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Optimizing the Diagnosis and Management of Overactive Bladder in Men and Older Adults

Announcer:

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Ms. Newman:

Welcome to the Practicing Clinicians Exchange CE/CME Medical Minute One, Improving Recognition of OAB in Men. This is the first in a series of 3 Medical Minutes on optimizing the diagnosis and management of overactive bladder in men and older adults.

I'm Diane Newman. I'm an Adult Nurse Practitioner and a Urology Specialist, and Adjunct Professor of Urology and Surgery Research Investigative Senior at the Perelman School of Medicine at University of Pennsylvania in Philadelphia. And I'm pleased to be joined by Dr. Scott MacDiarmid, Clinical Professor at the Department of Urology at the University of North Carolina, and Director of the Alliance Urology Bladder Control center in Chapel Hill, North Carolina. Welcome, Dr. MacDiarmid.

Dr. MacDiarmid:

Hi, Diane, I can't wait to do the program with you.

Ms. Newman:

Now let's go to our case study. Mike is our patient. He's 66 years old and he presents with a complaint of frequent voids during the day. He describes a sudden need to urinate, leading to leaks if he's not at home. No pain. Bladder feels empty after voiding but within a few hours, he has to go again. Embarrassment has had him avoiding outings with friends. He's a current smoker, 1 pack per week. Physical exam, BMI of 26, blood pressure 125/80. The digital rectal exam yielded 40-gram benign prostate, but his labs were within normal ranges.

I'm going to hand it over to Dr. MacDiarmid, and we will return to Mike in a little bit.

Dr. MacDiarmid:

Thanks, Diane. I'm Dr. Scott MacDiarmid, calling in from North Carolina. You know, we talk about prevalence here for a few minutes. And there's no question that millions of men have overactive bladder. The exact prevalence probably varies with the individual studies that are published. For instance, some of the data in this slide notes that approximately 25% of men over 40 have overactive bladder that they're bothered by just certain degree. I do like the longitudinal study that was from Sweden, where they took men over 44, followed them for just over 10 years, and the prevalence of OAB went up from 15% to 45%, so it tripled. There's no question in men and women, the prevalence of overactive bladder increases with age, you know, it does affect quality of life. Patients lose their self-esteem, they're embarrassed, it can affect intimacy, and especially if you have nighttime symptoms, it's associated with diminished productivity, absences, you know, you're just tired and trying to go to work. Overactive bladder in both sexes is associated with anxiety and depression. And there certainly with the frail and elderly, associated with a lot of risks.

I want to talk about the prevalence, one last point. And you might say, Scott, why is it so common in men as they age? In fact, in some papers it will say the prevalence is equal to men as it is in women. Well, it really comes down to terminology. If you have a male who's got frequency and urgency and maybe his flow is reasonable, let's say, or some days good, sometimes bad, and you sell an alpha blocker. You're supposed to call that patient BPH. That's what you're regulated to call them really because they're selling them that drug class. If you sell an OAB agent, you call them overactive bladder, even though it's the same male. You can see why so many men have overactive bladder, because in our practice, so many men have frequency and urgency. You may be calling them BPH, I may be calling them OAB, but it's the same patient. The bottom line is they're in our waiting room every day and they really do need her help. That's in a primary care office, geriatrician's office, as well as urology.

Now, what about common risk factors or things that are associated with overactive bladder? I started talking about BPH and that, again, may get down to terminology, but as you age, and you have a prostate, and it's getting larger, et cetera, a lot of them have OAB symptoms. I get in men and women, it's more common to people who smoke, they drink a lot of alcohol, drink a lot of caffeine. And also, if you think about the American population with diabetes and obesity, they are definitely related or associated with having overactive bladder in men and women; and hence, you can see why the prevalence is so high.

Diane, I'm going to go back to you and I think you have another question for us.

One of the definitions is urgency. You know, we have an International Continence Society, which really all these terms we define and, you know, again, urgency, I've got to go, look out, that sudden compelling urge that you need to pass urine almost immediately. Frequency is now defined sort of in the eye of the beholder, if the patient thinks they're going more frequently than their normal, that's frequency. I actually like the old definition, when someone was urinating 8 or more times a day. So that kind of gives you a good ballpark, someone's going 10-12 times a day they have a frequent bladder. Nighttime frequency, or nocturia, is really if you're getting up once or more at night. And urgency incontinence is when you've got to go, if you don't get there in time, you leak. And that's urge urinary incontinence. And as Diane just said, urgency is a driving symptom, because when you have urgency, you have frequency, if you get up in the middle of the night, and you have urgency, you don't get there in time, you leak.

