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ORIGINAL REPORT

Medication and fitness to drive

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SUMMARY

Purpose The aim of this study is to analyze the consumption patterns of medicaments among motor vehicle drivers who attend 'Medical Driving Test Centres' and the relation between habitual consumption of medicaments and fitness to drive.
Methods The study was carried out on 8043 drivers who attended 25 Medical Driving Test Centres.
Results 24.7% of drivers chronically consume medicaments while 6.8% consume medicaments along with alcohol every day. Of those who chronically consume medicaments with a warning about the medications on driving, 65.8% were considered 'fit' to drive, 27.3% 'fit with restrictions', 5.1% 'suspended' and 0.4% 'unfit'.
Conclusions The results show how frequent the consumption of medicaments along with alcohol is and that the great majority of drivers who take medicaments are considered fit to drive. Copyright © 2003 John Wiley & Sons, Ltd.

KEY WORDS — drug-utilization; prescription-patterns; alcohol-drinking; automobile-driving; ability-to-drive

INTRODUCTION

Road accidents represent a major health problem worldwide and their prevention is on a high priority. A factor that may influence their occurrence is driving under the effects of psychotropic substances. Although alcohol is the main substance involved in these accidents, the consumption of medicaments is also increasing, resulting in growing interest in this subject. Estimates indicate that at least 10% of the persons killed or injured in traffic accidents had consumed psychotropic medication and that could have been a contributory factor.[1]

Within the EU, the drug–driving (either illegal and/or medicinal drugs) relation can be seen from a dual perspective: First, European countries have different regulations concerning illegal and medicinal drug–driving, sanctioning those under the influence of substances (both illegal and medicinal drugs) who show impaired driving ability. Obviously, this situation applies to both those who take illegal and/or medicinal drugs occasionally, and to those who take these habitually. Unlike with alcohol, establishing a dose concentration–effect relationship is much more complex.[2] Thus, concentration levels above which driving should be prohibited is still difficult to establish,[2] although recently a benzodiazepine drug–concentration relationship with impairment has been reported which opens the possibility to establish concentration limits.[3] At present, legislators have two options[4,5]: (i) 'zero tolerance' or (ii) to evaluate impairment by specifically trained police officers on the roadside. These approaches are not mutually exclusive. Zero-tolerance, that is, '*per se*' laws in which analytical cut-off levels for illicit drugs are established, exists in some countries (e.g. Belgium, Germany, Sweden and Portugal). However in Sweden, medicinal drugs — i.e. benzodiazepines — are included if they are not on prescription or at high levels). Moreover, research to develop practical and reliable detection equipment for roadside checking for drugs and medicines should continue.[4,5]

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Second, current European legislation does not permit the issuing or renewal of licences for those without adequate driving ability. The different EU member countries possess national regulations on driving licences (Royal Decree 772/1997 for Spain) in accordance with Council Directive 91/439/EEC (29 July 1991 on driving licences).[5,6] This indicates that 'driving licences shall not be issued to or renewed for applicants or drivers who regularly use psychotropic substances, which can hamper the ability to drive safely where the quantities absorbed are such as to have an adverse effect on driving. This shall apply to all other medicinal products or combinations of medicinal products which affect the ability to drive'. Member states implement this regulation differently. For example, legislation in Spain establishes that to obtain a driving licence, or to renew it, a medical-psychological examination, carried out in specific 'Medical Driving Test Centres', is obligatory.[5]

The relation between medicaments and fitness to drive is complex as the medicaments used to treat illness may, by their very nature, impair a person's fitness to drive.[6] However, the joint consumption of alcohol and medicaments, which is frequent,[7] may cause even greater impairment.

Furthermore, one problem is that from the point of view of traffic authorities, they usually consider illegal and medicinal drugs together regarding either driving under the influence or fitness to drive, as they share some similarities when compared with alcohol. Both should be treated as two separate issues where driving is concerned.[6] The present study focuses on medicinal drugs and fitness to drive.

The aim of this study is to: (i) analyze medicament consumption patterns among drivers attending 'Medical Driving Test Centres' including their alcohol consumption and (ii) analyze the relation between habitual consumption of medicaments and fitness to drive.

METHODS

The study was planned as a multi-centre based study on a national scale. A full description of methods is reported elsewhere.[5,8] A sample of 8043 drivers (5435 (67.6%) male, 2608 (33.4%) female) attending 25 Medical Driving Test Centres to obtain or renew driving licences were approached, informed about the study, stressing that it was separate from the clinic assessment and their consent was taken for participation. Participation by Centres was voluntary.

