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VOLUME 2 – ISSUE 11: TRANSCRIPT

Risks and Benefits of SGLT-2 Inhibitor Agents

Our guest author is Anne Peters, MD, from the Keck School of Medicine of the University of Southern California in Los Angeles, California.

After participating in this activity, the participant will demonstrate the ability to:

- Describe the glucose lowering effects of SGLT-2 inhibitors.
- Discuss the cardiovascular outcome data of empagliflozin with regards to its impact on patient care.
- Discuss common side effects of SGLT-2 inhibitors and how to avoid them.

This discussion, offered as a downloadable audio file and companion transcript, covers the important topic of SGLT-2 inhibitor agents. This program is a follow up to the [Volume 2, Issue 10 eDiabetes Review newsletter – Risks and Benefits of SGLT-2 Inhibitor Agents](#).

Unlabeled/Unapproved Uses

Anne Peters, MD has indicated that her discussion today will contain references to the unlabeled or unapproved uses of SGLT-2 inhibitor agents for the management of type 1 diabetes.

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Guest Faculty Disclosure

Anne Peters, MD, has indicated that she has been on the advisory board and/or consulted for Abbott Diabetes Care, Becton Dickinson, Bigfoot Biomedical, Biodel, Boehringer Ingelheim, CVS/Caremark, Eli Lilly and Company, Bristol-Myers Squibb, AstraZeneca, Intarcia, Merck, Janssen, Lexicon, Novo Nordisk, OptumRx, and Theralin. She has received research grant funding from Janssen and Medtronic Foundation and editorial fees from Medscape.

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BOB BUSKER: Welcome to this eDiabetes Review Podcast.

Today's discussion is a companion piece to our newsletter issue on the *Risks and Benefits of SGLT2 Inhibitor Agents*. With us today is that issue's author, Dr. Anne Peters, Professor at the Keck School of Medicine at the University of Southern California, and Director of the USC Clinical Diabetes Program.

eDiabetes Review is jointly presented by the Johns Hopkins University School of Medicine, and the Institute for Johns Hopkins Nursing. This program is supported by educational grants from AstraZeneca and Merck.

Learning objectives for this audio program include:

- Describe the glucose lowering effects of SGLT-2 inhibitor agents.
- Summarize the cardiovascular outcome data of the SGLT-2 inhibitor empagliflozin with regards to its impact on patient care.
- Discuss the common side effects of SGLT-2 inhibitor use and how to avoid them.

Dr. Peters has indicated that she has been on the advisory board and/or consulted for Abbott Diabetes Care, Becton Dickinson, Bigfoot Biomedical, Bidel, Boehringer Ingelheim, CVS/Caremark, Eli Lilly and Company, Bristol-Myers Squibb, AstraZeneca, Intarcia, Merck, Janssen, Lexicon, Novo Nordisk, OptumRx, and Thermalin. She has received research grant funding from Janssen and Medtronic Foundation and editorial fees from Medscape. She has indicated that her discussion today will contain references to the unlabeled or unapproved uses of SGLT-2 inhibitor agents for the management of type 1 diabetes.

Dr. Peters, thank you for joining us today.

DR. ANNE PETERS: Thanks for having me.

MR. BUSKER: In your newsletter issue, doctor, you reviewed much of the current data describing the safety and efficacy of a number of the available SGLT-2 inhibitors. What I'd like to do today is discuss how that information can impact actual practice in the clinic. So start us off, if you would please, doctor, with a patient scenario.

DR. PETERS: This is a 56 year old female who has type 2 diabetes; she is fairly typical. Her BMI is 30.2, her A1C is 7.9%, she's been on metformin alone, and she wants to get down to an A1C of less than 7% but hasn't been successful. She has normal renal function and is otherwise healthy. Her goal, in addition to reducing her blood sugars, is to lose some weight, and her only real complaint is that she's had intermittent mycotic vaginal infections in the past, but none within the past six months.

MR. BUSKER: As you said, she's a typical patient. She's overweight, she's not well controlled on metformin monotherapy, otherwise she's pretty healthy. What's your first step in making changes to her therapy?

DR. PETERS: With this patient, and with all my patients, I walk them through the steps in the ADA algorithm and talk about all the available options because I want them to feel engaged in the process of their care. Some settings in which I practice may not have an unlimited formulary, and often it helps me in advance to have some sense of what the patient's options are. But in a patient such as this one, where she has choice, I would go through why I would choose what I would choose.

Because her goal, and one of the things that will keep her working with me, is helping her with weight loss, I would not use a sulfonylurea agent, pioglitazone or insulin as a second line therapy. All of these agents are associated with weight gain, and sulfonylurea agents and insulin can cause hypoglycemia. It's particularly important not to say that insulin is a bad drug, because in the future we may need to use insulin in this woman, so I don't want to set her off thinking insulin is terrible. I just want to say something like, you don't need insulin now, and we can work with some of the other agents, but I want you to understand that if that's necessary in the future I can help you use insulin in an effective way.