Now the American Urological Association and our Incontinence Society called SUFU, we have diagnostic and treatment guidelines for overactive bladder. In that orange box, it's really for us as well, but at a primary care level, especially the basic workup is a history, a physical, and a urinalysis. You know the history, do you have stress incontinence, do you have urge incontinence? And we're going to come back to history a little bit more on another slide. The physical in a male, you check in his prostate size, but it really doesn't correlate with symptoms at all. Now, if you want to tell the patient that their prostate is large, and that's why they go so often, that's fine, but it really doesn't correlate with function, the size of the prostate. In women, why you do a pelvic, you're looking for prolapse, vaginal dryness, or stress incontinence. That's really the 3 reasons you do physical in a woman. And the urinalysis in men and women, in this case male, the 3 things you're looking for is sugar, blood, and infection.

Now in the blue box, or the middle box, I simply call these my diagnostic stethoscopes. Get lots of urine cultures. We're under-culturing our country, there's no question. Get cultures, find them one - find people that truly have an infection. If they're resistant to the antibiotic, you can switch them. A post void residual is the history behind that. If you void 200 and leave 100, then void 200 and leave 150, the glass is half full so you're peeing all the time. And you think you have overactive bladder, but to actually due to not emptying well. It would be nice to check a residual in men with OAB at a primary care level, but it's not necessary. It's not the guidelines. If you have a bladder scanner, go ahead, but otherwise you don't. And a bladder diary, I use a lot for nighttime frequency.

And now this is sort of a differential diagnosis. Overactive bladder, I've already talked about who they are. If you have urgency and frequency, maybe urge incontinence, but you also have poor flow and hesitancy, and you know, they have flow symptoms and OA – and urgency symptoms, call them BPH, that's fine. The obstructed patient is different. You know, 'I can hold it for 4 hours. I don't have urgency, but my flow is slow. I hesitate, I strain.' That's the prostate. That's the obstructed male patient.

What about referrals? I think all doctors, you know when to refer. I'll go through these quickly. If your suspected patient has a neurogenic bladder, they have a lot of pelvic pain or pain in their abdomen, possibly related to their bladder. I think men who have incontinence, to see a urologist. If you did measure the residual, it's elevated, they're having recurrent UTIs, you've been trying to treat them with various medications, but they're not reaching their treatment goal, please send them on. Your suspicion they may have cancer due to a DRE, digital rectal examination, or a PSA? And of course, send us hematuria.

What about educating your patients? It's nice to talk about normal bladder function and normal fluid intake as such, and we'll cover that in the next module. But what you really have to know here is you have overactive bladder, it's common, it's a chronic problem. There's a lot of treatment options. We can often get you a lot better, but we don't cure it. We don't fix it. But we can help you with many of the treatment tools that we have, so set up good expectations. As far as asking them about questions, you know, I'll say, 'Mr. Smith, on

average, how frequently do you go during the day? Every hour? Every 2 or 3 hours?' And if he's all over the place, I'll say, 'Look, could you sit through a 2-hour movie without needing to urinate?' I just liked that question. 'What about nighttime frequency? How many times a night do you get up? One? Three? Five?' I give them a choice and they tell me. 'Do you know what urge incontinence is? Stress incontinence is linked with coughing, sneezing, bending.' It's nice to ask people if they leak while they're asleep, if they have bedwetting. If they are incontinent, I say, 'How many pads a day do you use? One? Three? Six?' Give them a high number and they might be embarrassed to say they use 6 pads a day. Then I'll say, 'On average, are they damp? Moderately wet? Or soaked?' With male flow symptoms I say, 'Would you say in general your flow was good? Poor? Reasonable?' If they say it's poor, I say, 'Do you have to hesitate? Are you're straining? Are you stopping and starting? Do you feel empty when you're done?' And finally, probably the most important question if a lot of those were positive, 'Are your lower urinary tract symptoms bothering you? Because then we can help you.'

In terms of optimizing care, I think the general message is a condition in men and women is that overactive bladder is underdiagnosed and undertreated. It's underdiagnosed in many cases, because the patients aren't telling and the doctors aren't asking. Even the men think it's a normal consequence of getting older, they're not sure if there's good treatments, they're embarrassed. That's really why the docs and the primary care are doing so much better over the years in screening and saying, 'Hey, is your bladder bothering you a lot? And in what way? And can we help you with that?'

