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Alcohol Consumption for People Admitted in French Emergency Departments: A Protocol for a Multi-Center Cluster Trial

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Abstract

Background

According to a 2014 report by the World Health Organization, the highest alcohol consumption levels per capita continue to be found in the developed world, particularly in the European region. Drinking alcohol does not only lead to alcohol dependence; it also be linked to a higher risk for acute medical and surgical events. In France, recent data show that alcohol consumption levels in the general population are important and have remained relatively stable since 2010. In the Emergency Department population, few French data are available, while studies conducted across the Atlantic show that patients admitted into emergency rooms are reported to have high levels of alcohol consumption. Emergency Departments are an important location for the identification and early intervention of issues related to alcohol consumption. Therefore, the aim of this study is to carry out an epidemiological picture of alcohol consumption and search for indicators of harmful alcohol use in patients in the French emergency rooms of the Rhône-Alpes-Auvergne interregion.

Methods and Analysis

This observational, and descriptive and randomized clinical study on human beings will consists of a collection of clinical variables on all patients that will be admitted to the Emergency Departments of the RAA Rhône-Alpes-Auvergne interregion aged of (16 years or older) and who will be agree to participate to the study. It will include one visit where the patient will respond to three auto-administrating screening tests on his or her alcohol consumption: Alcohol Use Disorders Identification Test – C (AUDIT C), Cut-down, Annoyed, Guilty, Eye-opener test (CAGE) and the Rapid Alcohol Problems Screen – Quantity Frequency test (RAPS4 – QF). Similarly, they will answer two self-administering questionnaires on socio-demographic and emergency data.

Key words:

Substance misuse; Epidemiology; Public Health; Accident and emergency medicine; France Lander; Self-questionnaire

Introduction

According to a new report published by the World Health Organization (WHO) in May 2014 in Geneva, around the world, people aged 15 or older consume, on average, 6.2 liters of pure alcohol per year. But it is in Europe that alcohol consumption per person is the most prevalent. In 2012, harmful use of alcohol was responsible for 3.3 million deaths worldwide. Drinking alcohol can not only lead to alcohol dependence, but it also increases the risk of developing more than 200 diseases, including liver cirrhosis and some cancers [1].

In France, recent data from a national epidemiological study [2] show that in the general population in 2014, 86% of persons aged 15–75 said they had drunk alcohol in the last 12 months, an estimated average weekly consumption of 5.5 drinks. Almost half of 15–75-year-olds had consumed alcohol at least once a week, and one in 10 drank it daily. These consumption levels were relatively stable in 2010, except

for the daily alcohol consumption, which decreased from 11% to 10%, in line with a trend that has been observed over several decades. Regarding clinical populations, i.e. those hospitalized in medical services or surgery, prevalence of misuse was higher. Reynaud et al.[3] found, in a study of about 10,000 patients hospitalized in medicine, surgery, obstetrics and gynecology and psychiatry departments, on a given day in Auvergne, the prevalence of patients with excessive alcohol consumption and/or possibly alcohol dependence was approximately 20% using the CAGE screening questionnaire [4]. Half of these patients has been classified as having alcohol dependence. Men has been more frequently classified as experiencing alcohol-related issues (34%) than women (8%).

The Emergency Departments (ED) will constitutes a privileged center of care for the identification, early intervention and orientation of patients suffering from alcohol-related issues, especially when the emergency admission is related to somatic or surgical problem [5]. Regarding (ED) in France and despite little available data, 16.5% to 37.5% of all injuries seen by emergency room staff have been reported to be linked to drinking [6,7]. An older work in United States has observed that 40% of patients entering the ED had consumed alcohol within the six hours before admission [8]. Among these patients, over

half have presented pathological consumption of alcohol (risk use, abuse or dependence as defined by the DSM IV–TR). Most studies in the ED have been conducted across the Atlantic [9-12] and highlight several key points. First, patients admitted into the emergency rooms have reported, more often, high levels of alcohol consumption compared to patients in the general population (48% of patients admitted to ED would be classified as being an alcohol abuser and/or alcohol dependent, or may present with an "alcohol use disorder" according to the DSM – 5 [13]). Possible reasons for this high figure are that the ED is a frontline access to care for people without resources compared to the general population, and those without financial resources for non-ED medical care are also often affected by alcohol problems [14]. Finally, excessive alcohol consumption may be linked to a higher risk for acute medical and surgical events, not only in situations of alcohol abuse and dependence, but also in purely quantitative misuse [15].

