Safer use of driving impairing medicines by elderly road users

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Content overview

- The elderly driver
- The role of psychoactive medicines in traffic safety
- Chronic medical conditions, medications and traffic accidents in the elderly
- Development and effectiveness of warning symbols
- Conclusions
- Recommendations
Physiology & Ageing

- Body mass ↓
- Renal function ↓
- Balance ↓

Morbidity: 2 - n?

Changes in Pharmacokinetics and Pharmacodynamics

Drug-drug + Drug-disease interactions

Decreased effectiveness of homeostasis
More Dutch elderly aged over 85 years have a car

- Number of elderly people > 85 years with a car tripled compared to the year 2000 (21,000 to 72,000). The number of people aged > 65 years with a car increased to 2.9 million.

Source: NRC 2014-10-28/CBS 2014
Older adults knowledge about driving impairing medicines (DIMs) (AAA Foundation for traffic safety, 2009)

- Survey of 630 community dwelling drivers, average age 70.4 yrs:
  - 92.1% driving as their preferred mode of transportation;
  - 60% 6 or 7 days/week;
  - 94.6% one or more medical conditions;
  - 78% currently used one or more medicines;
    - 19.1% 5 or more medicines
    - 10.2% 5 or more DIMs
  - 68.7% used DIMs;
  - 27.6% some awareness of DIMs (decreased with increasing age and for those with less education)
  - 17.6% received a warning about DIMs from doctor, nurse or pharmacist
Medical conditions, medicines and risk of at-fault traffic accidents in 901 drivers > 65 yrs (McGwin et al 2000)

<table>
<thead>
<tr>
<th>Condition or R/ use</th>
<th>OR</th>
<th>95% CI</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart disease</td>
<td>1.5</td>
<td>1.0-2.2</td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td>1.9</td>
<td>0.9-3.9</td>
<td></td>
</tr>
<tr>
<td>Arthritis</td>
<td>1.9</td>
<td>1.1-2.9</td>
<td>Females</td>
</tr>
<tr>
<td>NSAIDs</td>
<td>1.7</td>
<td>1.0-2.6</td>
<td></td>
</tr>
<tr>
<td>ACE inhibitors</td>
<td>1.6</td>
<td>1.0-2.7</td>
<td></td>
</tr>
<tr>
<td>Anticoagulants</td>
<td>2.6</td>
<td>1.0-73</td>
<td></td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>5.2</td>
<td>0.9-30</td>
<td></td>
</tr>
<tr>
<td>Calcium channel blockers</td>
<td>0.5</td>
<td>0.2-0.9</td>
<td></td>
</tr>
<tr>
<td>Vasodilators</td>
<td>0.3</td>
<td>0.1-1.0</td>
<td></td>
</tr>
</tbody>
</table>
# The role of psychoactive substances in road traffic

DRUID 2011 (Adjusted ORs)

<table>
<thead>
<tr>
<th>Psychoactive substance</th>
<th>% in general driving population (range)</th>
<th>Injured drivers OR (C.I.)</th>
<th>Killed drivers OR (C.I.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol ≥ 0,1 g/l</td>
<td>3.48 (0.15-8.59)</td>
<td>8.27 (7.03-9.74)</td>
<td>12.06 (8.85-16.42)</td>
</tr>
<tr>
<td>THC</td>
<td>1.32 (0.03-5.99)</td>
<td>2.41 (1.36-4.28)</td>
<td>n.a.</td>
</tr>
<tr>
<td>Benzodiazepines and Z-drugs</td>
<td>0.99 (0.14-2.73)</td>
<td>2.41 (1.58-3.70)</td>
<td>7.42 (5.29-10.41)</td>
</tr>
<tr>
<td>Opioids as R/</td>
<td>0.35 (0.03-0.79)</td>
<td>5.14 (3.08-8.57)</td>
<td>4.82 (2.60-8.93)</td>
</tr>
<tr>
<td>Comb.(drug-drug)</td>
<td>0.39 (0.02-1.22)</td>
<td>4.48 (2.51-8.00)</td>
<td>15.05 (8.23-27.53)</td>
</tr>
<tr>
<td>Comb.(alc.-drug)</td>
<td>0.37 (0.03-1.14)</td>
<td>29.05 (18.38-45.90)</td>
<td>31.52 (16.83-59.05)</td>
</tr>
</tbody>
</table>
Background for improving patient information- EU Legislation

- European Council Directive 83/570/EEC (October 1983) > SmPC, Article 4: Information on clinical particulars, among which the “effects on the ability to drive and to use machines”

- European Committee for Medicinal Products for Human Use (CHMP) (October 1991) > SmPC, Section 4.7: On the basis on the pharmacodynamic profile, reported adverse drug reactions and/or impairment of driving performance or performance related to driving, the medicine is: a) Presumed to be safe or unlikely to produce an effect; b) Likely to produce minor or moderate adverse effects; c) Likely to produce severe effects or presumed to be potentially dangerous