I'm going to send that back to you, Diane.

Ms. Newman:

Thank you so much, Scott, for such a good review of overactive bladder in men. I know that we see this in urology, but also these men present to primary care. So we're hopeful this helped you understand the initial assessments that you can do on this population.

So thank you very much for participating in this Medical Minute. Be sure to click on the button below your screen to earn your credit. We also invite you to view the other 2 medical minutes in this series on Optimizing the Diagnosis and Management of Overactive Bladder in Men and Older Adults.

Welcome to the Practicing Clinicians Exchange CE/CME Medical Minute Two - Management of OAB in Male and Older Patients. This is the second in a series of 3 Medical Minutes on Optimizing the Diagnosis and Management of Overactive Bladder in Men and Older Adults.

I'm Diane Newman. I'm an Adult Nurse Practitioner, and Adjunct Professor of Urology and Surgery at the Perelman School of Medicine at the University of Pennsylvania. I've been practicing in urology for many years, specifically seeing individuals with pelvic floor dysfunction and overactive bladder. I'm at the University of Pennsylvania in Philadelphia. And I'm very pleased to be joined by Dr. Scott MacDiarmid, Clinical Professor in the Department of Urology at the University of North Carolina, and Director of the Alliance Urology Bladder Control Center in Chapel Hill, North Carolina. So welcome, Dr. MacDiarmid.

Dr. MacDiarmid:

Thank you, Diane.

Ms. Newman:

I want to move on to our first patient, Susan. She's 68 years old. Physical exam was unremarkable. Blood pressure normal, healthy weight. She drinks 6 plus cups of caffeinated beverages daily at her stressful job as an office manager. She presented to your office 3 months ago with symptoms of frequent voids, urgency incontinence, not related to stress or activity. She was diagnosed with uncomplicated OAB. She received education and support for recommended behavioral management.

So now I'm going to hand this presentation over to Dr. MacDiarmid, and we'll return to Susan in a bit.

Dr. MacDiarmid:

Thanks, Diane. What I want to do in the next few slides is talk about behavioral therapy. Diane, be ready, I want to hear some tips from you because I know you're the expert on this. But I sort of want to give my general things that I do in my urology office, utilizing my nurses, but certainly advanced practice providers and primary care providers can use these tips. Let me give you 3 fluid tips. One, I actually tell patients with incontinence and overactive bladder, they should drink about 5 to 6, 8-ounce glasses of fluid a day. My daughter has those big cups. And if you're drinking many of those a day, you're just going to go much more often. So 5 to 6 glasses a day. Two, reduce the irritants, the caffeine, the carbonated beverages, the alcohol, and in some people that can make a really big deal. It may not irritate my bladder, but the next patient it does. And third, especially for the elderly, it's not healthy to dehydrate yourself. Plus concentrated urine really could actually irritate your bladder. So those are the 3 fluid tips.

Let's go into bladder training. I call it a holding drill, and I'll paint you the picture. Let's say this is a male or female and they're voiding every 45 to 60 minutes, they can't sit through a 2-hour movie, you happen to bladder scan and check the residual; you don't need to, but

if you did and it was almost empty, the patient is emptying fine. They're going every 45 to 60 minutes because they're having bladder spasms. Their bladder's lying to them that it's full when it's really not full. And if they have to realize that concept, so let's say in 45 minutes when they got to go, they take deep breaths that count backwards from 100, they tighten their pelvic floor muscles a little bit, and they hold the spasm and let it settle down. And each week they add 15 minutes to that holding drill and you're trying to retrain your bladder to stop telling you at low volumes that you have to go all the time. And you can really do that. Time or scheduled avoiding, at least when I use that term, it's when I walk in the room and it's usually a more elderly patient, and they don't have the pelvic floor or cognitive ability to kind of do holding drills, so I just get them to go, let's say, every 90 minutes or so with their watch, because if they hold it too long, they're just going to leak.

What about pelvic floor exercises? Let's talk about in this case, women but men do them as well, is that they actually Kegels or pelvic floor exercises, work for stress incontinence, they may even work better for urge incontinence. Of course, that's unproven. Because when you're putting that key in the door, and you've got to go really badly, you can contract that pelvic floor muscle, you can hold it in this neurologic negative reflex arc, goes back to your bladder and tells the contraction to settle down; that it actually really works neurologically. You want to be able to identify the muscle. And the muscle's really the one that if you're on an elevator trying not to pass gas, that muscle that you're squeezing, that is the Kegel muscle. You want to work at it almost like a weightlifting program. So you want to do 3 or four sets a day, let's say, do sets of 10. You want to contract the muscle, you want to relax it. The relaxation phase is as important as the contraction phase. And you can use reminders like every time you're at a red light or, for instance, on the phone, you're going to do, let's say, a set of 10.

