Psychotropic Management and CMS Regulations

INFINIUM PHARMACY

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- No conflicts of interest to disclose

Learning Objectives

- Define types of psychotropic medications
- Review appropriate use/appropriate diagnosis of psychotropic medications
- Review CMS regulations for gradual dosage reductions and clinical contraindications
  - 2025 updates to F757 and F605
- Understand the use of psychotropic medications in dementia
- Recognize adverse effects of psychotropic medications including Serotonin Syndrome and Neuroleptic Malignant Syndrome
- Understand Tardive Dyskinesia and AIMS scoring

Psychotropic Medications

- CMS defines a psychotropic medication as “any drug that affects brain activities associated with mental processes and behavior”
- These medications fall into the following therapeutic categories
  - Antipsychotics
  - Antidepressants
  - Anxiolytics
  - Sedative/hypnotics
  - Other
    - Antiepileptics
    - Antihistamines

42 CFR §483.45,

Psychotropics in LTC

- Psychotropic Utilization in the Long Term Care setting is quite prevalent with approximately 60% of nursing home residents' medication regimen having a psychotropic medication order

"CASPER Reporting User's Guide for MDS Providers | QIES Technical Support Office." *CASPER Reporting User's Guide for MDS Providers | QIES Technical Support Office*, qtso.cms.gov/reference-and-manuals/casper-reporting-users-guide-mds-providers. Accessed 26 Jan. 2023.

Knowledge Check 1

Which of the following is **NOT** one of the therapeutic categories of psychotropic medications?

A. Antipsychotics
B. Anxiolytics
C. Skeletal Muscle Relaxants
D. Anti-Depressants

Appropriate Use of Psychotropic Agents

- All psychotropic medication orders must show appropriate documentation in medical record for indication of use, along with the diagnosis for the condition which its being prescribed
  - For example, if a LTC resident has an order for an antiepileptic that can also be used to manage behaviors (i.e., divalproex, carbamazepine, etc.) and lacks a seizure diagnosis, this medication order must adhere to psychotropic medication requirements.
  - Per the State Operations Manual, "CMS is aware of situations where practitioners have potentially misdiagnosed residents with a condition for which antipsychotics are an approved use (i.e., new diagnosis of schizophrenia) which would then exclude the resident from the long-stay antipsychotic quality measure."
- Ensure diagnosis is consistent with medical condition and not external factors such as:
  - Other medical condition (i.e., increased confusion / delirium from UTI)
  - Adverse drug events from poly pharmacy regimens common in LTC setting
  - Behaviors from change in environment (i.e., relocation to LTC facility, change in daily routine, change in caregivers)
  - Various psychological stressor (i.e., loneliness, grief, etc.)

https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/downloads/appendix-pp-state-operations-manual.pdf. Accessed 26 Jan. 2023.

Regulations

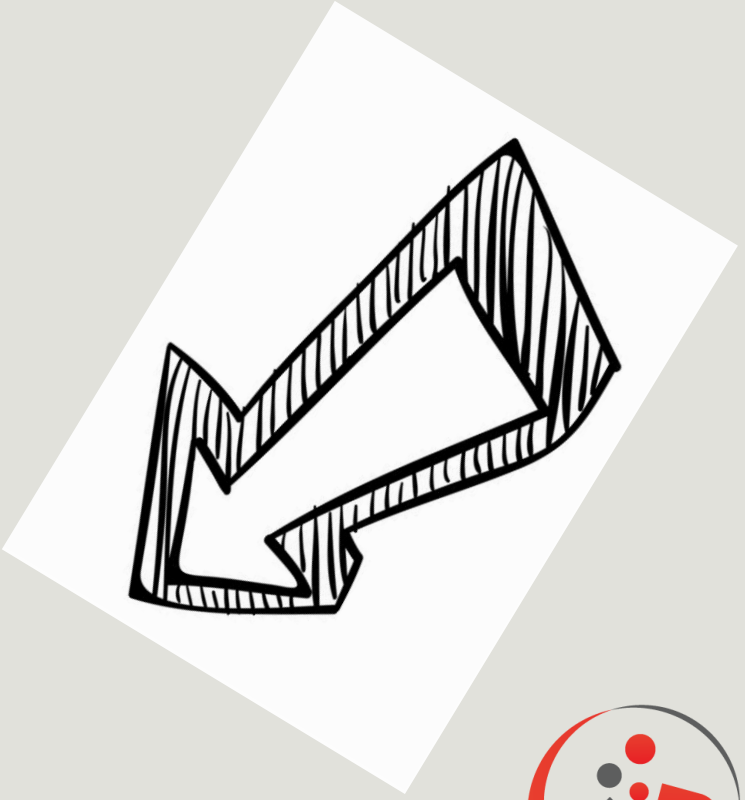
- Consultant pharmacists conduct an in-depth review of Long Term Care (LTC) residents' medication profile known as a *Medication Regimen Review* (MRR)
- During the MRR process, psychotropic agents are identified and assessed
- Psychotropic agents must be prescribed to treat a **specific** medical condition indicated by the overseeing physician
- Psychotropic agents must be assessed for *Gradual Dose Reductions* (GDRs)