- New SmPC guideline (September 2009) > SmPC, Section 4.7: On the basis of the pharmacodynamic and pharmacokinetic profile, reported adverse reactions and/or specific studies in a relevant target population addressing the performance related to driving and road safety or using machines, specify whether the medicinal product has: a) No or negligible influence; b) Minor influence; c) Moderate influence; d) Major influence on these abilities
Categories for health care professionals and patients

Category 0
Presumed to be safe or unlikely to produce an effect on fitness to drive.
- Confirm that the medicine will be safe for driving, provided that combinations with alcohol and other psychotropic medicines are excluded.

Category 1
Likely to produce minor adverse effects on fitness to drive.
- Inform the patient that impairing side effects may occur especially during the first days and that they have a negative influence on his/her driving ability.
- Give the patient the advice not to drive if these side effects occur.

Category 2
Likely to produce moderate adverse effect on fitness to drive.
- Inform the patient about the possible impairing side effects and the negative influence on his/her driving ability.
- Advise the patient not to drive during the first few days of the treatment.
- If possible, prescribe a safer medicine, if effective and acceptable by the patient.

Category 3
Likely to produce severe effects on fitness to drive or presumed to be potentially dangerous.
- Inform the patient about the possible impairing side effects and the negative influence on his/her driving ability.
- Urgently advise the patient not to drive.
- Consider prescribing a safer medicine, if acceptable by the patient.

Warning for patients
[no warning needed]

Warning level 1
Do not drive without having read the relevant section on driving impairment in the package insert.

Warning level 2
Do not drive without advice of a health care professional. Read the relevant sections on driving impairment in the package insert before consulting the physician or pharmacist.

Warning level 3
Do not drive. Seek medical advice after a period of treatment about the conditions to restart driving again.

Pictograms
Category distribution based on consensus

- CATEGORY 0: 11%
- CATEGORY I: 26%
- CATEGORY II: 51%
- CATEGORY III: 6%
- MULTIPLE CATEGORIES: 4%
- DEPEDING ON COMBINATION: 2%
Evidence from pharmacoepi-studies


- A similar study was also undertaken within the Netherlands with similar findings (DRUID Deliverable 2.3.1, 2010) where the risk of accident was only considered significant for categories of level II and above.
**DRUID Pictograms for communicating risk to patients**

<table>
<thead>
<tr>
<th>Category</th>
<th>Your risk in traffic</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td><img src="image" alt="Category I Chart" /></td>
</tr>
<tr>
<td>II</td>
<td><img src="image" alt="Category II Chart" /></td>
</tr>
<tr>
<td>III</td>
<td><img src="image" alt="Category III Chart" /></td>
</tr>
</tbody>
</table>
Be careful! Read the patient information leaflet before driving.

Be very careful! Don’t drive without the advice of your GP or pharmacist.

Attention: danger! Do not drive. Seek medical advice before driving again.

Risk communication & pictograms comparing the triangle model (e.g. French model) with rating model

Your risk in traffic

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Low</td>
</tr>
<tr>
<td>1</td>
<td>Medium</td>
</tr>
<tr>
<td>2</td>
<td>High</td>
</tr>
<tr>
<td>3</td>
<td>Very High</td>
</tr>
</tbody>
</table>

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Pharmacotherapy & Pharmaceutical Care

SHARE
Graduates School for Health Research
Patient’s willingness to change driving behaviour
(Monteiro et al., 2014)

- Patients (n=270) visiting Dutch community pharmacies
- Asked for preferences for the best pictogram expressing a warning message and levels of impairment
- 78.8% were likely or very likely to change their behaviour (regardless of the pictogram or category presented)
74.4% found the rating model pictogram clear
82.6% of participants found the rating model self-explanatory

(Monteiro et al., 2014)
Recommendations

- Tailor-made risk communication to elderly drivers and campaign development based on DRUID materials
  - Drivers using benzodiazepines and medicinal opiates
  - Combined use of medicines and alcohol/illicit drugs

- Implementation of the 4-level categorisation and labelling system

- Improvement of the package information leaflet for cat. II and III medicines

*People are willing to change driving behaviour if properly addressed with clear and useful information from a preferred source (health care professional, peers, government……credibility of communicators?)*
Barriers and opportunities

- Medicines and driving not taken up by DG Sanco (Public health and consumer protection).

- 74% of General Practitioners and 67% of community pharmacists did not receive specific (post-graduate) education on how to counsel patients on driving impairing medicines (DRUID, 2011).

- Health care professionals can do a better job if supported by DRUID materials (by integrated software applications), but emphasis on (post-graduate) education and implementation of DRUID materials at a national level is needed.
Thank you for your attention

And see you in a Google car