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Limitations of Current Treatments: FDA-Approved and Off-Label Approaches

Announcer:
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Dr. Goldberg:
Hello, everyone. This is CME on ReachMD. I'm Dr. Joe Goldberg. I'm joined here today by my good friend and colleague, Dr. Roger McIntyre. Welcome, Roger.

Dr. McIntyre:
Joe, great to work with you.

Dr. Goldberg:
As always. So we're discussing the limitations of current treatments for PTSD both on- and off-label. Roger, what can you say about current treatments for PTSD, and what are the limitations when it comes to on-label and off-label?

Dr. McIntyre:
Joe, I think the question the way it's posed is so pertinent in PTSD, because we do have on-label and we certainly have a lot of off-label therapeutics that are applied to people with PTSD. Very briefly, Joe, the FDA has approved 2 medications for PTSD, sertraline and paroxetine. And frankly, they were approved quite some time ago, about a couple of decades ago. So these are indications that have been with us for quite some time.

Sertraline, of course, well known, and paroxetine, well known, as, in quotes, SSRIs, and they're well known for other therapeutic indications. But today, PTSD, we see efficacy and we see efficacy across the symptoms of PTSD. Now, Joe, there are different dimensions of psychopathology in PTSD: intrusion, avoidance, arousal, and disturbance and mood and cognition. And frankly, when these drugs were developed, sertraline and paroxetine, they were kind of developed with the older definition of PTSD that didn't have that fourth dimension, disturbance of mood and cognition, at the time. What I could say is, is that we have an overall significant improvement. Although, Joe, as you know, it's a somewhat modest overall improvement with sertraline and paroxetine, at least as evidenced by a total change score on a PTSD scale. And then, more sort of granularly, if you will, when you look at some of the subdimensions of PTSD, the treatments have differential efficacy. For example, certainly in my own experience, which would align with the evidence, is that they haven't been as strong, for example, in treating some of the avoidant symptoms in some patients.

Now, for those who are looking for a decision support, there are clinical practice guidelines. The VA has one, for example, the International Society for Traumatic Stress Studies, and the American Psychiatric Association. And in there, what you're going to see is a very brief description of what's on-label, I just covered it. And then, we get into the off-label pretty quickly. Now, off-label needs to be prefaced with, Joe, as you know, not FDA-approved. These are treatments that don't have the body of evidence, perhaps, that would be considered large, adequately designed studies, and so on. But there's been anecdote experience.

SNRIs, for example, venlafaxine comes to mind in that area. Other antidepressants could be considered, but not, again, well studied. I think about vortioxetine and its ability to treat anhedonia, emotional blunting, and cognition. We think about anticonvulsants, I think, off-label. We hear clinicians not infrequently will use anticonvulsants, GABAergic-type anticonvulsants, or valproate-type treatments.

Next category would be atypical antipsychotics. Have a long history of use in PTSD with varying degrees of quality. Lots of heterogeneity in the data. At least until recently, more sort of moderate certainty in the data, if you will. But helping certain symptoms that are very distressing, intrusion, especially some of the hyper-reactivity phenomenon in patients.

There's others which are guided by interesting academia in terms of antioxidants targeting glutamate, like ketamine. Other therapies targeting proteins like oxytocin and things like that, that people have looked at over the years. My own personal experience has been that CBT can be very helpful trauma-focused therapies. That to me is first line, but other therapies as well, including, not limited to, EMDR. For the future, virtual reality, augmented reality, that's interesting. Maybe the metaverse will come to treating PTSD, who knows? But that's certainly something we cross our fingers could be helpful.

So consult the guidelines. We have some on-label, but a lot of off-label treatments for our patients. And I'd be amiss, Joe, if I don't mention some of the drugs like prazosin, treatments like that. Again, these are more symptomatic, and I think that's the guiding principle. What are the key symptoms of PTSD? Try to find a treatment that makes coherence and sense and try to apply that in our patients.

Dr. Goldberg:
Wonderful overview. I would just add that if the clinician is implementing any treatment, they want to track its outcome with a scale like the PCL-5. If the patient is not showing signs of improvement, that's evidence for you to say this isn't working or it is working or in what domain. Someone might see improvement in sleep, but not necessarily hyperarousal. So this is part of the challenge. And I love the way you describe, Roger, that so many things have been looked at with variations in success and we very much look to the future for new things that are coming along.

Well, we're about out of time for now, but thank you all for joining us today. We hope this was helpful. Thank you, Roger, for sharing your wisdom with us, as always.

Dr. McIntyre:
Great to be with you, Joe.

Announcer:
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