2025 rule changes

- QSO-25-07-NH
- Pain, CPR, Infection Control, Covid, QAPI/QAA, MDS, Survey software, Physical Environment, Admission/transfer,
- Professional Standards and Medical Director: F658
  - Diagnosis without sufficient supporting documentation where antipsychotics are an approved indication
- F758 Combined into → F605 “Chemical Restraints/Unnecessary Psychotropic Medications”
- F757 – “Unnecessary Medications” revised to solely focus on non-psychotropic medications
- Effective date: 2/24/2025

Gradual Dose Reductions (GDR)

- Goals of GDR
  - Use of lowest effective dose of psychotropic agent
  - Decreased medication burden of agents no longer providing benefit to resident
  - Mitigating adverse effects of psychotropic agents by using lowest effective dosage
- All LTC residents' receiving psychotropic medication orders must be assessed for GDRs
- A GDR "is the stepwise tapering of a dose to determine if symptoms, conditions, or risks can be managed by a lower dose or if the dose or medication can be discontinued".
- <u>Must be conducted twice in the first year (separate quarters) then annually thereafter</u> *(unless clinically contraindicated)*



GDR Guidance

- Psychotropic medication usage should not increase during periods of antipsychotic medication dose reductions
- Other medications not classified as a psychotropic agent, that may affect cognition (i.e., anti-histamines and anti-epileptics) should not be used as a substitution for psychotropic medications and shall still require documented GDRs
- Be scrutinous of psychotropic agents (especially antipsychotics) with listed indication of Delirium
  - Often delirium symptoms have subsided, and a psychotropic agent is continued to be given by facility staff as they often help with occasional behaviors (**common deficiency during surveying**)

GDR Contraindications

- The physician has documented rationale that [further] dose reduction(s) is likely to decrease resident's function and/or increase behaviors

- The resident has failed previous [most recent] GDR attempt and has rationale why further attempts may be detrimental to resident's condition

Verduin, Marcia L. "The American Psychiatric Association Practice Guideline on the Use of Antipsychotics to Treat Agitation or Psychosis in Patients With Dementia." *Journal of Psychiatric Practice*, vol. 23, no. 2, Ovid Technologies (Wolters Kluwer Health), Mar. 2017, pp. 160–61. *Crossref*, https://doi.org/10.1097/pra.0000000000000212.

Knowledge Check 2

How often must a Gradual Dose Reduction (GDR) be assessed for a routine order in a *skilled* Long-Term Care facility without the presence of a clinical contraindication.

A. Monthly for the first year, then yearly thereafter
B. Quarterly for the first year, then yearly thereafter
C. Twice in the first year in separate quarters, then yearly thereafter

PRN Psychotropics

- Psychotropics medication orders may be written on a PRN basis in some situations to facilitate treatment of acute or emergent symptoms/behaviors
- All PRN *non antipsychotic* psychotropic medication order must have a defined stop date (14 days if not specified)
  - Therapy may be prescribed longer than 14 days if physician deems it necessary, documents rationale, and defines stop date to order
- All PRN *antipsychotics* **MUST** have a defined stop date within 14 days ***NO EXCEPTION***
  - If order is renewed, it must be documented in the medical record that the prescribing physician re-evaluated resident for appropriateness of new order

(§483.45(e)(3))

Knowledge Check 3

True or False: All PRN Antipsychotics must have a defined stop date within 14 days

