

THE ALCOVE TOOLBOX FOR ANTIPSYCHOTICS LIMITATION IN DEMENTIA

A WORLDWIDE SHARED SAFETY ISSUE



ALzheimer COoperative Valuation in Europe

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WHY SUCH A TOOLBOX? _____ 85

THE WORLD HEALTH ORGANISATION POINT OF VIEW _____ 85

ILLUSTRATIONS _____ 86

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All the contents of the ALCOVE Toolbox are available on line: www.alcove-project.eu

WHY SUCH A TOOLBOX?

Overprescribing of antipsychotics for the behavioural disorders in dementia represents a major worldwide safety & ethical issue that has been underlined by the World Health Organisation [1]. It is well known today that chronic exposure to antipsychotics (AP) is non-effective and deleterious for people living with dementia as it can lead to falls, excessive sedation, stroke and an increased risk of mortality, with an overall profoundly negative impact on the individual's health, ability to communicate and quality of life.

The ALCOVE sustainable network has provided the opportunity to make a statement in Europe on the crucial issue of iatrogenicity and overuse of antipsychotics in dementia, underlined by the WHO and identified by the European Medicine Agency [2] as a priority research for 2013. In Europe, methods, references, tools and expertise are available in the field of safety & antipsychotics risk reduction. These successful experiences might be useful for those European countries wishing to promote risk reduction programmes.

To avoid deferring to other sedative drugs or physical restraints & to achieve improvements in outcome for people living with dementia, antipsychotics reduction in behavioural and psychological symptoms of dementia (BPSD) should be developed along with BPSD prevention and management improvement, using non pharmacological alternatives to antipsychotics and individualised patient and carer interventions, including psychosocial interventions.

ALCOVE European Member States have chosen to build a shared Toolbox to tackle the safety issue of limiting antipsychotics in dementia (Figure 1). This Toolbox provides concrete tools, key messages and experiences for all actors and in all dimensions of care: dedicated risk measurement (Figure 2) & risk reduction programmes (Figure 3), timely diagnosis, prevention & management of BPSD, and ethics in practice (Figure 4), all related to the use of antipsychotics.

WORLD HEALTH ORGANISATION POINT OF VIEW

85

Issues in the use of antipsychotic medication for people living with dementia, WHO, 2012 (1)

"There has been increasing concern about the use of antipsychotic drugs for the management of behavioural and psychological symptoms in dementia. These drugs appear to be used too often and, at their likely level of use, potential benefits risks may be more than the benefits. This is a problem across the world.

Although the first-line treatment for behavioural and psychological symptoms of dementia is non pharmacological, the prescription of psychotropic medication remains high and it appears that current systems deliver a largely antipsychotic-based response. These drugs appear to have only a limited positive effect in treating these symptoms but can cause significant harm to people with dementia. The risks include cerebrovascular adverse events and mortality. Clearly, some people benefit from these medications (e.g. where there is severe and complex risk). However, the current level of use of antipsychotics for people with dementia presents a significant issue in terms of quality of care, with negative impacts in patient safety, clinical effectiveness and the patient experience.

The mounting body of evidence documenting these risks has led North American and European regulatory authorities to issue warnings against the use of atypical antipsychotics to treat patients with dementia, and the US Food and Drug Administration now requires both atypical and typical antipsychotic drugs to carry a "black box" warning label highlighting the increased risk of mortality. Despite these warnings, antipsychotic drug use still seems to be widespread, particularly in care settings. Studies indicate that prescribing rates for antipsychotic medication use in dementia varies from 20% to 33% and most cases are residing in nursing homes. Less is known of the use of these medicines in the community and in acute hospital settings.

Evidence exists that, in many cases, difficult behaviour can be safely managed by use of psychosocial interventions or a person-centred care approach. Staff should receive training and guidance in delivering psychosocial interventions. Antipsychotics should be considered as an option only in cases of imminent risk of harm to self and other. If these drugs must be used, they should be prescribed in low doses over short periods and maintained only if benefits are apparent. Discontinuation should be attempted regularly."

ILLUSTRATIONS

Figure 1. The online ALCOVE TOOLBOX for antipsychotics limitation in Dementia: the Home page.

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ALCOVE TOOL BOX

FOR LIMITING ANTIPSYCHOTICS IN DEMENTIA

WHY SUCH A TOOL BOX FOR LIMITING ANTIPSYCHOTICS IN DEMENTIA?

i Antipsychotics prescribed for behavioral disorders in dementia represents a crucial safety & ethical issue.