However, there are few epidemiological data on alcohol impact in French EDs, especially in specific sensitive regions like Auvergne and Rhône-Alpes, which have been identified as having a disproportionately higher prevalence of adult drunkenness compared to other regions [16].

Objectives

The main objective is to carry out an epidemiological picture of alcohol consumption in the emergency room of the Rhône-Alpes-Auvergne (RAA) interregion, particularly through the occurrence of specific acute medical events and binge drinking patterns. The secondary objective is to search for indicators of harmful alcohol use in patients in the emergency room used for this inter region.

Methods and Analysis

Study Design

This is a naturalistic, observational, descriptive and clinical study on human beings. It consists of a collection of clinical variables on all patients admitted in the EDs of the RAA inter region (greater than 3000 accesses per month), namely those of the University Hospital of Clermont-Ferrand, Saint-Etienne, Grenoble, Edouard Herriot hospital and north hospital group in the Lyon and Chambery hospitals. This region consists of several cities, representing a panel of about eight million inhabitants living in urban and rural areas. It is also the second economic zone of France. An alternative method of cluster sampling will be used; we define the target population as all patients admitted to the emergency department within the inter region demarcated by well-defined limits of territory for the health inter region boundaries.

Study Participants

The proposed study participants (male and female) will include those aged 16 years or older who agree to participate in the study upon admission to the ED in one of the six hospitals named above. Eligible patients with somatic (serious life-threatening emergencies), psychiatric and cognitive states or those having a language barrier preventing them from completing the questionnaires will be excluded.

Sample Size

The number of accesses is estimated at 120 patients per day per institution for the Clermont-Ferrand, Grenoble, Lyon and Saint-Etienne hospitals and about 70 per day for the Chambery hospital. The number of patients and the rationale of the study have been estimated on the basis of the ED's activity during the previous year. With 20,000 patients coming to the ED in the RAA inter region, and because of eligible criteria and refusal to participate [17], we have estimated the patient recruitment potential as 11,750.

Recruitment and Data Collection

The cluster random sampling design and area sampling method will be used to conduct this study. Clusters have been defined along geographic areas. The month of recruiting will be randomly assigned, and all patients admitted in each ED unit over the course of one month will be defined as a single cluster) [18,19].

During the inclusion of an emergency arrival at the period corresponding to the investigated area, study participation will be suggested to the patients. Patients will then be fully informed regarding the objectives and constraints of the study, potential risks, necessary surveillance and security measures, their rights to refuse to participate in the study and the possibility of withdrawal at any time. This information will be available on the form they are given. The study includes one visit per person, and participants will be asked questions related to socio-demographic data and the reason for presenting to the ED (patient admission pattern), as well as questions on frequency and average volume of alcohol consumption. The participants will be given three auto-administrating screening tests – AUDIT C, CAGE, and the RAPS4 – QF. Data collection will be performed by a medical team, who will also determine the number of admissions to the emergency unit over the previous two months, as well as reasons for admission to the ED.

Study Measures

Sociodemographic and General Data

Data collected on sociodemographic factors will include age, sex, marital status, number of children, educational level, and socioeconomic status. Reasons the participants came to the ED will also be collected.

Alcohol Consumption

Most short questionnaires used daily by clinicians in the ED are based on a qualitative approach. Using qualitative questionnaires to assess presenting disorders leads to an underestimation of certain problematic consumption behaviors. Using a quantitative approach for investigating alcohol consumption, according to Smith [15], would in turn multiply by 10 the number of patients identified in the ED as having a drinking problem. Thus, in this study, qualitative and quantitative/qualitative self-administering surveys will be used to assess alcohol consumption (average volume of alcohol consumption and pattern of drinking).