Dementia

- Dementia is a broad condition characterizing various syndromes with a progressive decline in cognition and is a highly comorbid among the geriatric population
  - WHO estimates 55 million current diagnoses worldwide with approximately 10 million new diagnoses annually
- Dementia can present with behaviors such as agitation, delirium and psychosis for which psychotropic/neuroleptic agents may be needed to manage

Guidelines and Implementation | Practice Guidelines (psychiatryonline.org)

Dementia (who.int)

Dementia Pharmacotherapy

- NMDA receptor antagonist
  - Memantine
- Cholinesterase Inhibitors
  - Donepezil, Rivastigmine
- Both work to help lessen symptoms and slow progression of disease

Dementia and modifiable causes of agitation and psychosis

- Important to rule out modifiable factors contributing to agitation and psychosis
  - Appropriately managing resident's pain
  - Vision and Hearing loss
  - Environmental Factors
  - Bowel and Bladder issues
  - Trigger recognition
  - Medication titration (Think Beers list meds)

Dementia with Behaviors and Antipsychotic Regimens

- Antipsychotics carry a US boxed warning for increased mortality when treating elderly patients with dementia related psychosis

- The American Psychiatric Association (APA) recommends antipsychotic therapy in dementia patients should be reserved for agitation or psychosis that is severe, dangerous, or significantly distressing to the resident

Guidelines and Implementation | Practice Guidelines (psychiatryonline.org)

Preferred Antipsychotic Agents in Dementia

- Second Generation Antipsychotics > First Generation Antipsychotics
  - 2nd generation antipsychotics: aripiprazole, clozapine, quetiapine, olanzapine, risperidone, ziprasidone
  - 1st generation antipsychotics: chlorpromazine, haloperidol, fluphenazine
- Long-Acting Antipsychotic injections not recommended
- Haloperidol not recommended for nonemergent use (in the absence of delirium)
- Quetiapine and Clozapine recommended in patients with Lewy Body Dementia or Parkinson's Disease related dementia due to decreased incidence of worsened motor symptoms

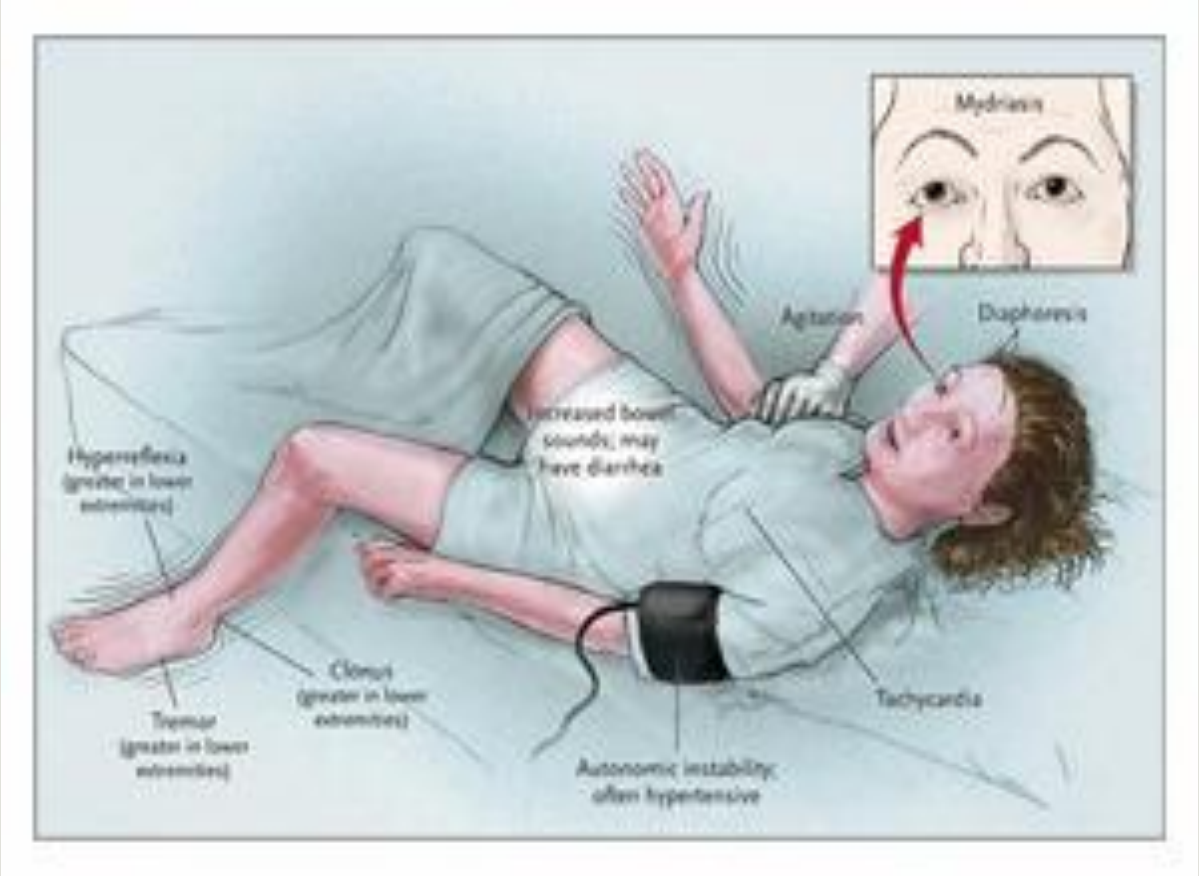
Generalized Psychotropic Adverse Drug Reactions (ADRs)