The Centre staff gather information from applicants relating to sight, hearing, locomotor system, cardiovascular, neurological and renal diseases, diabetes mellitus, mental disorders, medication use, alcohol and drug related problems.[5,8] Additionally, Spanish legislation (Royal Decree 772/1997) decrees that 'perceptual motor skills' be evaluated, including: (i) speed anticipation, (ii) senso-motor co-ordination, (iii) multiple-reaction time. A report is issued after this process stating whether the person is: (i) fit, (ii) fit with restrictions, (iii) suspended or (iv) unfit.[5,8]

The present study collected information relating to: (i) socio-demographic aspects, (ii) medical pathology, (iii) medication use, (iv) alcohol consumption patterns and alcohol related problems (dependence)[5] and (v) the Centre's evaluation of psycho-physical abilities.

Drivers were asked about medicaments they were consuming when the interview was carried out, the registered name of the medicine they were using, the length of time they had been taking them and the reason for taking them. Information was recorded concerning up to four different medicinal drugs. Each registered pharmaceutical preparation was coded following the Anatomical Therapeutic Chemical classification system. Habitual use was defined as using the drug on a daily basis for at least 1 month.[7] The Summary of Product Characteristics (SPC) for each medication was reviewed and it was recorded whether there was any warning about the medication's effect on fitness to drive. The frequency of alcohol consumption and the average quantity of pure alcohol consumed in grams/day was analyzed, as well as the presence of alcohol related problems (dependence, DSM IV criteria[5]).

Statistical analysis was performed using variance analysis and chi-square test with results expressed in odds ratio (OR) and 95% confidence interval (CI), when appropriate. SAS software version 6.07 was used and p-values of <0.05 were considered significant.

RESULTS

24.7% of drivers chronically consume medicaments (Table 1), it being more frequent among men than women (OR 1.08, 95% CI 0.97–1.20) and increasing with age ($p < 0.0001$). The mean ($\pm$SD) number of medicaments consumed among chronic consumers is 1.28 ± 0.56 (1.26 ± 0.55 women, 1.29 ± 0.56 men; $F = 0.64$, $p > 0.05$) increasing with age ($F = 12.0$, $p < 0.0001$). The therapeutic groups most frequently consumed are: cardiovascular system (7.8% of population) followed by alimentary tract and metabolism (4.8%) and central nervous system (4.3%) (Table 2).

6.8% of the population consume medicaments and alcohol on a daily basis (Table 1) (27.4% of these take

Table 1. The use of medicines and alcohol among Spanish drivers

		Total drivers 8043	Males 5435	Females 2608	Age <25 1509	25–34 1631	35–44 1673	45–54 1454	55–64 1097	>64 679
Take medicines	(%)	24.7	25.3	23.8	14.2	16.74	19.1	27.17	38.10	55.96
Mean n° of medicaments	mean	1.28	1.29	1.26	1.15	1.16	1.20	1.30	1.34	1.42
	$\pm$ SD	0.56	0.56	0.55	0.37	0.39	0.48	0.60	0.61	0.67
Take medicines+ drink daily	(%)	6.82	9.03	2.22	0.26	0.92	4.24	8.04	15.67	25.0
Gr/day of pure alcohol	mean	27.52	28.28	21.08	33.21	37.71	31.27	30.27	27.31	23.25
	$\pm$ SD	0.56	18.50	16.38	13.92	20.42	25.98	20.77	15.52	14.23

medication habitually). It is more frequent among men, than women, (OR 4.73, 95% CI 3.31–5.75) and increases with age ($p < 0.0001$). The mean $\pm$ SD grams/day of pure alcohol consumption among those consuming both alcohol and medicaments is 27.52 ± 18.29 grams/day (21.08 ± 16.38 women, 28.28 ± 18.50 men; $F = 8.03$, $p < 0.05$), and varies with age, the maximum being among the 25–34 age group, decreasing thereafter ($F = 4.0$, $p < 0.01$).

In the Centre's examination, 88.3% were 'fit' (91.5% of those not taking medicaments, and 78.6% of those habitually consuming medicaments, OR 2.92, 95% IC 2.54–3.35); 10.3% were 'fit with restrictions' (7.6% and 18.4% respectively, OR 0.36, 95% IC 0.31–0.42); 1.2% were 'suspended' (0.7% and 2.5%, OR 0.27, 95% IC 0.18– 0.41); and 0.3% were 'unfit' (0.2% and 0.4%, OR 0.47, 95% IC 0.20–1.11).