AUDIT C (Alcohol Use Disorders Identification Test – Consumption) [20]

The AUDIT C is a modified version of the AUDIT instrument [21] developed by the World Health Organization and validated in general and specific populations to identify problematic drinkers in primary care settings. It is a three-item alcohol screen that can help to identify persons who are hazardous drinkers or who have active alcohol use disorders (with a cut-off ≥4 for men [20] and 3 for women [22]).

CAGE [4]

The French translation of CAGE (Cut-off, Annoyed, Guilty, Eye-opener), proposed by Ewing [4], which includes four issues resolutely oriented towards the search for alcohol misuse, explores the whole life of the person: (1) Have you ever felt you should cut down on your drinking? (2) Have people annoyed you about your drinking? (3) Have you ever felt bad or guilty about your drinking? (4) Have you ever had a drink first thing in the morning to steady your nerves or get rid of a hangover (Eye opener)? Two or more positive answers is a common cut-off point for detecting alcoholism.

RAPS4 – QF [23]

Cherpitel et al. [23] developed the RAPS4 as a qualitative screening test for alcohol misuse. This test presents psychometric performance that is identical to the CAGE for alcohol dependence screening, with slightly higher data regarding the detection of alcohol abuse in the ED [24]. It consists of the following four items: (1) During the past year, have you had a feeling of guilt or remorse after drinking? (Remorse), (2) During the past year, has a friend or family member ever told you about things you said or did while you were drinking that you could not remember? (Amnesia, also called Blackouts), (3) During the past year, have you failed to do what was normally expected from you because of drinking? (Perform), and (4) Do you sometimes take a drink in the morning, when you first get up? (Starter, also called Eye opener). The RAPS4 – QF includes the RAPS4 items plus two additional questions: (a) During the past year, have you had five or more drinks on at least one occasion? (Quantity) and (b) During the past year, did you drink as often as once a month? (Frequency) . A positive response on any one of the four RAPS4 items or both of the quantity–frequency items is considered positive on the RAPS4 – QF for alcohol abuse or dependence. The RAPS4 and RAPS4 – QF were translated into French using the well-recognized forward–backward translation technique [25].

Supplementary Questions

Since a secondary purpose is to explore binge and moderate drinking, two other questions referring to the definition of each group will be included. The latest consensus on moderate drinking places this point at no more than one to two drinks per day for men, and no more than one drink per day for women [26]. Regarding binge drinking, the American National Institute on Alcohol Abuse and Alcoholism (NIAAA) defines binge drinking as a pattern of drinking at least four drinks for women and five drinks for men over the course of about two hours. To assess for this, questions regarding the number of drinks over the course of two hours, as well as its frequency over the previous two months, will be asked.

The choice for using these self-administering questionnaires is justified by the conduction of a study involving data collection for a population on-site over a short time. Our desire to be exhaustive leads us to choose a simple and rapid method, i.e. short questionnaires for patients that have good feasibility in the ED. The choice of this type of questionnaire is also made due to the difficulty of investigating using interviews in the ED, which is often overcrowded with patients and a very large number of practitioners.

"Emergency Department" questionnaire

This questionnaire asks about the number of admissions over the previous two months and the reasons for admission. The London St.

Mary Hospital team provides arguments for the existence of target populations in the hospital with recurrent admission patterns and who have pathological alcohol consumption patterns [14]. We propose these 10 reasons for admission: falls, discomfort, assault, palpitations and chest tightness, head injuries, digestive complaints, psychiatric disorders, carelessness, multiple admissions, and suffering of unknown or imprecise origin, as well as an open question termed 'other reason'. Multiple choices are also possible.

Procedure and Timeframe of the Study

Each ED will have a distribution and collection point for all of the questionnaires, and this point will be available to each patient admitted to the emergency department during the specified period (four weeks, 24-hour-a-day, seven-days-a-week). Self-administered questionnaires will be distributed during the admission of patients who agree to participate in the study, and completing the surveys is estimated to take about five minutes. Prior to each inclusion, the patient will be informed of the study and will be included if they raise no objection to participation and the processing of non-personal data. The study will take into account a single visit. Self-administered questionnaires will be given to each patient upon admission and will be recovered by the health care team before departure. The surveys will include the reasons for admission and recurrent hospitalizations over the previous two months.

