Identifying Patients with PBA

Onscreen Text: Identifying Patients with PBA

VO: Are your patients with a neurologic condition or brain injury who have been diagnosed with and treated for depression still experiencing uncontrollable laughing and/or crying episodes? Is it time to start thinking about PBA?

Onscreen Text: Actor portrayal

Onscreen Text: Is it time to start thinking about PBA?

Dr. Palladino: Hi, my name is Dr. Nick Palladino.

Onscreen Text: Dr. Nick Palladino, MD, JD
Internal Medicine Specialist

Dr. Palladino: I have a 70-year-old patient who has MS and a history of hypertension, diabetes, arthritis, and depression. She had been coming into my office monthly with her son and daughter who said to me, "Mom is just not right. She just starts crying and can't control it. What's going on? What can we do to help her?" Multiple drug therapies have been unsuccessful in controlling her crying outbursts.

Onscreen Text: "What can we do to help her?"

VO and Onscreen Text: Pseudobulbar Affect, or PBA, occurs secondary to a variety of otherwise unrelated neurologic conditions or brain injury. PBA is characterized by involuntary, sudden, frequent laughing and/or crying that is exaggerated or incongruent with the underlying mood.

Dr. McVige: Hi, I'm Dr. Jennifer McVige.

Onscreen Text: Dr. Jennifer McVige, MD, MA
Neurologist

Dr. McVige: I had a patient in his 20's who had two traumatic brain injuries. He was run over by a car when he was younger and on a separate occasion, he had a TV fall on his head. He was diagnosed with depression and oppositional defiant disorder.

Onscreen Text: He was crying and laughing uncontrollably in inappropriate situations.

Dr. McVige: After understanding his symptoms, I realized he was crying and laughing uncontrollably in inappropriate situations, and that his reaction to these behaviors may have contributed to his oppositional defiant disorder diagnosis.

VO and Onscreen Text: The number of patients who have PBA secondary to a neurologic condition or brain injury may be higher than you think.

VO: One study showed that 37% of patients with one or more of six underlying neurologic conditions may have PBA.

Onscreen Text: 37%* of patients with one or more of six underlying neurologic conditions may have PBA.

[Footnote]
*In a multicenter registry (N=5,290), a CNS-LS score greater than or equal to 13, suggesting the presence of PBA symptoms, was reported in 37% of patients with any one of six neurologic conditions.

Dr. McVige: I see the substantial impact PBA is having on the lives of some of my patients. That's why I think it's important to investigate if – and how – PBA might be affecting my other patients with an underlying neurologic condition or brain injury, particularly those who may also have a mood disorder like depression since I know how commonly they can occur together. Here are the steps I take to investigate PBA and I'd encourage you to use these too.

Onscreen Text: Steps to Diagnosing PBA

Dr. McVige: First, I ask my patient: Can you tell me about any changes in your laughing or crying since [your underlying neurologic diagnosis or brain injury]? to better understand if PBA symptoms are present and impacting their life.

Onscreen Text: Can you tell me about any changes in your laughing or crying since [your underlying neurologic diagnosis or brain injury]?

Dr. McVige: If I believe a patient may be experiencing PBA symptoms based on their answer, it's time to initiate the steps to diagnose. Hearing about the impact that PBA is having on my patient shows me the importance of continuing on to confirm a diagnosis. I start by confirming that the patient has an underlying neurologic condition or brain injury, which is a requirement for a PBA diagnosis.

Onscreen Text: Confirm the underlying diagnosis.

Dr. McVige: I always give the PHQ9 and the CNS-LS to all patients with TBI at our first consultation appointment. In the case of the patient I was just mentioning, he scored high on the CNS-LS.

VO: PBA occurs secondary to these underlying neurologic conditions, including brain injury: stroke, dementia, traumatic brain injury, Parkinson's disease, amyotrophic lateral sclerosis, multiple sclerosis.

Onscreen Text: Underlying Neurologic Conditions
- Stroke
- Dementia
- Traumatic Brain Injury
- Parkinson's Disease
- Amyotrophic Lateral Sclerosis
- Multiple Sclerosis

VO: And it may often co-occur with mood or behavioral disorders.

Onscreen Text: Common Comorbid Mood or Behavioral Disorders
- Depression
- Delusions
- Aggressions
- Personality changes
- Anxiety
- Post-traumatic stress disorder (PTSD)

Dr. Palladino: I find it beneficial to employ this process with my patients who I suspect could have PBA. And, once I've confirmed the underlying neurologic condition or brain injury, I determine if my patient's laughing or crying symptoms and presentation suggest PBA.

Onscreen Text: Determine if their laughing or crying symptoms and presentation suggest PBA.

Dr. Palladino: Are their laughing or crying episodes, involuntary, sudden, frequent, exaggerated, or incongruent?

Onscreen Text:
- Involuntary
- Sudden
- Frequent
- Exaggerated
- Incongruent

Dr Palladino: When I spoke to my patient and her family, they shared that she had been crying frequently at the dining room table and during weekend visits with her kids. Her son said to me that

there was no reason for her to be upset. He said to me, "she just starts crying and can't control it. It happens with her grandchildren, while she's cooking, even in the car driving home." My patient also shared that she had no idea why she was crying, since she wasn't even upset. It was clear to me that her symptoms and presentation suggested PBA.

Dr. McVige: The last step is to document my patient's PBA diagnosis with the proper ICD-10 Code, F48.2.

Onscreen Text: Document the diagnosis.

ICD-10 Code for PBA equals F48.2*
*Code is provided for informational purposes only and does not guarantee that coverage or reimbursement will result. Providers should use their professional judgment.