For 20% of the medication used chronically (513 out of 2566), there was a warning in the SPCs about the effect of the medication on the ability to drive (Table 2). This data shows that 4.9% of drivers (20% of the drugs taken chronically by 24.7% of the population) were using medication that impairs driving performance. When the final results of the medical examinations of those who were taking medicaments chronically were compared with 'whether there was a warning about the effect on fitness to drive on the package inserts of the medication', or not it was found that in the cases considered to be 'unfit', all nine of them (100%) were taking medicaments that had a warning. Of those considered to be 'suspended', 26 out of 51 (51%) were taking medicaments with a warning. Of those considered 'fit with restrictions', 140 of the 368 (38%) were taking medicaments with a warning and of those considered 'fit', 338 of the 1572 (21.5%) were taking medicaments with a warning.

Those found 'unfit', who were also consuming medicaments (9 cases), all suffered from some pathological process included in the list of pathologies that can interfere with fitness to drive (Royal Decree 772/1997 and Council Directive 91/439 EEC). They were also consuming medicine that could potentially interfere with fitness to drive (there was a warning in the SPCs). Case 1 was taking a tryciclic antidepressant drug; case 2 was taking a tryciclic antidepressant drug plus a long acting benzodiazepine; case 3 was taking a long acting benzodiazepine; case 4 was taking a first generation antihistamine H-1 drug; case 5 was taking an antipsychotic drug; case 6 was taking an antiepileptic drug; case 7 was taking an antihypertensive drug plus a nonsteroidal antiinflammatory drug; case 8 was taking an antihypertensive drug plus a nonsteroidal antiinflammatory drug plus a hypouricemic drug;

Table 2. Types of medication used by Spanish drivers

Class of medication	Total $n = 8043$ (%)	Male $n = 5435$ (%)	Female $n = 2608$ (%)	OR (95% CI) Male/female	Warning in the SPC about the effect of the medication on the ability to drive or use machinery (%)
Alimentary tract and metabolism	4.8	5.2	4.1	1.26 (1.01–1.59)	5.6
Blood and blood forming organs	4.2	4.8	2.9	1.64 (1.27–2.13)	0.4
Cardiovascular system	7.8	9.3	4.8	2.03 (1.66–2.48)	25.7
Dermatologicals	0.8	0.7	0.8	0.91 (0.53–1.55)	0.0
Genito-urinary system and sex hormones	2.1	1.3	3.9	0.32 (0.23–0.43)	0.7
Systemic hormonal preparations, excluding sex hormones	0.9	0.3	2.3	0.12 (0.07–0.22)	0.0
General antiinfectives for systemic use	0.8	0.9	0.6	1.33 (0.76–2.32)	4.5
Antineoplastic and inmunomodulating agents	0.0	0.1	0.0	0.99 (0.99–1.00)	0.0
Musculoskeletal system	2.7	3.0	1.8	1.68 (1.21–2.32)	5.4
Central nervous system	4.4	4.1	5.0	0.80 (0.64–1.00)	32.2
Respiratory system	3.0	2.8	3.4	0.81 (0.62–1.06)	24.8
Sensory organs	0.2	0.2	0.3	0.82 (0.32–2.09)	0.0
Various	0.2	0.1	0.2	0.55 (0.18–1.66)	0.0

and finally case 9, was taking an antihypertensive drug plus a nonsteroidal antiinflammatory drug plus a hypolipidemic drug and an antiarrhythmic drug. Six of these nine patients had no alcohol related problem (five were tea-totallers), and three had a diagnosed dependence on alcohol. The percentage of 'unfit' cases increased with respect to the number of medicaments consumed ($1 = 0.3\%$, $2 = 0.5\%$, $3 = 1.2\%$, $4 = 9.1\%$), likewise with respect to those found 'fit with restrictions' ($1 = 16.2\%$, $2 = 21.2\%$, $3 = 43.2\%$, $4 = 45.4\%$).

DISCUSSION

The present study shows that medicaments consumption is frequent (24.7%) among drivers attending Medical Driving Test Centres. In a study carried out earlier in Spain in a representative sample of drivers,[7] chronic medicament consumption was observed in 17.3%, a little lower than in the present study. Likewise, studies carried out previously in surrounding countries show similar medicament consumption.[9] Nevertheless, a comparison of such data is difficult as there is little standardization, and different methodologies are used with different reference populations.

