What are the main safety issues of restraints and antipsychotic treatments?

Consensus Conference of RECAGE Project (GA No: 779237)

Project funded by the European Commission

H2020-SC1-2017-Single-Stage-RTD

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21st – 22nd February 2023

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Rationale

Physical restraints

High variability in the prevalence of physical restraints (definition, setting)

- Prevention of Falls
- To control challenging behavior
- Allow invasive intervention

Perception that it is justified to minimize the risk of harm

No effectiveness demonstrated vs. adverse events

Antipsychotics

When non-pharmacological intervention are not available.
When symptoms are refractory to such interventions.

Modest effectiveness in the short-term symptomatic management of agitation, aggressiveness and psychosis

High rate of adverse events vs. possible benefits

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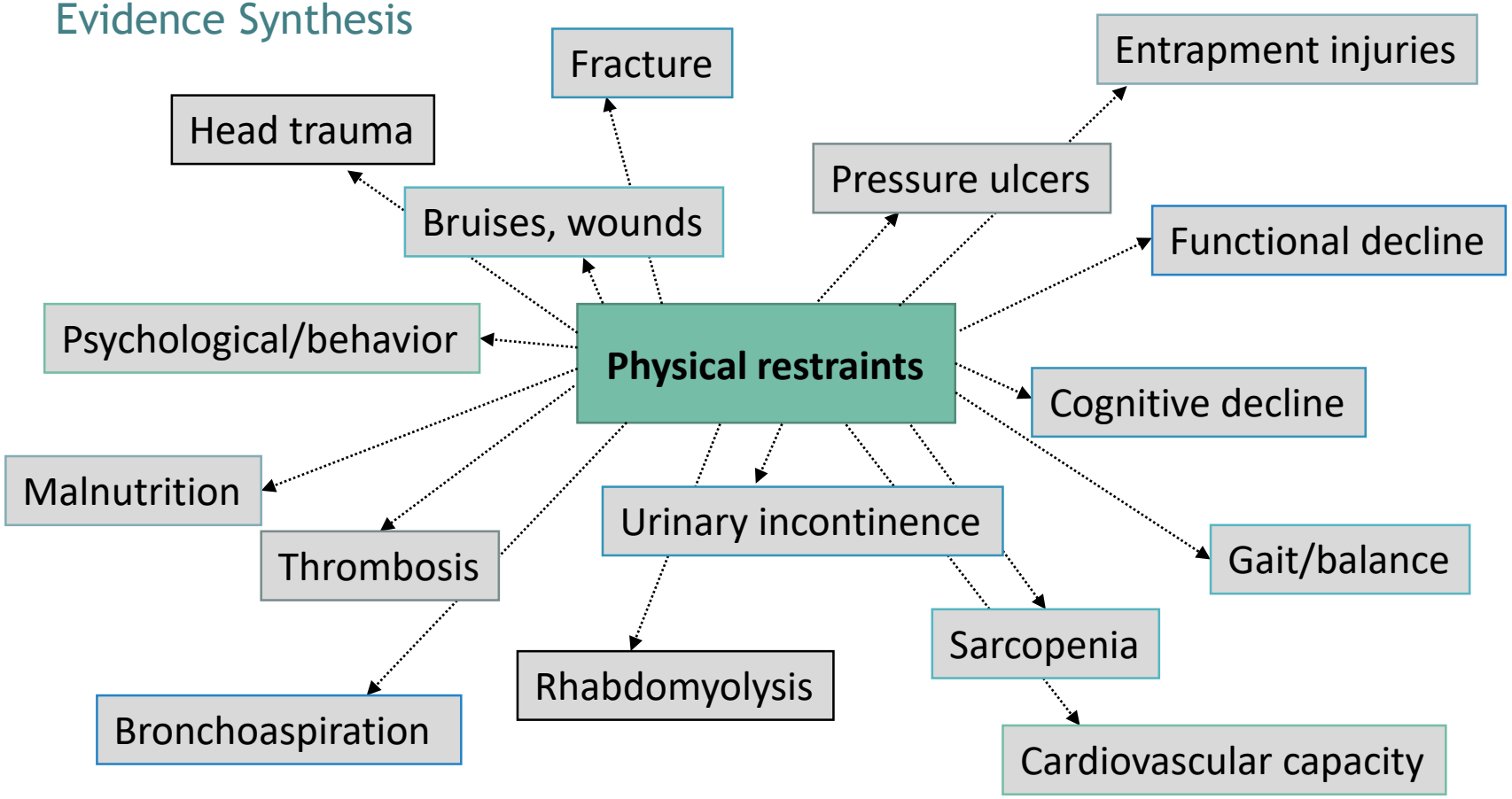
Evidence Synthesis



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Evidence Synthesis

Exceptional situations, as a last resort, for a limited duration and with a regular and close reassessment for a clear objective, respecting the principle of proportionality

Information/consent patients and representatives

Local legislation Institutional rules

Effectiveness of multicomponent interventions?