Diane, what do you do? Are those reasonable tips?

Ms. Newman:

Scott, that was a really nice review of behavioral therapy. And I want to reinforce a few things that you mentioned. Number one is that there are bladder irritants such as caffeine. And I'm always surprised by how much caffeine intake people have. You know how many cups of coffee in the morning, and they tell me they're going frequently. So please review that. There was actually a recent article that was just published in *Menopause*, about artificial sweeteners affecting urgency incontinence and mixed incontinence. So go over the diet, and I tell patients do elimination diet. One of the complaints I get is, 'Diane, you took away everything I like.' The point is, let's see if any of those things do irritate your bladder and cause overactive bladder symptoms.

The other thing too, is that urgency, you're right with urge suppression, trying to control that urgency, that works. And probably 99% of my patients say they do Kegels. And what the literature has shown is that women are not isolating their muscle. So, you know, I really recommend that you in practice, do a digital exam in women to check whether they understand where their muscle is, and whether they can contract it. And to teach men Kegels with a rectal exam.

But Scott's going to go into drug therapy now, and I will tell you that actually, the best outcomes is when you combine behavioral therapy with drug therapy.

Dr. MacDiarmid:

Thank you, Diane. On this last behavioral therapy slide, I'll just summarize it by saying that, you know, we're always setting goals high, but we always have to have realistic goals with our patients. I think behavioral therapy, you know, the more motivated someone is, it probably would work better. Of course, that you'd want them to have cognitive and functional ability. But you'd be surprised on how many elderly, more frail people, when they see our physical therapists, they really help them a lot.

That makes the American Urologic Association, we have our guidelines for diagnosis and treatment. This is the treatment guidelines for overactive bladder in men and women. First line is behavioral. Second is that beta-3 agonists and anti-muscarinics. Third, there's 3 refractory treatments. One's called onabotulinum toxin A, and there's a peripheral nerve stimulation device, and sacral neuromodulation. We'll show a little bit of those or speak to them briefly in module 3.

You know, we're really proud of our Continence Center in North Carolina. We've got 3 or 4 physical therapists and offer first-line therapy. Second, we use a lot of anti-muscarinics and beta-3's. We combine them or you're almost like an internist treating blood pressure. Try this one, try this one. And in a very, you know, I think patient-centric way, we offer a lot of third-line therapies and do research in those. You know, I know it's cliché, but these are sort of tools in the toolbox. They're all imperfectly good. They're great tools. And we need more. And Diane's going to talk about one more case and then I'll talk a lot about the second-line therapies and the rest of the module. Diane?

Ms. Newman:

Before we go off our female patient case study, I just want to bring up a few points. She is postmenopausal at 68. He wants to rule out atrophy in that area of vagina. I remember there's estrogen receptors in the bladder, base of bladder, and the urethra. Because

transvaginal estrogen can really help overactive bladder symptoms, urgency, frequency, so you don't want to rule that out.

The other thing that we actually have quite a bit of data on women and men now who are moderately overweight. If they lose 5 to 10% of their weight through a weight reduction program, these symptoms can improve. So I just want to stress to you there are some things that you can do in the primary care environment that can really make an impact on this population, especially in women.

So let's go on to our next case study, which is Thomas, our 72-year-old male patient. Now he's a little bit more complicated. He has a 10-year history of type 2 diabetes, cardiovascular disease, hypertension. You can see his current medications there. He's on tamsulosin. Probably he has some degree of BPH. You can see his hemoglobin A1c, his GFR, blood pressure. And you can kind of see that, you know, he has some comorbidities there. He's socially active with his wife and friends. And he was diagnosed with overactive bladder 2 months ago. Ongoing management has been behavioral therapy. Despite symptom improvement, though, he had frequent daytime urination continues. And it concerns his wife, because he tripped recently and fell rushing to the bathroom. That is so common. That comes up in a lot of epidemiological studies, as far as when does that occur? When do people fall? And actually, it's on the way to the bathroom. Urgency is still bothersome. And he's requiring incontinence pads, when not socializing, to contain the urine leakage.