- Anticholinergic
  - Drowsiness, vision changes (blurred), dry mouth, urinary retention, confusion, and increased fall risk
- Cardiac
  - QT prolongation, orthostatic hypotension
- Mental Status Changes
  - Confusion, delirium, drowsiness,
- Extrapyramidal Symptoms (EPS)
  - Parkinsonian like movements
    - Tremor, Rigidity, Bradykinesia, Akathisia
    - Tardive dyskinesia (more later)

Antipsychotics in Seniors (uspharmacist.com)

Serotonin Syndrome (SS)

- Rare but potentially life-threatening syndrome from overstimulation of serotonin receptors characterized by:
  - elevated heart rate
  - hyperthermia
  - muscle rigidity
  - tremors
  - GI symptoms
  - various mental status changes



SS Causative Agents

- Selective Serotonin Reuptake Inhibitors (SSRIs)
  - Sertraline, Paroxetine, Citalopram, Escitalopram
- Selective Norepinephrine Reuptake Inhibitors (SNRI)
  - Venlafaxine, Desvenlafaxine, Duloxetine
- Tricyclic Antidepressants
  - Amitriptyline, Doxepin, Imipramine
- Other Antidepressants
  - Trazodone, Bupropion
- Anxiolytics
  - Buspirone
- Monoamine Oxidase Inhibitors (MAOIs)
  - Selegiline, phenelzine
- Triptans (migraine medications)
  - Sumatriptan, Rizatriptan, Rizatriptan
- Some Opioid Analgesics
  - Tramadol, Meperidine, Methadone, Tapentadol, Fentanyl
- Antiemetics
  - Ondansetron, Metoclopramide
- Anticonvulsants
  - Carbamazepine, Divalproex
- Linezolid (antibiotic)