ALCOVE, the European Joint Action on dementia, has benchmarked between European MS in order to propose concrete tools and supports to tackle this safety issue.

Several countries have already set up dedicated strategies to limit the antipsychotics in dementia.

- ↓ ANTIPSYCHOTICS RISK MEASUREMENT IN EUROPE
- ↓ ANTIPSYCHOTICS RISK REDUCTION PROGRAMES IN EUROPE
- ↓ TIMELY DIAGNOSIS & ANTIPSYCHOTICS
- ↓ BEHAVIORAL & PSYCHOLOGICAL SYMPTOMS OF DEMENTIA (BPSD)
- ↓ ETHICS IN PRACTICE & ANTIPSYCHOTICS
- ↓ ALL THE TOOLS

Figure 2. The online ALCOVE TOOLBOX for antipsychotics limitation in Dementia: Antipsychotics' Risk Measurement

ANTIPSYCHOTICS' RISK MEASUREMENT IN EUROPE

Being chronically exposed to antipsychotics in Alzheimer's disease leads to increased severe side effects risk; it is crucial to measure & monitor this risk.

Risk exposure in Europe
- Alcové surveys results
- The data in the literature

- A wide difference between prevalence use of antipsychotics in dementia patients
- A large inappropriate use of antipsychotics

ALCOVE WP4 report

European projects
- The UK audit
- The French survey
- The Swedish registry

Recommendations and Tools to support data collection for risk measurement

- The collection of data on the use of antipsychotics by dementia patients should be characterised to allow for prescription analysis (notably, as appropriate or inappropriate).
- A European database on the use of antipsychotics by dementia patients should be implemented. Such a database would be used to monitor antipsychotic prescriptions in Member states & to assess the efficacy of national programmes for antipsychotic use risk reduction.
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- List of antipsychotics
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Figure 3. The online ALCOVE TOOLBOX for antipsychotics limitation in Dementia: Antipsychotics' Risk Reduction Programmes

ANTIPSYCHOTICS' RISK REDUCTION PROGRAMMES IN EUROPE

Different strategies have been implemented in Europe to limit the prescription of antipsychotics & then the risk of exposure in dementia.

Risk reduction in Europe:
- Alcove surveys results

European projects
- The UK Call for Action
- The French AMI Alzheimer programme

Recommendations and Tools for risk reduction

- Optimising treatment and care for behavioural and psychological symptoms of dementia. A best practice guide. Antipsychotic prescription, Safety monitoring guidance & Monitoring plan, Review guidance & Review chart
http://www.alzheimers.org.uk/site/scripts/download_info.php?downloadID=609
- Alert & Mastering Indicator for iatrogenicity (AMI)
Alert indicator: measures the risk "rate of people living with dementia exposed to long-term antipsychotics prescription"
Mastering indicator: measures the management of the risk "rate of appropriate antipsychotics prescription (revised and argued)"
- Medicines Management Tool for Antipsychotics. NHS 2013
<http://www.hey.nhs.uk/content/files/prescribingCommittee/guidelines/antipsychotics.pdf>
- The Italian Legislation framework for Antipsychotics' Risk Reduction: a programme of active pharmacovigilance for antipsychotics prescription, and their role in the treatment of psychotic and behavioural disorders in persons living with dementia.

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Figure 4. The online ALCOVE TOOLBOX for antipsychotics limitation in Dementia: Ethics in practice & Antipsychotics

ETHICS IN PRACTICE & ANTIPSYCHOTICS

The use of AP must be analyzed from several ethical perspectives: e.g. distinguishing situations where AP are used in response to particular symptoms & where they are as a form of restraint (as an alternative to physical restraint).

Ethical aspects of the use of antipsychotics in dementia

What do we know about APs & competence assessment?

Key points to consider & tools for ethics in practice

ALCOVE "Ethics in practice & Antipsychotics" Key points to consider:

- Before prescribing antipsychotics
- Consider alternatives to antipsychotics
- When antipsychotics are being prescribed
- At the level of the caretakers in residential care or homecare setting
- At the level of decision makers

REFERENCES

[1] World Health Organisation «Dementia, a public health priority ». 2012 http://whqlibdoc.who.int/publications/2012/9789241564458_eng.pdf
 [2] European Medicines Agency. European Medicines Agency 2013 priorities for drug safety research. Long term safety effects of antipsychotics in patients with dementia. 2012
 [3] The online ALCOVE TOOLBOX www.alcove-project.eu