Dr. MacDiarmid:

Yeah, the title, Diane, basically summarizes that it's really the same conclusion is that as we get older and have overactive bladder, and by the time you start treating them, these same patients have a lot of comorbidities, and they're on a lot of medication. And as I'm aging, I'm really realizing my pill count is going up as well. And you know, the data is pretty similar in some of the studies that is by the time you're actually treating your OAB patient who's older, they've got up to 18 comorbidities and are on 10 or more meds, which is greater than non OAB population. So, it has that association.

Let's now talk about some of the treatments you know, there's anti-muscarinics and the beta-3 agonists. This lists the majority of the anti-muscarinics, which are almost all now are generic except for fesoterodine. You know, the anti-muscarinics block the cholinergic receptors, so it relaxes the bladder by hopefully taking away involuntary bladder urgency contractions. But these medicines, three tricks, one, there's no question that if you increase the dose, it can make a drug work better. Two, I call it hit or miss. The individual response of one of these agents in patients, whether its efficacy or side effects, is very heterogeneous. If one doesn't work, you try another. If one gave side effects, you throw it away and try another. So there's a lot of try this, try this. The third trick, and I wouldn't do it at a primary care level, I don't do it that often anymore at a urology level, because there's so many other things I can add or switch to, but I used to combine 2 anti-muscarinics in people who were partial responders to both of them. So, increase the dose or switch to a different one, really you'll help a lot more patients with any muscarinic so if you're using that drug class.

As far as side effects, because you're blocking the M2 receptor in the end, 3 – the muscarinic M3 or M2 receptor in other parts of the body, that's why you get the dry mouth. That's why you get the constipation. Rarely you get blurred vision. Sometimes you can increase in heart rate. And of course, sometimes people get sleepy and really have more acute CNS side effects. They're not that common. And we'll talk about in a moment, the possibility or the potential link to dementia or memory issues.

As far as, if you look at our guidelines, this anti-muscarinic is superior efficacy to others. And the main reason we don't is because there's been very few head-to-head studies. That's a difficult study for industry to sponsor, especially if they're not convinced they may win. Now as far as choosing them, I sort of use the hit-and-miss, if you've already been on one, well here, try another one. Two, there are some of them, I won't go into it in detail, but I think some anti-muscarinics have more dry mouth and have more constipation statistically than others. So, if you're concerned about that, you may use some others in patients. And finally, the co-pays vary. Even now, it's mind boggling on drugs that are 12 and 15 years old, how expensive some of them can be when other people are paying for them. So that is another variable.

Now what about anti-cholinergic burden that Diane alluded to? And by the time you're a Medicare patient with overactive bladder, about 75% of them are on at least one anti-muscarinic. You know, it's basically because we're getting older, you may not be clearing as well in your kidneys, you may not be metabolizing as well, maybe your blood-brain barrier is getting leakier. But this drug class may, you know, may be more related to cognition, or the negative effects of the anti-cholinergic burden. You know, as this accumulates, there may be some decreased cognition or physical - decrease in physical performance. And of course, any impairment even leading to falls and fractures. I was sort of anti this for a long time when I was in formal academics, and because I still think they're a very good treatment tool for our patients. But there's more and more and more data, hasn't proven it, but there's just this potential association between dementia and the anti-cholinergics. And here's some more data that says, if you've been on anti-muscarinics or anti-cholinergics versus not, your relative risk, as you age of being diagnosed with dementia, is greater.

Now, what about the beta-3's? The beta-3's relax by stimulating the beta-3 in the bladder, so the balloon relaxes, because these receptors are in the balloon or the bladder dome, and it relaxes the bladder. But we have 2 agents now, which you may or may not

realize that, but mirabegron has been around at 25 and 50 mg once a day for 8 or 9 years now. And in the last year, we have vibegron, it's once a day at 75 mg.

As far as side effects, you know, I tell patients this drug is very low and side effects, rarely a stuffy nose, rarely a headache, rarely some loose bowel movements. And if you look at those numbers, they're almost placebo-like but they're a little bit higher than placebo. And hence, that's why their side effects are on the package label. UTIs is on the label, but I can say in a CME-type arena, that I don't think they cause urinary tract infections, but the patient just got a urinary tract infection during the study. So of course, that goes into side effects box. Mirabegron, in a smaller percent of cases, can elevate your blood pressure. It's not very common, but it can. Patients should realize that. But the vibegron does not increase blood pressure based upon this data. And there's no blood pressure concern or warning on its label.