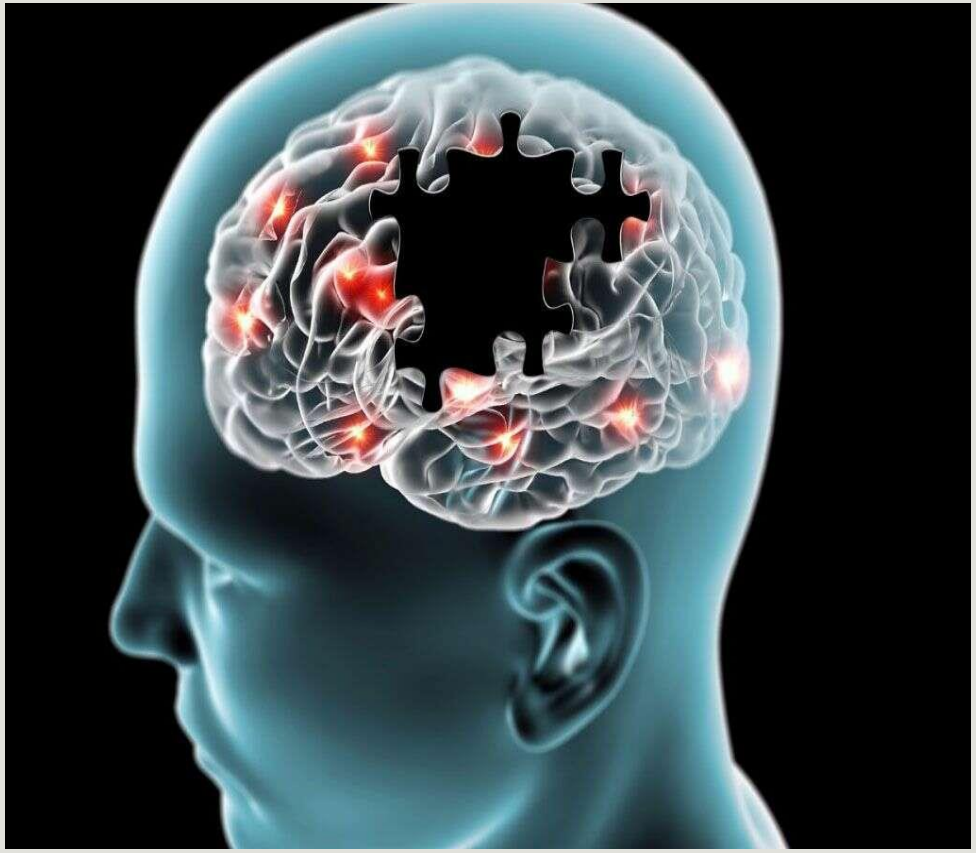
SS Management

- Recognition and response to symptoms of toxidrome
  - Degree of treatment depends on severity of SS symptoms
- Withdrawal or tapering of offending agents
- Benzodiazepine therapy may be helpful for agitation and tremors
- Cyproheptadine an antihistamine and serotonin antagonist is a widely used antidote
- Managing fever with antipyretics

Prevention, Diagnosis, and Management of Serotonin Syndrome | AAFP

Neuroleptic Malignant Syndrome (NMS)

- Presents similarly to Serotonin Syndrome
- Rare but potentially life-threatening syndrome resulting from usage of dopamine receptor antagonists (antipsychotics)
- Characterized by:
  - **muscle rigidity**
  - **fever**
  - elevated heart rate
  - diaphoresis
  - altered mental status
  - elevated blood pressure



NMS Causative Agents

- Typical Antipsychotic
  - Haloperidol, Fluphenazine, Chlorpromazine, Perphenazine, Trifluoperazine, Loxapine
- Atypical Antipsychotics
  - Olanzapine, Quetiapine, Clozapine, Risperidone, Aripiprazole, Ziprasidone
- Antiemetics
  - Metoclopramide, Prochlorperazine, Promethazine
- Miscellaneous Neuroleptic Agents
  - Desipramine, Lithium, Phenelzine, Tetrabenzine
- Withdrawal of Dopaminergic Agents
  - Carbidopa/levodopa, Bromocripine, Cabergoline, Ropinirole

