

Why Didn't They Say Something

Onscreen Text: Why Didn't They Say Something?

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.

VO: Although you may already be aware of PBA...

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: In fact, 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.

*In a multicenter registry (N=5290), a CNS-LS score ≥ 13 , suggesting the presence of PBA symptoms, was reported in 37% of patients with any 1 of 6 neurologic conditions.

VO: While you may think your patients would talk to you about their symptoms, that's not always the case. Why not?

Simply put, a patient may hesitate to say something to their doctor, even if their PBA symptoms are having a substantial impact on their life.

Onscreen Text: Many PBA patients remain undiagnosed.

*Work SS, Colamonico JA, Bradley WG, Kaye RE. Pseudobulbar affect: an under-recognized and under-treated neurologic disorder. *Adv Ther.* 2011;28:586-601.

VO: Let's talk to two physicians to learn more about why their patients may have been hesitant to open up about their PBA symptoms.

Onscreen Text: Dr. Adam Sky, MD, DFAPA Community Psychiatrist
Dr. Jennifer McVige, MD, MA Neurologist

Dr. Sky and Dr. McVige were compensated for their participation.



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Dr. Sky: Hi, I'm Dr. Adam Sky.

Onscreen Text: Adam Sky, MD, DFAPA Community Psychiatrist

Dr. Sky: The one thing that Pseudobulbar Affect patients have in common is that they don't have anything in common! But in all seriousness, it's impossible to generalize about PBA patients' responses and attitudes. One reason patients may not speak up about their PBA symptoms is frankly because they're just embarrassed.

Onscreen Text: Reason 1: They're embarrassed.

Dr. Sky: I'll give you an example. I have a patient who has multiple sclerosis whom I've been following for years. I noticed she'd missed a bunch of appointments and hadn't been seen in almost a year. We called her to see what was going on, and she said: "Oh I just can't seem to get out of the house anymore." My first thought was that "Oh no, the multiple sclerosis has gotten worse," and I asked her about this, and she said: "No, it's really about the same. It's just that when I'm in a busy place like a doctor's office or a restaurant or a public place, I just start crying for no reason. It's so embarrassing to me."

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

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

Dr. McVige: I've seen it, too. Patients may be embarrassed to bring up their symptoms because they've already been a source of embarrassment and stress in their daily lives. They may also believe that it's just another part of a previously diagnosed neurologic condition.

Onscreen Text: Reason 2: They believe it's just another part of a previously diagnosed neurologic condition.

Dr. McVige: I have a patient with MS. I noticed the signs of PBA and brought them up at an appointment. When I asked why she had not discussed them with anyone she said she was embarrassed. She said she felt like she had too many things to discuss at the appointment and the findings were just another part of having the diagnosis of multiple sclerosis. She told me how she remembered not going to her son's school functions because she would cry too much and draw attention to herself and that she was really embarrassed. She felt like she was out of control.



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Many other patients have said the same thing. They also don't understand that this can be treated and helped. Many say that they assume, and their doctors assume that this is depression or related to their MS symptoms or other conditions.

Onscreen Text: They don't understand that PBA can be treated.

Dr. Sky: I've experienced that with patients, as well, Dr. McVige.

And when I look at this challenge – why patients may not say something about their PBA symptoms even though the impact of these symptoms on their life is significant – there's one more likely scenario I want to mention. Some patients simply may not understand what's happening or understand that their episodes can be managed and treated. This is because they may not know what PBA is.

Onscreen Text: Reason 4: They may not understand what's happening.

Dr. Sky: I had a patient, a businessman in a rural area who had suffered a series of strokes. Cognitively he was as sharp as can be, but as a result of the neurologic condition he had developed one of the more pronounced cases of PBA I've seen. Because of his uncontrollable laughing and crying, he withdrew completely from work and social activities to the point where the only way he would leave his house was if his children would literally force him to come to the doctor.

Once I asked him about what he was experiencing and determined that this was a case of PBA, I was able to explain the risks and benefits of treatment, and we started him on NUEDEXTA. Just knowing that what he was going through was a real condition and he now had a name for it was a huge relief for him.

I've found that the right question helps patients open up and talk about their PBA symptoms, even if they don't know how to – or if they even should – initiate the conversation themselves.

Onscreen Text: THE RIGHT QUESTION HELPS PATIENTS OPEN UP AND TALK ABOUT THEIR PBA SYMPTOMS.

VO: Great advice, Dr. Sky. Start with one simple question to uncover how PBA may be impacting your patient's life.

Onscreen Text: START WITH ONE SIMPLE QUESTION

VO: Ask your patient:

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



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Dr. Sky: It really is true. A single question can help you navigate the challenges that patients face in sharing their Pseudobulbar Affect symptoms, and in doing so open the door to a conversation about PBA's impact on their life.

VO and Onscreen Text: Patients shouldn't have to suffer in silence when PBA treatment is available.

VO: No patient should have to say:

VO and Onscreen text:

- It's so embarrassing.
- I never heard about PBA before.
- I thought it was just part of my depression.

VO: Fortunately, once you ask your patient the right question, learn about the impact of PBA on their lives and confirm a diagnosis, there is treatment available:

Onscreen Text:

Ask The Question
Learn About The Impact
Confirm A Diagnosis
PBA Can Be Treated

VO: NUEDEXTA, the first FDA-approved treatment for PBA, can help your patients manage their PBA symptoms.

Onscreen Text: NUEDEXTA logo

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 (eg, rash, hives).

Dr. Sky: Just because your patients aren't saying something, doesn't mean they aren't suffering.

Dr. McVige: Ask the right question and open up the door to diagnosis because the right treatment can make a real impact on a person's life. PBA diagnosis and treatment started with me –



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NUEDEXTA[®]

(dextromethorphan HBr and 20 mg
quinidine sulfate) capsules 10 mg

Dr. Sky and Dr. McVige: ...and it can start with you, too.

VO: Learn more about Diagnosing PBA at [NUEDEXTAHCP\[dot\]com](http://NUEDEXTAHCP.com).

End Slate:

NUEDEXTA logo

Visit NUEDEXTAHCP.COM

Adam Sky, MD, DFAPA, and Jennifer McVige, MD, MA, are paid consultants of Avanir Pharmaceuticals, Inc.

Onscreen Text and Narrator:

INDICATION and IMPORTANT SAFETY INFORMATION for NUEDEXTA[®]
(dextromethorphan HBr and quinidine sulfate)

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



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and pimozone), 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 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 $\geq 3\%$ 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).



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NUEDEXTA[®]

(dextromethorphan HBr and 20 mg
quinidine sulfate) capsules 10 mg

Please see [FULL PRESCRIBING INFORMATION](#) at [NUEDEXTAHCP.com](#).

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