As far as the mirabegron has, again, been around many years, they've got great data in the elderly. In fact, the PILLAR study was - they took patients who had to be 65 or older. And then he did a placebo-controlled study. And they basically show that the side effect profile is about the same as the general population versus placebo with no increased sort of outliers or concerns. Vibegron, they studied 1,500 patients, and approximately 30% were over 65. So they've got lots of 65 and 75 and older data. And it's summarized on this slide that once again, it's the same side effect profile, very similar. There's no any real call-outs to say that oh, in the older people - persons, you have to realize that there may be an increased side effect; that data does not support that.

Diane and I have done a lot of, you know, in clinical practice, even academics, looking at combining a beta-3 agonist with an anti-muscarinic. And the literature is pretty full of some very good studies on mirabegron plus solifenacin at 5 mg because the mechanisms of action are different. So if you combine the 2, you think you may get a combined benefit just like 2 different blood pressure pills for blood pressure. And basically, if you look at the older population in this particular study, where they're over 65 on the left or over 75 on the right, the combination of solifenacin 5 mg with mirabegron on 50, statistically outperformed the either monotherapy in reducing urge incontinence in both populations. It's a nice treatment tool to combine these.

What about side effects? The side effects are exactly what you'd expect when you add a beta-3 and an anti-muscarinic. So you get the anti-muscarinic side effects and you get the uncommon beta-3 ones. So the most common side effects are the dry mouth and the constipation. There's no synergism or increased side effect. It's just almost if you just added the 2 together.

One other combination that this gentleman in our case study could enjoy was combining the beta-3 agonist to an alpha blocker. And in this particular PLUS study, it took men who were on an alpha blocker, but they still had residual overactive bladder symptoms, urgency, and frequency and the added mirabegron to the beta-3 and compared it to the placebo. And at 12 weeks, the beta-3 statistically outperformed adding placebo to the alpha blocker in reducing urgency and reducing frequency and increasing volume voided. And once again, very well tolerated in terms of safety and side effects.

You know, I think I like this last slide. A lot of my patients, oh at least 30% in an average day, are over 80, and maybe higher than that. And I just really sort of treat them generally the same. And the data would support that, you know, if you're older and you're more frail, we often can help you. But when it really gets more difficult is when their cognitive and their functional status is being jeopardized. I mean, they're frail, they're in a wheelchair, they can't get to the restroom quickly. That's the group that's just more challenging, but we still try to help them.

Back to you, Diane.

Ms. Newman:

Thank you very much, Scott. That was a really nice review of the current drug therapy we have for overactive bladder. And, you know, as clinicians, we have many to choose from. And we have to think about the pros and cons. You brought up some really good points about the fact that in an older population who has comorbidities, we may not want to give an anti-cholinergic because we may be concerned about the effect on cognition in that individual, and also that anti-cholinergic burden, which all of us are learning more and more about. And it's the accumulation of those medications that can be adversely affecting that patient.

But you know, what's so important, I feel what you said is the fact that age is not a deterrent to treating these individuals. We know that overactive bladder is very devastating to older and younger men and women. And that primary care is really the setting where this condition should be addressed. We try to provide you with the information to either do some behavioral therapy, talking about their diet, talking about, I don't know if there's a possibility of weight loss, talking about fluid intake, and also maybe how to control urgency. And can they use the pelvic floor muscle to control urgency, but also to prevent urine leakage. Those things do work. And in those individuals where they've gotten some benefit with behavioral, add on that medication, or like what I do is combine the 2, behavioral and drug therapy.

Is that usually your approach also, Scott?

Dr. MacDiarmid:

We're - behavioral therapy is just part of the treatment in many of our patients. And then we use a lot of monotherapy. I've given a beta-3 agonist first for years, because it's really based upon its safety and efficacy, still use anti-muscarinics but less so in the elderly. And they usually dictate that that's my concern that often will help the preauthorization process. It is a great treatment tool to add a beta-3 to an anti-muscarinic or a beta-3 to an alpha blocker.

Ms. Newman:

I think what you really nicely outline is there's 2 classes now, right? We have the anti-cholinergic, anti-muscarinics, and we have the beta-3's, we now have choices with a second beta-3 with vibegron. We now have Myrbetriq and vibegron, so you have something to choose from. And there's pros and cons for both. And I think that this makes us really be able to address overactive bladder in our patient population in both men and women. So I think that's so very important.

So thank you so much for participating in this Medical Minute. Be sure to click on the button below your screen to earn your credit. We also invite you to view the other 2 medical minutes in this series on Optimizing the Diagnosis and Management of Overactive Bladder in Men and in Older Adults. Thank you so much.

