Forensic Science International 282 (2018) 127–132

Contents lists available at ScienceDirect

Forensic Science International

journal homepage: www.elsevier.com/locate/forsciint

Alcohol and illicit drugs in drivers involved in road traffic crashes in the Milan area. A comparison with normal traffic reveals the possible inadequacy of current cut-off limits

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ARTICLE INFO

Article history:
Received 7 September 2017
Received in revised form 2 November 2017
Accepted 4 November 2017
Available online 22 November 2017

Keywords:
Blood test
Legal limits
Cocaine
THC
Alcohol

ABSTRACT

Background: Driving under the influence of alcohol and/or illicit drugs in Italy is regulated by the articles 186 and 187 of the National Street Code. Epidemiological studies on drivers involved in road traffic crashes (RTC) provide useful information about the use/abuse of these substances in the general population. Comparison with case control studies may reveal important information like the cut-off limits adequacy.
Methods: Data from 1587 blood tests for alcohol and 1258 blood tests for illicit drugs on drivers involved in RTC around Milan between 2012 and 2016, were analyzed and compared with a published random survey (DRUID) from the European Community.
Results: Our data from RTC-involved drivers show that alcohol abuse is not age-related whereas illicit drugs are more common in young people. Cannabinoids are frequent among younger drivers (median age 27) whereas cocaine is more often detected in adults (median age 34). The calculated odds ratio after comparison with the DRUID survey shows that a blood alcohol concentration below the legal limit does not represent a risk factor in having a car accident whereas concentrations of cocaine and cannabinoids within the legal limits are associated with being involved in a car accident.
Conclusions: Despite authority efforts, the abuse of alcohol and illicit drugs is still common in young drivers. We suspect that the cut-off limits for cannabinoids and cocaine and/or the pre-analytical procedures for these substances are inadequate. We suggest a better standardization of the procedure by shortening the time interval between the request for investigation and blood collection and propose the adoption of more stringent cut-off limits.

1. Introduction

Driving under the influence (DUI) of alcohol in Italy is regulated, since 1992, by the article 186 of the National Street Code (NSC) which delineates fines and eventually penalties for drivers with blood alcohol concentration (BAC) higher than 0,5 mg/ml. The sanctions increase if the BAC exceeds 0,8 mg/ml and increase furthermore if above 1.5 mg/ml. Since July 29, 2010, the article 186 bis of the NSC [1] introduces a zero tolerance for drivers younger than 21, for drivers who have been licensed for less than 3 years and for professional drivers (trucks, buses, etc.). In contrast, DUI of illicit drugs is regulated by the article 187 of the NSC [2] which defines the penalties and fines for convicted drivers whereas the list of the substances to be searched and their threshold concentrations are left to the 20 Italian regional authorities.

Concern about DUI of alcohol or illicit drugs in the European Community (EU) is constantly under the spotlight because it poses a serious threat for public safety [3]. In this context epidemiological studies provide useful information that can be used to determine the impact of drug use in the general population of drivers, especially in those countries, like Italy, where experimental studies on the effects of illicit substances in humans are not allowed for ethical reasons. Comparison of roadside epidemiological studies, involving randomly stopped drivers (control group), with data from drivers involved in road traffic crashes (RTC) reveals

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https://doi.org/10.1016/j.forsciint.2017.11.005
0379-0738/

that in the latter group the percent of people under the influence of alcohol or illicit drugs is much greater, confirming a major role for such substances in impairing the person's driving ability and incrementing the risk of having a car accident [3,4]. In a recent paper, a Spanish roadside survey [5] shows that about 17% of drivers were positive to either alcohol or illicit drugs. In contrast, data from almost 6000 blood samples of drivers who died on the Spanish roads between 1991 and 2000 show that alcohol and illicit drugs were detected in the 52% of cases [6]. More recent data from 2010 based on 855 blood sample analyses confirmed the same trend with alcohol and illicit drugs detected in the 42.5% of Spanish drivers involved in RTC [7]. Similar results are observed in toxicological investigations on RTC-involved drivers across Europe, where the percent of positive cases for either alcohol or illicit drugs ranges between 40% and 70% [4,8,9].

Several studies have shown that alcohol and illicit drugs impair brain functions essential for accomplishing a complicated task like driving and increase the chances of having a car accident [10–13]. However, although the effect of alcohol on driving skills has been extensively studied [11,14,15], the literature regarding illicit substances is generally sparse and there are still debates on both the effects of such substances on driving skills [16,17] and the adoption of appropriate cut-off limits [18].

