years of potential life lost because of excessive alcohol use is 2,763,055 (CDC, 2013). The economic burden of this public health issue is also colossal; in 2010, excessive alcohol drinking cost was $249.0 billion in the United States (Sacks et al., 2015). Implementing effective prevention interventions can help to reduce excessive alcohol drinking and its harmful effects (Stahre et al., 2014).

Alcohol use data collected for research or public health programming has relied mostly on self-report (Leffingwell et al., 2013). However, this approach may not result in high quality data which can influence the outcomes and efficacy of intervention programs. Self-reported alcohol use data is prone to measurement error, such as social desirability and recall bias, specifically due to the fact that excessive alcohol consumption, e.g. binge drinking, causes impaired cognitive function (Weissenborn and Duka, 2003). Hence, self-reported data might misclassify binge drinking and heavy drinking cases (Leffingwell et al., 2013). Additionally, most self-reported data are not in real-time which rules out use of interventions that respond to real-time alcohol use.

Since their development in 1950s (Borkenstein and Smith, 1961), breathalyzers have been a reliable source for law enforcement practices. Additionally, breathalyzers have been used in research for collecting alcohol use data (Alessi and Petry, 2013; Klimas et al., 2018) and development of different intervention programs and alcohol contingency management treatments (Hämäläinen et al., 2018; Koffarnus et al., 2018). Breathalyzers collect real-time, objective alcohol use data through measurement of breath alcohol concentration (BrAC) and thus, unlike self-reports, are not susceptible to recall bias. Nonetheless, the data that breathalyzers collect are discontinuous and highly susceptible

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to measurement errors caused by shallow breathing and alcohol in the mouth (Luczak and Rosen, 2014). Additionally, since breathalyzers are active, not passive, data collection tools, there is an increased chance of reactivity/Hawthorne effect (McCarney et al., 2007).

In 1936, scientists found that a small proportion of ingested alcohol is excreted through skin (Nyman and Palmlöv, 1936). This transdermal alcohol content (TAC) correlates with blood alcohol concentration (BAC) (Nyman and Palmlöv, 1936; Swift, 2003). Wearable alcohol monitors can collect TAC data to estimate the BAC in a non-invasive, unobtrusive, passive, real-time, and objective approach (Greenfield et al., 2014; Leffingwell et al., 2013), with the potential to minimize the biases from self-report and breathalyzers discussed above.

The first commercial wearable alcohol monitor to measure TAC was produced in 1997, Secure Continuous Remote Alcohol Monitoring (SCRAM) anklet by Alcohol Monitoring Systems, Inc (SCRAM Systems, 2020). SCRAM anklets are large and heavy anklet alcohol monitors that collect quasi-continuous alcohol use data. Its main purpose is for law and sobriety enforcement (Wang et al., 2019). The first wrist-worn alcohol monitor was introduced in 1990s, WrisTAS by Giner lab (Swift and Swette, 1992; Wang et al., 2019). This device uses a fuel cell-based sensor which generates detectable electric current in the presence of alcohol (Wang et al., 2019). The failure rate of WrisTAS has been found to be high (Greenfield et al., 2014; Wang et al., 2019). In recent years, prototypes of novel and even smaller sized wrist-worn alcohol monitors have become available that can potentially improve on the disadvantages associated with previous models. These prototypes are: 1. BACtrack Skyn (BACtrack company, 2019) that also uses a fuel cell-based sensor, and 2. PROOF by Milo Sensors, Inc (Milo Sensors Inc., 2020) which uses enzyme-based sensors (Wang et al., 2019). A growing body of validation studies have been conducted to evaluate the reliability of the TAC data that wearable alcohol monitors produce (Davidson et al., 1997; Dougherty et al., 2012; Fairbairn and Kang, 2019; Fairbairn et al., 2019; Giles et al., 1987; Hill-Kapturczak et al., 2015; Hill-Kapturczak et al., 2014; Karns-Wright et al., 2018, 2017; Marques and McKnight, 2009; Roache et al., 2019, 2015; Sakai et al., 2006; Simons et al., 2015; Swift et al., 1992; Wang et al., 2019).

However, to the best of our knowledge, no systematic review has been published to identify, assess, and summarize the findings of these individual validation studies. A systematic review would advance our understanding of TAC data accuracy and the ability of wearable alcohol monitors to detect alcohol use. Validation studies have used different study settings, designs, and benchmarks to evaluate the accuracy of TAC data. Most studies used BrAC data (Fairbairn and Kang, 2019; Karns--Wright et al., 2017; Wang et al., 2019), some used self-reported alcohol use data (Karns-Wright et al., 2018; Simons et al., 2015), and a few older studies collected BAC data as benchmarks to assess TAC data (Davidson et al., 1997; Giles et al., 1987). Further, these validation studies used different alcohol monitor devices/brands to collect TAC data, e.g. SCRAM (Roache et al., 2019), Skyn (Fairbairn and Kang, 2019), etc. Lastly, some of these studies also developed models to predict BAC/BrAC using TAC data (Dougherty et al., 2015; Li et al., 2019; Sirlanci et al., 2019; Zheng Dai et al., 2016).

1.1. Objectives

The objectives of this systematic review are to 1) identify the validation studies on TAC data (i.e. index test) among adults, 2) evaluate methodological quality of the studies, and 3) synthesize the estimates of validity (i.e. sensitivity, specificity, and other similar estimates) across the existing validation studies.