Welcome to the Practicing Clinicians Exchange CE/CME Medical Minute Three – Patient Engagement and Long-Term Management. This is the third in a series of 3 Medical Minutes on Optimizing the Diagnosis and Management of Overactive Bladder in Men and Older Adults.

I'm Diane Newman. I'm a Nurse Practitioner in Urology, and Adjunct Professor of Urology and Surgery at the Perelman School of Medicine at the University of Pennsylvania. I've been practicing in urology for many years, and I'm very pleased to be joined in this presentation by Dr. Scott MacDiarmid, who's a Clinical Professor in the Department of Urology at the University of North Carolina, and Director of the Alliance Urology Bladder Control Center in Chapel Hill, North Carolina. Welcome, Dr. MacDiarmid.

Dr. MacDiarmid:

Hello, Diane.

Ms. Newman:

We're going to start here now with our case study, who's Marian. She's a 72-year-old librarian. She was diagnosed with overactive bladder 5 months ago. First-line behavioral treatment was prescribed by her clinician and she got some benefit at 6 weeks. Usually, by the way, it takes about 4 to 6 weeks to see benefits from behavioral therapy. But she found the exercises and the dietary changes problematic with her job and complained that urinary incontinence and urinary urgency was disruptive. She was started on medical treatment with darifenacin 7.5 mg. Today, she presented for 8-week follow-up visit, still taking darifenacin 7.5 mg. Despite improvements with the medication, she's still not satisfied with that response that she's getting. Mild side effects, mainly dry mouth, is what she's experiencing, and they are continuing to be very bothersome.

Dr. MacDiarmid:

Just with, you know, any healthcare condition, it's really a shared decision-making process between the provider and the patient. And you want to sort of develop or set up a treatment care plan or strategy. I think there's sort of a balancing act, you want to have appropriate expectations, but then as the provider, try to set your goals for them quite high. You know, you're not going to get everybody perfect and 80% better, but they're counting on you to try to drive excellence by doing some of the tricks with switching medicines and increasing doses or using third-line therapies. So you know, set goals high, but again, with reasonable expectations.

I think when it comes to treating overactive bladder, though it can take up to 12 weeks, the majority of efficacy of a beta-3 agonist or anti-muscarinic, is around 4 weeks, roughly. I have the luxury of having samples. I tell the patient, 'You're having bladder spasms, I'm going to give you a medicine that relaxes the bladder or the balloon, that medicines are hit or miss, if one doesn't work, we'll try another, I'm going to give you a month of samples but don't fill the prescription unless it helps, or you'd be wasting money.' I give them a month really, because of that, you know the drug has most of its effect by then. And it's kind of cliché to say, but overactive bladder is a little bit like golfing, you'll have good days and bad days. And after a month, when they go to the pharmacy to pay for that prescription, whether it's \$20, \$90, or \$50, what have you, they can kind of get a good feeling of is it worth it for them, you know, looking back over that month. So just sort of give them those expectations.

I think if you want to improve adherence, and we'll talk about adherence more and more in the next few slides, the patient just really needs to buy into their part of the treatment. And they have to be adherent to their behavioral therapy and their pharmacotherapy. And again, encourage them you're on this pathway, we want you to come back. There's lots of other things that we can fine tune, hopefully to

reach your treatment goal.

You know, the adherence numbers, especially with anti-muscarinics, are not very good in the literature. Let's go to the middle part of that box. And also, to summarize some of the data, I would say if you're taking an anti-muscarinic, probably 65% of the patients aren't taking it at 6 months, and even 90% or so are not taking it at the year, you'd say, why; I'd say well, decreased efficacy, increased side effects, or maybe cost, especially years ago. The beta-3 data is better, you know, the adherence rate could be as high as 40% at 1 year. That's actually very good for any drug. That's actually a very good number. And perhaps that's because that's a testimony perhaps to its low side effect profile. But no question that adherence is an issue with any health condition taking medications, and OAB is not an exception.