I go through what I don't want to use and then I go through what the options are that might be reasonable here. A DPP4 inhibitor is a nice choice. It doesn't cause hypoglycemia or weight gain, but her A1C is 7.9%. You're not likely to get an adequate A1C reduction and you're not likely to get her down below 7% with a DPP4 inhibitor, so that might not be as useful, and you don't get weight loss.

We do have two agents, though, that I would tell her about. The GLP1 receptor agonist class and the SGLT2 inhibitor class would help fit her goals and lower her A1C. I would describe how those agents work and then talk about risks and benefits.

MR. BUSKER: A GLP1 receptor agonist or a SGLT-2 inhibitor — what are the key factors that would influence your decision between those two agents?

DR. PETERS: When I'm helping a patient decide between starting a GLP1 receptor agonist or an SGLT2 inhibitor, I go through the risks and benefits of each and let the patient decide. It's not up to me. In fact, in my experience, if a patient chooses an agent they're much more likely to take it and be willing to put up with some of the side effects.

The key difference is that a GLP1 receptor agonist is an injection and an SGLT2 inhibitor is a pill. They work very differently, so I describe how each of the agents works and what side effects the patient might experience.

If I discuss the GLP1 receptor agonist first, which is an injection, I make sure that I show the patient what the pen device looks like, because I don't want them to have some horrible image of an injection as a big needle; I want to show them the tiny needles they will be using so they can make an informed decision. I also tell them it's either a once a day or a once a week injection, and then I talk about the GI side effects that might occur.

Then I discuss the SGLT2 inhibitor class, discussing that it's a pill — which patients obviously like. But because she has a history of mycotic vaginal infections, which can occur more often with an SGLT2 inhibitor because patients are more glucosuric, there is an increased risk for mycotic vaginal infections and urinary tract infections.

I go through the options with the patient and judge their preference for the agent they would like to start next. Knowing that diabetes is a progressive disease, I always make sure that patients don't reject an agent in their mind, because in the future we may need to try another drug. I want to engage the patient in a discussion about the options available without putting a negative spin on any of them, just be informative and neutral as long as the patient doesn't have contraindications to any of these drugs.

MR. BUSKER: Well let's say she does choose the SGLT2 inhibitor. What advice would you give her before she starts therapy?

DR. PETERS: When I start a patient on an SGLT2 inhibitor, I am very clear about what to expect, because if I'm not, and they start an SGLT2 inhibitor and start urinating more frequently — especially if they wake up at night to urinate — they will be unhappy. So I tell patients, especially if they've ever been on a diuretic, that this is, in essence, a diuretic for glucose. If they haven't been on a diuretic I tell them the drug pulls both water and sugar out of their body. Most patients understand this, and they like the idea that instead of the sugar being in their blood, they will pee it out in their urine. I get them used to the notion of what this drug is going to do from the get-go.

I'll often start with the lowest dose, but even before that, I may have the patient split the pill at first, particularly if their blood sugars are very high, because if you're going to make them glucosuric, the higher their blood sugar, the more glucose they'll put into their urine and the more symptomatic they'll be.

Regardless, at the start I make sure they take it in the morning and either the lowest dose or half the lowest dose, and then I make sure they're prepared to urinate more often.

Then I make sure they don't become dehydrated, particularly if it's summer and they're sweating a lot. I don't want them to be urinating more often but not drinking enough fluid. Occasionally I've had a patient who started drinking so much fluid that they became even more polyuric and it was a real issue, so I just want to talk about normal hydration, not over- or underhydrating.

In our patient, I would discuss the other issues with these agents, including the increased risk for yeast infections and urinary tract infections.

MR. BUSKER: You noted in your initial description that this patient has suffered from yeast infections before. So if you would please, give us some specifics about what you'd tell her about the increased risk of recurrence?

DR. PETERS: Patients who have had a mycotic vaginal infection know what the signs and symptoms

are. My role as provider is to make sure it doesn't escalate. I want her to catch an infection from the beginning when it's a minor irritation, before it becomes a more significant problem.

So I talk about having some sort of local antifungal cream available at just the slightest bit of irritation and apply it topically to help deal with the mycotic infection just when it starts. You can also give an oral antifungal, fluconazole, if necessary, to have on hand. I don't necessarily do that unless somebody has had a lot of difficulty and may be going out of town, for example. I want to know if a patient is having significant symptoms that might require oral medication to treat it. So I make sure that they're aware of this, have at least some topical preparation to use, and tell them to contact me if there's more of a problem.

