ProCare HospiceCare January/February Edition 2019

On-Demand Clinical News

How to Manage Dementia-Related Behaviors in a Red-Tape Environment

By Kristin Speer, Pharm. D., BCPS

Background

Until the CMS "Mega Rule" was published, antipsychotics (APs) and psychotropics (PTs) in general had been used rampantly, and perhaps inappropriately, for the management of dementia-related and other types of behaviors within the nursing home (NH) and long-term care (LTC) settings. This was a problem, as APs were found to be linked with an increased risk of death in the elderly dementia population – this is a published Black Box Warning (BBW) by the FDA. The larger class of PTs do not come with this BBW, but they do not come without significant side effects, either. Under the CMS "Mega Rule", prescribing and useage restrictions have been placed on all PTs within the NH and LTC settings, with even tighter control placed on APs, which is a subgroup of PTs. Currently, for any PT that is not an AP, an as-needed (PRN) prescription must be limited to 14 days, with no refills. Renewals are only allowed when the rationale for continuation and expected duration of therapy are documented. A PRN prescription for an AP must also be limited to 14 days, with no refills. Renewals for APs are only allowed when the patient has been assessed in person by the renewing prescriber, and the rationale for continuation and expected duration of therapy are documented. No such restrictions are currently placed on *scheduled* PT orders, including those for APs.

The CMS "Mega Rule" does not say that the use of PTs or APs are banned in NH and LTC environments. It does not specify any particular medication names. Instead, it sets parameters around when and how these medications can be used or prescribed. Put simply, the guidance wants prescribing of these medications to be more judicious and appropriate, with good use and documentation of non-pharmacologic management as part of the patient-centered care plan. PT and AP medications should not be used alone without efforts directed at non-pharmacologic management and assessment/treatment of potential underlying causes of behaviors.

CMS guidance is confusing, and can be fear-invoking. Due to this Rule, some NHs/LTC facilities will not allow haloperidol, while others will not allow any AP at all. Many have their own established policies and procedures surrounding the use of PTs, also (such as lorazepam). It is easy to understand why prescribers and other clinicians are struggling to manage symptoms of their dementia and other patients who present with distressing behaviors within NHs/LTC facilities.

When Can (Should) we use an Antipsychotic?

Of course, addressing pain, infection, constipation, and any other potential contributing factors is best practice for management of dementia-related behaviors, alongside or before AP use. Taking a non-pharmacologic approach is also a mainstay to behavior management. CMS F248: §483.15(f) Activities is a good resource for specific non-pharmacologic ideas that are listed according to the behaviors a patient is exhibiting. These concepts should be first and foremost practiced before or alongside utilization of any AP and PT medications.

With all the red-tape surrounding the use of PTs and particularly APs in these settings, how can we ensure we are using and prescribing these medications appropriately in our patients? The answer simply put: use an antipsychotic when there is an indication, or a 'suspected' indication for use (see further below regarding suspected indications). And of course, use them alongside or after non-pharmacologic approaches. Thus, forget about whether the patient has dementia; look at whether the patient (dementia or none) has an indication for AP use. See Table A.

Table A: Indications for Antipsychotics:*

Symptoms	Conditions
Immediate danger to self/others; dangerous aggression/violence	Obsessive Compulsive Disorder
Mania	Schizophrenia (and types)
Hallucinations/Delusions	Depression adjunct** (not monotherapy)
Paranoia	Bipolar Disorder
Delirium	Huntington's
Nausea/Vomiting	Tourette Syndrome

**Includes well-supported off-label indications*
***Indication only for certain antipsychotics*

Continued on Page 2

A 'suspected' indication may be present when several other non-pharmacologic and pharmacologic therapies, including treatments for underlying factors, have failed. Perhaps redirection with simple puzzles or soft music failed. Perhaps the patient is not responding to an analgesic trial; and infection, constipation, and other possible underlying causes have been ruled out. Assessment of underlying causes for behaviors is often difficult in dementia patients, and there may exist some hallucinations or some other indication that is difficult to assess or diagnose. Trying an antipsychotic in these cases who appear to have a 'suspected' indication is reasonable.

It is important to note that antipsychotics are the only class of medications that are indicated, and have been shown to treat, symptoms of psychosis (ex: hallucinations/delusions). If your patient has symptoms of psychosis, and causative medications have been stopped or cannot be stopped, an AP should be used. Medications like lorazepam, trazodone, or others that are not APs will not treat symptoms of psychosis, and may even contribute to these symptoms.

When Can (Should) we use Psychotropics?

A PT is "… any drug that affects brain activities associated with mental processes and behavior." Since there are possibly hundreds of psychotropics, refer to labelled and well-supported off-label indications per drug references and guidelines when using a psychotropic. It would be impossible (perhaps malpractice in some cases) to avoid the use of psychotropics in patients who need them. Simply use them when/if indicated, alongside or after non-medication approaches and treating any underlying causes. Consult a clinical pharmacist about which PT medication may be best for your patient. Also, see Table B as a general guide, and the "Examples" section below.

Table B: Which Psychotropics Should we Use?