Dr. McVige: And here's the good news – a proper diagnosis can lead to the right treatment, because fortunately, PBA can be treated.

Onscreen Text: PBA can be treated.

VO and Onscreen Text: NUEDEXTA is the first and only FDA-approved treatment for PBA.

VO: NUEDEXTA contains quinidine, and should not be used concomitantly with other drugs containing quinidine, quinine, or mefloquine.

NUEDEXTA is contraindicated in patients with a history of NUEDEXTA-, quinine-, mefloquine-, or quinidine-induced thrombocytopenia, hepatitis, bone-marrow depression, lupus-like syndrome, or known hypersensitivity to dextromethorphan.

Dr. McVige: By knowing how to identify PBA in patients and treat it appropriately to reduce PBA episodes, you have the power to help patients. They can start getting back to living without PBA episodes interfering. All it takes is a simple question and a few minutes to administer a small measure (the CNS-LS) to make a huge impact.

VO: To learn more about Diagnosing PBA, visit NUEDEXTAHCP[dot]com.

Onscreen Text: Nick Palladino, MD, JD and Jennifer Mc.Vige, MD, MA, were compensated for their participation.

Onscreen Text and Narrator:
INDICATION and IMPORTANT SAFETY INFORMATION for NUEDEXTA®
(dextromethorphan HBr and quinidine sulfate)

NUEDEXTA®
(dextromethorphan HBr and quinidine sulfate) capsules 20 mg / 10 mg

INDICATION:

NUEDEXTA is indicated for the treatment of pseudobulbar affect (PBA).

PBA occurs secondary to a variety of otherwise unrelated neurologic conditions, and is characterized by involuntary, sudden, and frequent episodes of laughing and/or crying. PBA episodes typically occur out of proportion or incongruent to the underlying emotional state. PBA is a specific condition, distinct from other types of emotional lability that may occur in patients with neurologic disease or injury.

IMPORTANT SAFETY INFORMATION:

CONTRAINDICATIONS:

- **Quinidine and Related Drugs:** NUEDEXTA contains quinidine and should not be used concomitantly with other drugs containing quinidine, quinine, or mefloquine.
- **Hypersensitivity:** NUEDEXTA is contraindicated in patients with a history of NUEDEXTA-, quinine-, mefloquine-, or quinidine-induced thrombocytopenia, hepatitis, bone-marrow depression, lupus-like syndrome, or known hypersensitivity to dextromethorphan (e.g., rash, hives).
- **MAOIs:** NUEDEXTA is contraindicated in patients taking monoamine oxidase inhibitors (MAOIs), or in patients who have taken MAOIs within the preceding 14 days, due to the risk of serious and possibly fatal drug interactions, including serotonin syndrome. Allow at least 14 days after stopping NUEDEXTA before starting an MAOI.
- **Cardiovascular:** NUEDEXTA is contraindicated in patients with a prolonged QT interval, congenital long QT syndrome, history suggestive of torsades de pointes, heart failure, patients receiving drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine and pimozide), patients with complete atrioventricular (AV) block without implanted pacemaker, or at high risk of complete AV block.

Thrombocytopenia and Other Hypersensitivity Reactions: Quinidine can cause immune-mediated thrombocytopenia that can be severe or fatal. Non-specific symptoms, such as lightheadedness, chills, fever, nausea, and vomiting, can precede or occur with thrombocytopenia. NUEDEXTA should be discontinued immediately if thrombocytopenia occurs.

Hepatotoxicity: Hepatitis, including granulomatous hepatitis, has been reported in patients receiving quinidine, generally during the first few weeks of therapy. Discontinue immediately if this occurs.

Cardiac Effects: NUEDEXTA causes dose-dependent QTc prolongation. QT prolongation can cause torsades de pointes–type ventricular tachycardia, with the risk increasing as the degree of prolongation increases. When initiating NUEDEXTA in patients at risk for QT prolongation and torsades de pointes, electrocardiographic (ECG) evaluation of QT interval should be conducted at baseline and 3 to 4 hours after the first dose. Some risk factors include use with CYP3A4 inhibitors or

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drugs that prolong QT interval, electrolyte abnormalities, bradycardia, or left ventricular hypertrophy or dysfunction. If patients taking NUEDEXTA experience symptoms that could indicate the occurrence of cardiac arrhythmias (e.g., syncope or palpitations), NUEDEXTA should be discontinued, and the patient further evaluated.

Concomitant Use of CYP2D6 Substrates: NUEDEXTA inhibits CYP2D6 and may interact with other drugs metabolized by CYP2D6. Adjust dose of CYP2D6 substrates as needed.

Dizziness: NUEDEXTA may cause dizziness. Take precautions to reduce the risk of falls.

Serotonin Syndrome: Use of NUEDEXTA with selective serotonin reuptake inhibitors (SSRIs) or tricyclic antidepressants increases the risk of "serotonin syndrome."

Anticholinergic Effects of Quinidine: Monitor for worsening in myasthenia gravis.

Adverse Reactions: The most common adverse reactions (incidence of ⩾3% and two-fold greater than placebo) in patients taking NUEDEXTA are diarrhea, dizziness, cough, vomiting, asthenia, peripheral edema, urinary tract infection, influenza, increased gamma-glutamyltransferase, and flatulence.

These are not all the risks for use of NUEDEXTA.

To report SUSPECTED ADVERSE REACTIONS, contact Otsuka America Pharmaceutical, Inc. at 1-800-438-9927 or FDA at 1-800-FDA-1088 (www.fda.gov/medwatch).

Please see **FULL PRESCRIBING INFORMATION** at NUEDEXTAHCP.com.

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