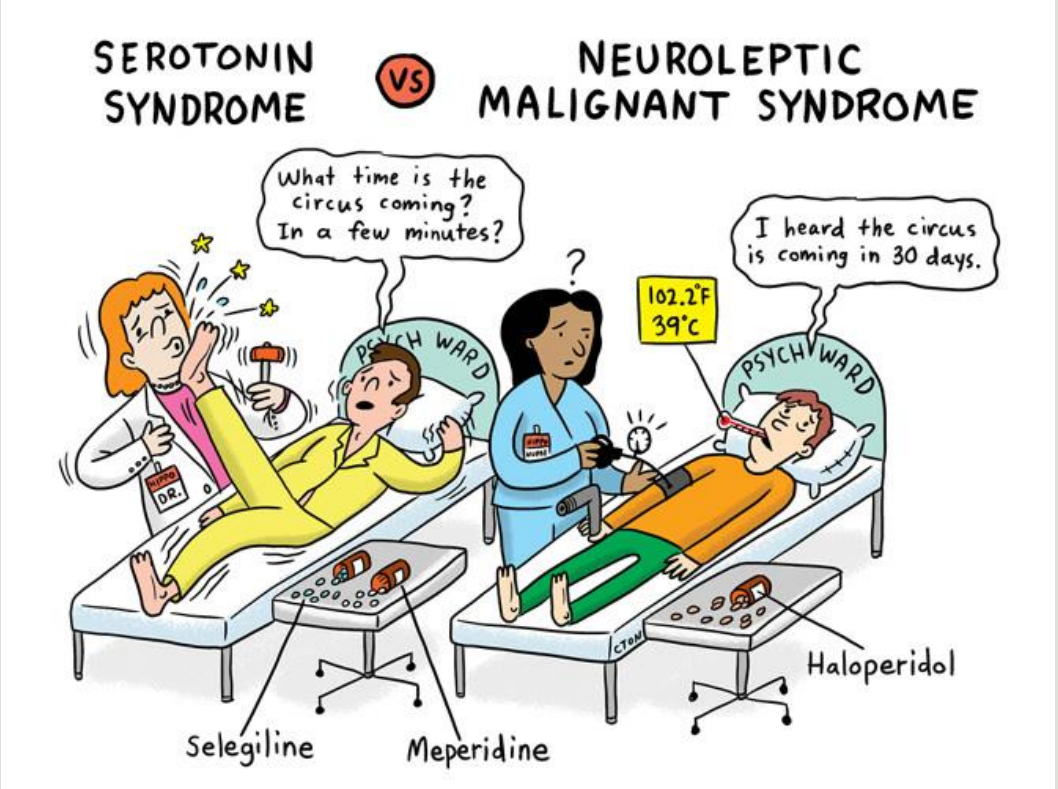
Neuroleptic Malignant Syndrome - StatPearls - NCBI Bookshelf (nih.gov)

Management of NMS

- Recognition and response to toxidrome
- Supportive therapy with antipyretics and fluid resuscitation
- Dantrolene (a skeletal muscle relaxant) for rigidity
- Benzodiazepines for anxiety, agitation and muscle spasms
- Dopamine agonists may be beneficial to correct hypodopaminergic state

Differentiating between NMS and SS

- Identification of causative agent is paramount
- NMS generally has a more gradual onset
- Fever and muscle rigidity are generally more pronounced in NMS
- Hyperreflexia and GI symptoms are more common in SS



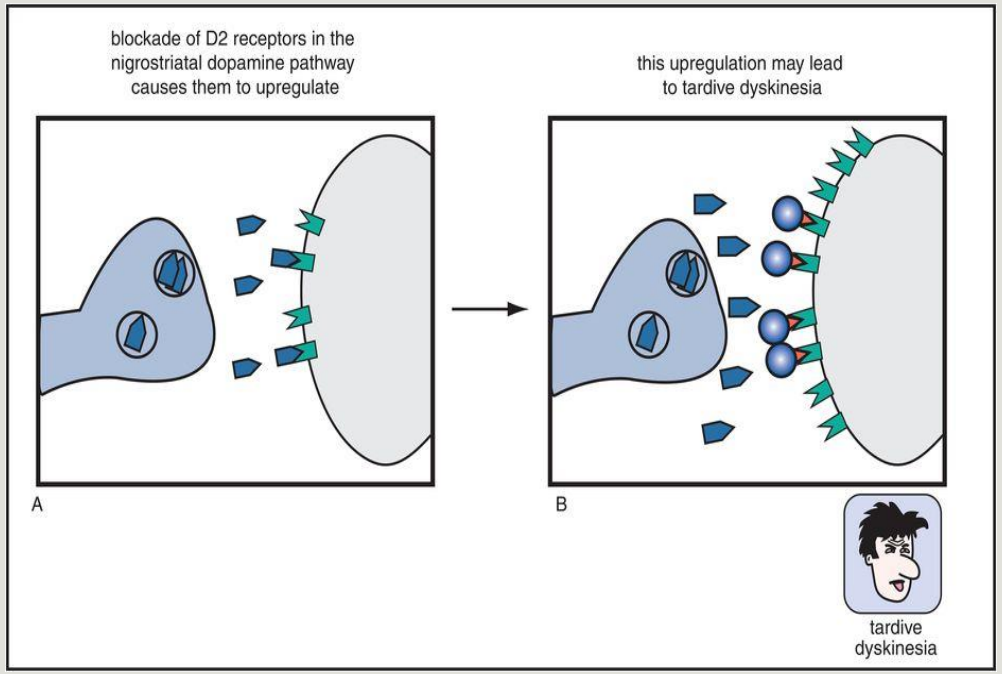
Tardive Dyskinesia (TD)