Statistical Methods

The primary outcome of this study is the determination of the level of alcohol consumption, as measured using the AUDIT C. We will also describe heavy (related to question 3 from AUDIT C), moderate and binge drinkers. Excessive drinking (CAGE cut-off score) and alcohol abuse (RAPS4) will also be studied. In order to investigate differences in sociodemographic variables, ANOVAs and Chi-square tests will be used. The results from young consumers (16–25 years) will be assessed separately because the expected prevalence of binge drinking is higher in this population.

A multivariate logistic regression analysis will be used to assess the risk of having one of the 10 above-described reasons for admission [14] related to alcohol consumption and will be adjusted for socio-demographic variables. Variables with $p < 0.20$ in a bivariate analysis will be included in this model, using a stepwise method to control for confounding factors.

Continuous variables will be described as means and standard deviations or medians and interquartile ranges. Categorical variables will be described using absolute and relative frequencies. The level of significance will be set at $p \leq 0.05$.

Discussion

The primary purpose of this multi-center study is to define an epidemiological picture of alcohol consumption in the emergency room of the RAA interregion and to identify recurring patterns intake in patients' abuse or alcohol dependence. Defining a specific profile of patients with alcohol dependence may raise the awareness of ED teams. Indeed, when medical aid is offered and an alcohol problem is identified, alcohol-specific care happens more frequently during the six months post-admission to the ED compared to during the previous 12 months [27, 28]. In addition, Cherpitel [29] suggests that the ED is one of the key entry points in the care path for people with alcohol misuse, provided that the disorder is identified. Brief interventions in these

services would lead to specialist consultations during the week for half of the patients, possibly reducing consumption in a quarter of the cases [29].

Most short questionnaires used daily by clinicians in the ED are based on a qualitative approach, and, in particular, address the psychological disorders and social damage caused by consumption. One example is the RAPS4 questionnaire [23]. The approach of assessing alcohol dependence through damage caused by alcohol meets the previous definition provided in the DSM–IV [30]. However, qualitative tools underestimate some problematic consumption behaviors, like drinking heavily on a frequent basis or binge drinking [31–33]. In the same way, qualitative tests, such as the CAGE or RAPS4 [34], present lower interest in screening for abuse and are poor at detecting at-risk use. Combined quantitative and qualitative tests, like the RAPS4 – QF, will increase the sensitivity of detection of the misuser or at-risk user [35], as well as for whom specific intervention for drinking problems can be offered, especially in the framework of the ED.

In addition, because emergency care services have a very high number of daily accesses, screening patients for alcohol-related struggles can be difficult. This study will show whether qualitative–quantitative screening tests are suitable for such services.

Competing Interest

Ingrid de Chazeron received honoraria for consultancy by Lundbeck Laboratory. F. Carpentier received financial support from Sanofi-Aventis for meetings for Emergency Medicine and from the Emergency Medicine French Society (SFMU) for the healthcare institution network of audits. Maurice Dematteis received honoraria and travel reimbursements for conferences by Merck/Serono and Lundbeck Laboratories, honoraria for consultancy by Lundbeck and D&A Pharma Laboratories, and participated as a co-investigator in the multicenter investigational drug studies (ALPADIR, ALPADE for baclofen) of Ethypharm Laboratory. Pierre Michel Llorca received honoraria and travel reimbursements for conferences by Lundbeck Laboratory. G. Brousse received a sponsorship to attend scientific meetings, speaker honoraria, and consultancy fees from Lundbeck and Merck-Lipha. The other living authors declare that they have no competing interests.

Authors' Contributions

LM, GB, PML and IdC conceived the trial and wrote the first draft of the protocol. MC is involved in monitoring the clinical trial and helping with the data collection. JG contributed expertise in urgency environments.

FC, FM, AV, XJ, PL, DR, AG, and MD are involved in the data collection. TG, GB, PML and IdC contributed to the literature review and are involved in writing the manuscript, as well as with critical revision of the work.

All living authors read, improve, and approve the final manuscript.

Ethics and Dissemination

This research has been approved by the research ethics committee of the Clinical Investigation

Centers of Rhône-Alpes-Auvergne interregion – France (No., 00005921) and by the National

Commission for Information Technology and Civil Liberties (CNIL No. DR-2015-402).

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