- Training teams
- Alternatives to the use of physical restraints

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Evidence Synthesis

Antipsychotics

1. Risk of unfavorable clinical outcome

↑ mortality (particularly with typical antipsychotics)

↑ cerebrovascular complications

acceleration of cognitive decline

2. Vulnerability to adverse effects

Neurological: seizures, delirium, sedation, extrapyramidal syndrome, akathisia, antipsychotics malignant syndrome; **Metabolic:** hyperglycemia, hypercholesterolemia, weight gain; **Cardiac:** QT interval prolongation, ventricular arrhythmia; **Others:** falls, orthostatic hypotension.

3. Risks related to clinical management and follow-up

Duration of treatment, monitoring adverse events, follow-up appointment interval, how to titrate dosage, how to assess for effectiveness, how to discontinue treatment.

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Evidence Synthesis – other molecules

- **Anticholinesterase drugs and memantine**

  Positive effect in BPSD management in people with Alzheimer's Disease. However, are often considered insufficient in the treatment of more challenging behaviors.

- **Antidepressants**

  Serotonin reuptake inhibitor and some serotonin-norepinephrine reuptake inhibitors action are often used in the treatment of BPSD.
  Adverse events: prolongation of the ECG-QTc interval, nausea, diarrhea, hyponatraemia, headache and increased risk of falls.
  Depressive symptoms: little or no impact, especially in the long term (beyond 12 weeks).
  Agitation: modest effect of citalopram and sertraline when compared with placebo or antipsychotics.
  Good clinical practice guidelines: use of antidepressants be considered in situations of depressive symptoms, anxiety, apathy, agitation or even sleep disturbances. The main reason that justifies this recommendation lies in the **better tolerability than antipsychotics.**

- **Benzodiazepines**

  Unfavorable risk-benefit balance: induce and perpetuate delirium, worsen cognitive and functional performance, favor sedation and respiratory depression, as well as increase the risk of falls with serious consequences and withdrawal syndrome.
  Absolute contraindication to the use of other therapeutic classes or in the acute management of a behavior crisis.

- **Antiepileptics**

  The use of this class of drugs is not currently recommended.

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Evidence Synthesis - Special Care Unit (SCU-B) for people with BPSD

- Trend to increased prescription of psychotropic drugs in previous studies, ↓RECAGE
- High variability regarding the use of physical restraints, from no prescription in a SCU-B with a no-restraint policy, to up to 43.5% in another study.
- Safety: poorly investigated, frequency of falls, only one study showed a higher incidence than that of patients admitted to standard units.

Available data do not allow drawing conclusions about the impact of specialized units on safety issues related to the use of physical and chemical restraints.

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Statements

Most of the recommendations were made in accordance with the **opinion of experts**, given the **low quality of the available evidence**. Each of the interventions mentioned above has its own **risks and benefits**, which is why clinical management should be **individualized** and discussed with the patient, their family members and formal caregivers. Furthermore, such recommendations must be adapted to the **legal context** and **available resources** of each country, city.

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Statements

With regard to the clinical management of patients with dementia and behavioral symptoms, in particular safety in the use of physical restraints and psychotropic treatments with an emphasis on antipsychotics, we state the propositions below.

- **S 4.1:** Psychotropic drugs and physical restraints are associated with high rates of adverse events and complications;
- **S 4.2:** They should be avoided as often as possible, and prescription must be preceded by elimination of a secondary cause and non pharmacological interventions;
- **S 4.3:** Caregivers and family members should be informed of the risks and benefits and involved in the decision-making process.
- **S 4.4:** Physical restraints should be limited to exceptional situations of immediate danger for patient or environment that cannot be mitigated by pharmacological treatment;
- **S 4.5:** Prescription of physical restraints must be made according to predefined procedures, including respect to the local legislation, identification of a specific objective, duration of use, followed by regular and close reassessment;

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- **S 4.6:** The use of physical restraints must comply with the principle of proportionality: use the least restrictive restraints to achieve the objective defined by the team;
- **S 4.7:** The implementation of alternatives to the use of physical restraints should be encouraged and made available to interdisciplinary treatment teams;
- **S 4.8:** Structured programs to reduce the use of physical restraints including staff training including clinical, ethical and legal issue should be encouraged;
- **S 4.9:** When prescription of a psychotropic drug appears mandatory, choice of the appropiate drug must be made based on several criteria including, non exhaustively:
  - Previous history of psychotropic drugs
  - Aetiology of dementia
  - Age of the patient
  - Comorbidities
  - Other medications, especially in case of polypharmacy
  - Type of BPSD
  - Severity of BPSD
  - International, national and local recommandations

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- **S 4.10:** Antipsychotics use are at particularly high risk of adverse event and unfavorable outcomes;
- **S 4.11:** Although there are limitations, the time-limited use of dose- and qualitatively-adjusted antipsychotics by a trained physician is nonetheless of great value for many patients suffering from BPSD.
- **S 4.12:** When no alternative to antipsychotic prescription exists, atypical antipsychotics should be preferred, prescribed at the lowest efficient dose, be regularly and closely reassessed in order to limit prescription in time (maximum of twelve weeks), with reduction titration before withdrawal;
- **S 4.13:** After psychotropic treatment is started, continued access to non-pharmacological interventions should be guaranteed.

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Thank you

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