Comparing the frequency of drug detection among drivers involved in RTC with that of a relevant control group, can offer important information about the magnitude of the influence of alcohol and illicit drugs in causing car accidents. In this study we present the retrospective evaluation of data from 1587 blood tests for alcohol and a subgroup of 1258 blood tests for illicit drugs, on drivers involved in RTC around the Milan area (Lombardia Region) between 2012 and 2016. The data, collected under the national and regional guidelines [1,19], will be compared with a published relevant control study which is part of the European Union granted project, DRUID (Driving under the Influence of Drugs, Alcohol and Medicines) [20]. Several European countries, including Italy, participated in the DRUID project with the purpose of carrying out epidemiological studies on the presence of alcohol and illicit drugs in random drivers. Within this project more than 1310 drivers in northern Italy were randomly stopped by the police and their blood was tested for alcohol and illicit drugs. Of the tested drivers 85% were negative for all substances whereas 8.6% and 4.9% tested positive for alcohol and illicit drugs, respectively. Another 0.5% samples indicated the presence of prescription drugs, not considered as illegal substances [20] and 1% indicated drug–alcohol combination.

Comparison of our data with the DRUID project provides important information on the association between drugs and RTC risks among drivers in northern Italy but also casts doubts on the suitability of the cut-off limits for some illicit drugs and/or on their respective pre-analytical procedures. In this work, most of the methodological weaknesses often encountered in other case-control studies (like non-equivalent biological samples for cases and controls [21], geographical, age and gender biases [22]) are overcome. Furthermore, bias due to drivers refusal [23] was absent because participation in the DRUID project was mandatory [20] as was blood analysis after RTC.

2. Materials and methods

2.1. Inclusion criteria

We included blood toxicology results from a population of 1587 drivers involved in RTC and suspected of driving under the influence of alcohol and 1258 drivers suspected of driving under the influence of illicit drugs, submitted by law enforcement officers in the Milan area and taken to the San Raffaele Hospital Emergency Room (Milan), or an affiliated hospital, from January 2012 to December 2016.

2.2. Analytical testing

Blood was collected into plastic tubes (BD Vacutainer Plus, gray cap) provided with potassium fluoride as preservative and potassium oxalate or ethylenediamine tetraacetic acid (EDTA) as anticoagulant. Samples were stored at 4 °C for short periods (<72 h), and then kept at −20 °C. Analysis were routinely completed within 2 weeks.

2.3. Analytical procedures

As requested by the Regione Lombardia and the national guidelines [1,19]. The concentration of ethanol in whole blood was measured by Gas Chromatography — Flame Ionization Detection (Agilent 7890A, Agilent technologies). The search for illicit drugs is performed by liquid chromatography tandem mass spectrometry (LC–MS/MS): substances are separated by HPLC using a Shimadzu Prominence system with a Synergi 2.5 μm Hydro-RP 100 Å (50 × 2 mm) column (Phenomenex) and detected by a coupled Qtrap 5500 mass spectrometer (AB Sciex). Samples were liquid-liquid extracted using the commercial kit "Abuse Drugs in Blood by LC/MS" (Eureka Lab Division) which also provides the calibrators and the quality controls.

Cut-off values for the different classes and analytes are summarized in Table 3. The concentration of analytes requested by the legal authority was calculated by comparing the corresponding signal with a 5 points calibration curve and accompanied by an analytical interval of 20%. The methods were validated "in-house" following the European Medicines Agency (EMA) guidelines [24]. The quality of the results is further assured by the participation of the San Raffaele Hospital to the LGC-Standards proficiency test (www.lgcstandards.com), an accredited international External Quality Assessment (EQA) scheme.

2.4. Statistical analysis

Comparisons of cases and controls (odds ratio) were computed using bi-variate cross tables, and statistical significance was calculated with the chi-square test (Supplementary material).

3. Results and discussion

Drivers in the Milan area involved in RTC between 2012 and 2016 were tested for the presence of alcohol (1587 drivers). A subgroup of 1258 drivers was also tested for the presence of illicit drugs. In general, the request by the legal authority for the illicit drugs blood test is concomitant to that for the blood alcohol test. However, because they follow different bureaucratic procedures,

Table 1
Characteristic of drivers involved in RTC and participating in the DRUID survey, tested for alcohol and illicit drugs.

Gender	Alchol (%)	Illicit drugs (%)	DRUID project[a] (%)
Male	1287 (81.1)	1072 (85.1)	993 (75.8)
Female	300 (18.9)	187 (14.9)	317 (24.2)
Age groups			
13–17	27 (1.7)	19 (1.5)	–
18–24	321 (20.2)	274 (21.8)	320 (24.4)
25–34	402 (25.3)	319 (25.4)	482 (36.8)
35–49	510 (32.2)	409 (32.5)	436 (33.3)
≥50	325 (20.6)	237 (18.8)	72 (5.5)