To improve adherence, again, we want to promote realistic expectations. There's no question when you give these behavioral therapies, if you have really good handouts, that really I think helps patients be much more compliant. And it's pretty easy to come up with some nice ones that can quickly be instructional to the patients, even the companies may be able to provide you some. But there's no question you want them to realize that, in this case, they're on the overactive bladder treatment pathway, come back, we have other ways of helping you. When they do come back, you want to ask them, you know, are they having side effects. If they're having side effects, you can switch them to another anti-muscarinic. Or if they're on anti-muscarinic, you can switch them to a beta-3. You could lower the dose. If you lower the dose, statistically, that can decrease the side effect. There's some times you have them on, let's say an anti-muscarinic, and it's the only pill that's really helping them but they're getting some dry mouth, they're getting some constipation, you can finally say, look, we're going to accept that that helped the dry mouth and constipation by taking some stool softener, or using sugar-free lozenges, some oral lubricants. And sort of help manage the, let's say, tolerable side effect, because this drug just works so well. When they come back, you want to assess about their efficacy. And also, a nice question I used to say, you know, to the patient, 'Mrs. Smith, don't sugarcoat it on my behalf, but is the medicine making you 20% better? 50% better? 80% better? Just give me a ballpark number.' And you want to again, try to set pretty good goals for them. If you're not getting the efficacy you want, what are the tricks? You can increase the dose, you can switch to a different drug in the same class or to a different drug class. You can combine them. And don't forget the behavioral therapy. And of course, you can always move on to the third line or refractory OAB treatments.

The third-line OAB treatments, I'm just going to summarize. I'll just spend a couple of minutes on these. You know, third-party payers really want you to fail in general 2 overactive bladder medications to have onabotulinum toxin A or the peripheral tibial nerve stimulation or the sacral neuromodulation. That's generally – and they don't care if it's due to efficacy or side effects. You know, onabotulinum toxin, we place a little catheter, patient's fully awake, little catheter goes in their bladder, we put some lidocaine or morphine in their bladder for 20 minutes, then come in, look in with a cystoscope. And I'm just injecting with a cystoscope right into the bladder, the patient's completely awake. They sometimes feel pinches, they sometimes don't feel anything. The odd one, they go, 'Ooh, that one hurt,' almost like when you get a dental cleaning like the odd time it hurts. And then you're done. It takes about 4 or 5 minutes to do. They get up and they leave. They may see a little blood in their urine for a couple of days. We give them antibiotics to prevent infection. And within 1, sometimes 2 weeks, about 70% of people are a lot better. They're not perfect, but they're a lot better. And it generally lasts about 6 months.

The tibial nerve stimulation, there's an acupuncture point, I guess I could call it the lower ankle. That's a tibial nerve. You can put this little needle next to it and stimulate it 30 minutes, once a week for 12 weeks, and about 70-80% of people are a lot better and they go down to 30 minutes once a month to maintain the OAB improvement. We would have hundreds of patients come into our center and have that done. We've been doing it now for 8 or 9 years. And then a sacral nerve stimulators is that implant that goes in the upper buttock. It's like a little pacemaker. It has a lead that goes to the S3 foramina, and it works really well for refractory overactive bladder. And I won't really go through that in much detail in the fact that, you know, now there's a competitor, but the original device has been around about 25 years. And it really helps a lot of patients.

There's now a new ankle implant that looks like a nickel, that you can actually, under local anesthesia, put it next to that tibial nerve down near that ankle bone. It's just got its code from Medicare so that it hasn't really become that popular yet because of that, but it just recently got its code in FDA approval. I think then hopefully that will sort of give the primary care providers and the practitioners a good feel for these third-line therapies.

Ms. Newman:

Yes, thank you so much, Scott. And you know, the thing I want to stress with what Scott was saying is that, you need to find out, number one, when you talk to a patient with overactive bladder, what's your most bothersome symptom? I can't tell you how many times I do a history, and when I listen to their history, think, Oh, it must be this. And then when you ask them, 'What do you really want to see improvement in,' it's totally different than what I thought they might say. They're not really satisfied unless you really find out what's most bothersome. You really want to be upfront with them and do shared decision-making. The other thing I ask too is, do they want an

immediate result? Medications usually work within 2 to 4 weeks. Behavioral therapy is going to take a little bit longer. What's sometimes a little bit discouraging to me is that these patients live with overactive bladder for many, many years. And finally, when they come forward, they may report it to you, they want to see improvement right away because, I don't know, they're going on a trip. They're going to an event like a wedding and they don't want to worry about having to always rush to the bathroom. So you really want to do a little bit of discussion as far as what is their goal? What's the most bothersome symptom? So that, you know, it's a win-win situation for both of you.

So thank you very much for participating in this Medical Minute. Be sure to click on the button below on your screen to earn your credit. We also invite you to view the other 2 Medical Minutes in this series on Optimizing the Diagnosis and Management of Overactive Bladder in Men and Older Adults. Thank you.

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