In that earlier study, carried out on the driving population,[7] chronic medication use was found to be more frequent among females (18%) than among males (16.9%), as well as the average number of medications used (2.16 vs 1.87, respectively). Data from the Spanish general population based on the National Health Survey,[10] shows that 47.1% of the population over 16 years had used some kind of medication in the two previous weeks, more frequently among females (53.2%) than males (40.5%). The average number of medications was also higher in females (1.6) than in males (1.4). However, in the present study there were no significant differences between males and females regarding frequency (23.8% females and 25.3% males) and number of medications used (1.29 for males and 1.26 for females) and the mean number of medicines taken was lower than in previous studies, both for the drivers population[7] and the general population.[10]

Apart from the fact of the limitations of data comparison between the different population sample sources (drivers attending medico-psychological centres for evaluation of their fitness to drive, general driving population and general population), there are two aspects to take into account. The first is that, of the 19 million driving licences in Spain, about 34% correspond to women, and in three out of four cases, the women are under 45 years of age. This implies that, of those female drivers who go to renew their licence, the majority are quite young and presumably healthy. This could account in part for the observed pattern of medication use by women. The second, deals with the possible reticence to tell the truth for fear of a negative report on their fitness to drive, although drivers were clearly informed that the information would be used only for scientific data and had no administrative and/or legal consequences. Thus, regarding patterns of alcohol consumption,[5] the

reported frequency of drinking does not differ from other studies, while the amount of alcohol intake was noticeably lower. Therefore, regarding medicines, we can not exclude the fact that the low average of medicines taken could reflect an underreporting of all medicines taken.

As for joint alcohol/medicament consumption, 27.4% of drivers who were habitually taking medication also consumed alcohol on a daily basis. This confirms previous findings.[7] This association may lead to a greater risk of interactions, deterioration in the psychomotor performance and an alteration of the fitness to drive. Physicians and chemists should pay greater attention to this aspect. In the present study of those habitually consuming medicaments, a high percentage (78.6%) are 'fit to drive' or 'fit with restrictions' (18.4%). Only 0.45% was considered 'unfit'. All suffered from a pathological process included in the list of pathologies and were consuming a medicinal drug, both of which could potentially interfere with the fitness to drive. A third also suffered from alcohol dependence. When we consider those taking medicaments with a warning about their effect on the capacity to drive, a high percentage were still considered to be 'fit to drive' (65.8%) or 'fit with restrictions' (27.3%). Only 5.1% were considered to be 'suspended' and 0.4% were considered 'unfit'. There are no studies within the EU analyzing these aspects.

Current European legislation (CD 91/439/EEC) does not permit the issuing or renewal of driving licences for those without adequate driving ability, including several medical conditions and medication use ('which can hamper the ability to drive safely'). The problem arises when evaluating fitness in clinical practice. This legislation is difficult to apply as the relation between illness, medication and fitness to drive is highly complex.[6,11] The side-effects of medicaments vary from person to person and are compounded by polypharmacy and self-medication. However, medicaments are used to treat illnesses and it is sometimes the illness itself that impairs fitness to drive. Moreover, the consequences for driving and not taking the medication can be worse. Even so, the medication prescribed may have an effect on the psychomotor performance.

That is, data from the present study indicate that, in clinical practice, the decision about whether a driver is fit to drive or not is based on individual clinical evaluation of each patient where the binomial illness–medication cannot be separated. In fact, a high percentage of those taking medicaments with a warning about their effect on driving ability are considered 'fit', in spite of the fact that the law says otherwise. The difficulties of implementing this directive have already been pointed out and the suggestion 'to adapt driving licence requirements in order to permit allowances or restrictions for drivers using chronic treatments influencing driving'[12] has been made. However doctors who prescribe medicaments to drivers should take note of the law and the legal repercussions and make an effort to prescribe the medicament that least affects the capacity to drive, to avoid both the risk of being involved in a traffic accident and that of losing their driving licence.

What can be done is to prescribe the safest medicament, avoid polypharmacy and ensure that alcohol is not consumed.[13] It must be said that not all medicaments affect fitness to drive equally. Within the EU, package inserts include a statement regarding the medication's effects on fitness to drive or use machinery. A three-tier classification of medicaments on this basis has been accepted: (i) presumed to be safe or unlikely to produce an effect, (ii) likely to produce minor or moderate adverse effects, (iii) likely to produce severe effects or presumed to be potentially dangerous (CPMP, III/9. 163/90 de la CEE).[6,14] This classification (which has not yet been implemented in the EU) would be extremely useful when selecting medicaments for drivers, and for evaluating fitness to drive when taking medication.[6] Recently some countries like Belgium[15] and Spain[16] have introduced a Drug Categorization System. France has introduced such classification only for antihistamines H1[17] and a pictogram has also recently been introduced in the package of drugs affecting driving.

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