Symptom	Therapy Type	Medication Examples
Anxiety/Restlessness, Non-Dangerous Agitation	Anxiolytic^; Antidepressant	buspirone^, SSRI (citalopram, trazodone), SNRI (venlafaxine), benzodiazepine (lorazepam)^, barbiturate (phenobarbital)^, promethazine^
Depression	Antidepressant	methylphenidate, ketamine (oral or intranasal compound), SSRI (citalopram), mirtazapine, SNRI (venlafaxine), DNRI (bupropion)
Mood lability (up/down; laughing/crying)	Mood stabilizer, Antipsychotic	valproic acid, lithium (only if monitoring serum levels), chlorpromazine ($$$), olanzapine, risperidone
Delirium	Antipsychotic	haloperidol, risperidone, quetiapine, olanzapine, etc.
Psychosis (hallucinations, delusions, paranoia)	Antipsychotic	haloperidol, risperidone, quetiapine, olanzapine, etc.
Meanness, aggression, hostile/violent agitation	Antipsychotic; Anxiolytic^; Other^^	haloperidol, risperidone, quetiapine, promethazine^, benzodiazepine (lorazepam)^, barbiturate (phenobarbital)^, carbamazepine^^

^generally, anxiolytic (anti-anxiety) = sedative=hypnotic
^^neither an antipsychotic nor sedative, but studies support use off-label for this symptom presentation

To summarize, use AP and PT medications with good clinical judgement, based on their appropriate indications for use, and alongside non-pharmacologic therapies and treatment of potential underlying causes in your dementia patients. Do not reach for them as initial, monotherapy. Document thoroughly, as this is as important as the treatment modalities.

Finally, always evaluate for the possibility of a dose reduction for APs and other PTs. Document any clinical contraindications against dose reductions or discontinuation, if appropriate (ex: "self-harm behaviors returned when dose reduced"). In hospice patients, continuation of antipsychotic may be needed for adequate symptom control, when other potential underlying causes have been addressed, ruled out, or unidentified.

Continued on Page 3

If antipsychotics are continued, document at each assessment what behavioral/non-pharm interventions have been and will be tried, what target behaviors are being monitored, and reasons for continued need, dose or frequency of AP or PT medication.

Examples:

If your dementia patient in a NH has cancer or other advanced illness with nausea and vomiting: a PRN order for haloperidol with the indication clearly documented ("for nausea/vomiting related to advanced illness") would be ok to use. However, it might be better to try (document) that other agents such as promethazine or ondansetron failed first. Or if your dementia patient had Huntington's disease, or hallucinations, these would be appropriate indications for trying an antipsychotic. Again, document the indications. Refer to Table A.

If your dementia patient with behavioral disturbances does *not* present with an indication for an AP, or the facility just won't allow them: in the majority of these cases, an anxiolytic (aka "anti-anxiety", a class of medications that falls under the PT definition) would be appropriate to start with. Buspirone is an anxiolytic that might be a good choice to start with in a patient who is a high fall risk and who needs more constant symptom control (as buspirone should be scheduled rather than PRN). Lorazepam might be a good option for a patient who is severely anxious/agitated, and who is not a high fall risk or unlikely to fall (bed-bound), or who needs occasional symptom control (as lorazepam can be used PRN). There are many other non-AP options for dementia-related behaviors, such as trazodone, mirtazapine, temazepam, phenobarbital, and others. Refer to Table B.

For assistance with determining whether an AP or PT medication may be appropriate, or what underlying causes or non-pharmacologic strategies might be considered, contact a ProCare clinical pharmacist at any time, 24/7.

References:

1. CMS "Mega Rule": Federal Register Volume 81, Issue 192 (October 4, 2016). URL: https://www.federalregister.gov/d/2016-23503
2. Lexicomp Online, Lexi-Drugs Online, Hudson, Ohio: Lexi-Comp, Inc.; 2018; July 19, 2018.

Upcoming Lunch and Learn Presentations

January: Updates on Regulatory Practice Guidelines in Hospice Care
Presenter: Brett Gillis, PharmD
Dates: Tuesday, January 8, 2019 at 3:00PM ET; Wednesday, January 9, 2019 at 12:00PM ET

February: Cost Effective Medication Management in End Stage COPD
Presenter: Kristin Speer, PharmD, BCPS
Dates: Tuesday, February 12, 2019 at 3:00PM ET; Wednesday, February 13, 2019 at 12:00PM ET

RSVP by contacting Suzanne Stewart, Lunch and Learn Coordinator, at:
1-800-662-0586 ext. 3303 or sstewart@procarerx.com

ProCare HospiceCare welcomes all suggestions and comments. If you would like additional information about our services, have ideas for articles, or wish to submit a comment, email us at **resources@procarerx.com**.

ProCare HospiceCare

1267 Professional Pkwy., Gainesville, GA 30507

Executive Editor: Meri Madison, PharmD
Editor: Kristin Speer, PharmD, BCPS

The information provided within this newsletter is proprietary to ProCare Rx. Any reprint or reuse of this information must be approved via written consent.