2. Methods

2.1. Protocol and registration

We follow the Preferred Reporting Items for a Systematic Review and Meta-analysis of Diagnostic Test Accuracy Studies (PRISMA-DAT) to report our findings (McInnes et al., 2018). We will register our study protocol to the International Prospective Register of Systematic Reviews (PROSPERO) and include the registration number in the final version of the manuscript. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

2.2. Information sources and search strategy

A literature review will be conducted starting late-September 2020. We will search the following bibliographic databases; MEDLINE (PubMed), EMBASE, PsycINFO, and the Social Sciences Citation Index (SSCI, Web of Science). Studies after 1936 (the year when scientists learned about TAC (Nyman and Palmlöv, 1936)) will be assessed for inclusion in the systematic review. We will use backward and forward citation searching techniques (on the included studies) to identify any additional eligible studies. We will consult a health sciences librarian to develop and refine the search query terms. Various combinations of two groups of terms will be included: 1) alcohol use measurement, and 2) validation studies (Table 1 shows some of the potential search terms). We also will filter the search results to only include studies on humans and in English language.

2.3. Selection of studies

We will use Covidence, a web-based software platform, for identification of eligible studies, full text review, data extraction, and reconciliation of any conflict(s) (Covidence systematic review software, Veritas Health Innovation, 2020 Melbourne, Australia. Available at www.covidence.org). Databases' search results will be imported to Covidence and two reviewers (SK and ML), independently, will perform an initial screening based on the title and abstract. Next, we will obtain the full text for studies that passed the screening phase and the reviewers will assess the full text for inclusion/exclusion criteria, independently. An independent researcher (MR, JA, and RG) will reconcile the disagreements between the two reviewers.

2.4. Eligibility criteria

The index test is the transdermal alcohol content (TAC) data collected by use of any wearable alcohol monitor. All types of published validation studies on the index test in English language that were conducted in lab or field settings after 1936 are eligible for inclusion in the current study. Only human studies on adults aged 18 or older will be included. Three reference standards will be used; 1) Alcohol use data collected by breathalyzers (BrAC), 2) BAC data collected using blood

Table 1
Preliminary search sets and search words. A combination of two sets of search terms will be searched (#1 AND #2).

Search sets	Search words
#1 Alcohol Use Measurement	alcohol use measurement OR transdermal alcohol content OR transdermal alcohol concentration OR TAC OR alcohol monitor OR transdermal alcohol monitor OR secure continuous remote alcohol monitoring OR SCRAM OR alcohol monitoring systems OR WrisTAS OR Giner lab OR BACtrack Skyn OR Quantac Tally OR Quantac Company OR Milo Sensors OR blood alcohol concentration OR breath alcohol concentration OR alcohol use self-report OR alcohol use self-assessment OR substance abuse detection OR wearable biosensors
#2 Validation Studies	validation study OR true positive rate OR TPR OR sensitivity OR probability of detection OR specificity OR SPC OR selectivity OR true negative rate OR TNR OR F1 score OR accuracy OR ACC OR correlation OR cross-correlation OR Pearson's correlation OR Correspondence OR diagnostic odds ratio OR true positive OR true negative OR false positive OR false negative

sample, and 3) Alcohol use data collected through surveys (self-reports). The eligible validation studies may target alcohol use, or any alcohol use related condition. Studies will be excluded if they use other reference standards.

2.4.1. Diagnostic accuracy measures

For studies to be included in the meta-analysis, reporting of at least one of the following diagnostic accuracy measures is required; accuracy, sensitivity, specificity, positive predictive value, negative predictive value, F_1 score, counts of false/true positive/negative values, or any linear correlation estimator. The unit of assessment can be alcohol drinking event or number of drinks in a drinking event.

2.5. Data collection and extraction

We plan to extract the following data from included studies; authors and year of publication, country, sample size, mean/median age, proportion of male participants, proportion of white participants, mean/median BMI, alcohol monitor used for collecting the TAC data, study setting (lab vs. natural drinking environment), reference test (BrAC, BAC, self-report), modeling and predictors (i.e. predicting reference test based on index test data), correlation estimates, diagnostic accuracy measure reported along with information on true positive, true negative, false positive, and false negative count data.

We will use Covidence for data extraction. We will develop a form for data extraction (including procedures for linking the multiple reports of the same study) and pilot it before the data extraction phase. Using the piloted form, two reviewers will independently extract all relevant data from included studies. If the above-mentioned data are not included in the study, we will contact the corresponding author by email up to three times to ask for the missing information.

2.6. Risk of bias and applicability

Two reviewers will use QUADAS-2 to assess the risk of bias and applicability of the studies (Whiting et al., 2011). This tool has four domains: patient selection, index test, reference test, and flow and timing. We will assess each of these domains for risk of bias and applicability.

2.6.1. Synthesis of results

To draw a conclusion from the included studies we will develop a synthesis of study characteristics. Each study will be reviewed qualitatively, and the findings will be summarized in a narrative synthesis of the data. We will make a forest plot for sensitivity and specificity of included studies.

2.7. Meta-analysis

A minimum of four studies is required to conduct a meta-analysis. We will potentially conduct a statistical synthesis of findings. If enough data are available to conduct a meta-analysis, we will use a hierarchical regression approach to pool the results and obtain summary point estimates and 95 % confidence intervals (Rutter and Gatsonis, 2001). Additionally, if there are enough studies, we will include characteristics of studies that could influence the summary estimate (e.g., BMI or gender).

2.8. Timeline

If registration review is successful at stage 1, we anticipate completing the study and submitting the manuscript for stage 2 peer review in five months. However, if meta-analysis is possible, we anticipate that the results will be ready for submission in six months.

Role of funding source

Nothing declared.

Contributors

S. Kianersi developed the study plan and wrote the first draft of the manuscript (registered report), C. Ludema contributed to study design, and manuscript preparation, M. Rosenberg contributed to study design, and manuscript preparation. All authors have approved the final article and will be involved in completing the systematic review and meta-analysis.

Declaration of Competing Interest

The authors report no declarations of interest.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.drugalcdep.2020.108304.

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