- TD is a non-life-threatening, chronic, and progressive movement disorder
- Per the DSM-V, "… a medication-induced movement disorder that persists despite discontinuation or change of the medications. As per DSM-V, to confirm a diagnosis of tardive dyskinesia, symptoms must persist for a month after discontinuation of the drug…"

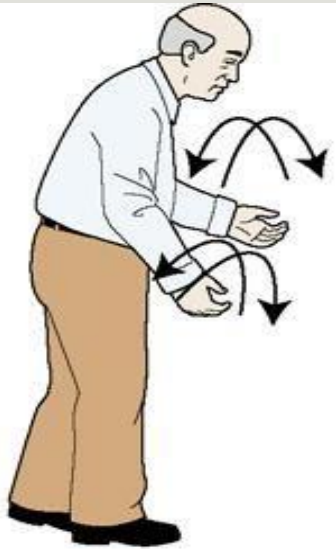
Tardive Dyskinesia - StatPearls - NCBI Bookshelf (nih.gov)

TD Pathophysiology

- Dopamine is a neurotransmitter important in regulating normal motor activity
- Chronic exposure to neuroleptic dopamine antagonists is the leading theory to the development of TD
  - Upregulation of postsynaptic DA receptors increases sensitivity to DA and causes TD symptomology

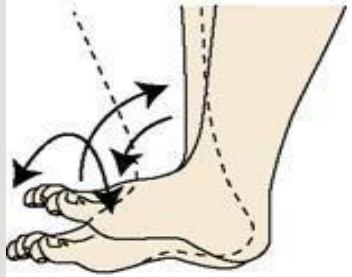


TD Presentation



Pseudo-parkinsonism
- Stooped posture
- Shuffling gait
- Rigidity
- Bradykinesia
- Tremors at rest
- Pill-rolling motion of the hand

Acute dystonia
- Facial grimacing
- Involuntary upward eye movement
- Muscle spasms of tongue, face, neck, and back (back muscle spasms cause trunk to arch forward)
- Laryngeal spasms



Akathisia
- Restless
- Trouble standing still
- Paces the floor
- Feet in constant motion, rocking back and forth

Tardive dyskinesia
- Protrusion and rolling the tongue
- Sucking and smacking movements of the lips
- Chewing motion
- Facial dyskinesia
- Involuntary movements of the body and extremities

TD Etiology

- Exposure
  - Typical Antipsychotics (highest incidence)
  - Atypical Antipsychotics
  - Antiemetics
    - Metoclopramide, Prochlorperazine
  - Long term anticholinergic linked to increased risk
- Incidence
  - Women > Men
  - Elderly

AIMS Evaluation

- The Abnormal Involuntary Movement Scale is a great single use dyskinesia scale for LTC
  - Originally developed for TD but can also be used in PD
- 12 item dyskinesia rating scale encompassing facial/oral, extremital, and trunk movements, dental status, and overall function
- Recommended to perform before initiation of neuroleptic agent (baseline) and quarterly thereafter

Management of TD

- Limited treatment options available
  - Primary prevention (avoidance of offending agent) is best option
- VMAT-2 Inhibitors have shown promise
  - Ingrezza®
    - KINECT 3 & 4 trials show statistically significant reduction in TD severity (via AIMS reduction) and long-term effectiveness and tolerability
  - Austedo®
    - AIM-TD, ARM-TD, and RIM-TD show statistically significant improvement of TD symptoms (with some patients having 50% AIMS reduction)

Knowledge Check 4

_____ is a rare a potentially life-threatening syndrome from dopamine antagonists, characterized by; elevated pulse, hyperthermia, muscle rigidity, and various GI symptoms

A. Tardive Dyskinesia
B. Neuroleptic Malignant Syndrome
C. Serotonin Syndrome

Recap

- Psychotropic agents are commonly seen in the LTC setting
- There are rules and regulations governing appropriate management of psychotropic agents
- It is important to appropriately and timely identify adverse effects of neuroleptic regimens so appropriate treatment and monitoring can follow

Thank You!