The same thing with the bladder infection issue. I make sure that patients are aware of it. Some patients have had recurrent UTIs in the past, and they may have an antibiotic on hand in case that happens. Bladder infections must be treated early, so if a patient develops symptoms, particularly dysuria or pyuria – something more than the just increase in urination with this drug – I want to be sure they are treated right away for that. The treatment is the same as for any urinary tract infection a patient might have, but it's important to treat it early and differentiate it from the increase in urination that comes with the drug.

In general, I haven't had a lot of trouble, given that I prepare patients and make sure that they contact me, but early recognition and treatment and patient education are essential to dealing with these side effects.

MR. BUSKER: Are there other side effects, anything more serious, that this patient should be informed about?

DR. PETERS: A few other side effects are important to be aware of. SGLT2 inhibitors have been associated with a risk of diabetic ketoacidosis. This risk has been most apparent when these agents have been used off-label in individuals with type 1 diabetes. This is a very rare phenomenon, but it can also occur in people with type 2 diabetes.

I have seen diabetic ketoacidosis in patients who have undergone general anesthesia for surgery. So I tell patients if they're going to have surgery, they should stop the SGLT2 inhibitor about three days in advance of that surgical procedure. That's about how long it will take the agent to fully leave their system. For smaller procedures like a colonoscopy, you don't have to stop it because of the diabetic ketoacidosis risk, but for smaller procedures I might stop it a day in advance anyway to make sure the patient doesn't become dehydrated when they're not eating normally. This is something to be aware of, and it can occur in type 2, which most of us don't usually think about.

Finally, diabetic ketoacidosis can occur at a normal blood sugar level. When we first started identifying these cases, they were euglycemic; they didn't have that typically high blood sugar level that we see in ketoacidosis. So just remember to think about ketoacidosis in a patient who has metabolic acidosis and who happens to be on an SGLT2 inhibitor.

Finally, one of these agents, canagliflozin, has been associated with an increased risk of bone fracture. This was primarily seen in the CANVAS study, which involved older people with type 2 diabetes. But some mechanistic studies have shown slight decreases in bone mass and bone density with these agents. So it's important that if a patient has significant osteoporosis, is having fractures, this might not be the right choice of drug. More research is underway on this finding, but for the moment I advise in patients for whom osteoporosis is a significant clinical issue to avoid an SGLT2 inhibitor.

MR. BUSKER: Thank you, doctor. And we'll return, with Dr. Anne Peters from USC, in just a moment.

SUSAN PORTER: Hello. I'm Susan Porter, clinical nurse practitioner and certified diabetes educator at the Johns Hopkins University School of Medicine. I'm one of the program directors of eDiabetes Review.

If you found us on iTunes or on the web, please be sure to subscribe. This podcast is part of Johns Hopkins eDiabetes Review, a new educational program providing monthly activities certified for CME credit and nursing contact hours, with expert commentary and useful practice information for clinicians treating patients with type 2 diabetes.

For additional information, or to subscribe to receive our newsletters and podcasts without charge, please visit www.ediabetesreview.org. Thank you.

MR. BUSKER: Welcome back to this eDiabetes Review podcast. I'm Bob Busker, managing editor of the program. Our guest is Dr. Anne Peters, from the Keck School of Medicine at the University of Southern California. We've been discussing the risks and benefits of SGLT-2 inhibitor agents in clinical practice. So let's continue with another patient scenario, if you would please doctor.

DR. PETERS: This patient is a 72 year old male who's had type 2 diabetes for about 10 years and a history of an MI about three years ago. He is a fairly typical patient with diabetes and cardiovascular disease, and he's had a stent placed. He's not terribly heavy, his BMI is 25, his A1C is 8%, and he's on metformin and a DPP4 inhibitor. He's also on appropriate statin medication and on hydrochlorothiazide and antiplatelet therapy. His blood pressure is 128/70. He does have trace diabetic retinopathy, and his renal function is essentially normal.

MR. BUSKER: Before we get into discussing therapeutic options, what A1C target goal would you set for this patient?

DR. PETERS: I individualize targets in nearly everybody, but in particular as patients age, their A1C target goes up. And we don't want to cause harm here, this is a man who has cardiovascular disease and we especially don't want him to become hypoglycemic. Because he's older, I might use an A1C target of 8% — but in this man in particular, there are two reasons why I'd have a lower target.

The first reason is, he does have trace diabetic retinopathy, which shows me that his higher glucose levels are causing harm. He's 72, he could live another 10 years, so I'd prefer to reduce his A1C below 8% to prevent progression of his retinopathy. But the wonderful addition we've found with empagliflozin, one of the SGLT2 inhibitors, is that it can also reduce the risk of recurrent cardiovascular risk in a patient like this.

So my goal not only becomes an A1C goal, it becomes how I further reduce his risk of cardiovascular events. With that in mind, I would consider adding

empagliflozin to what he's on, both to reduce his A1C and to reduce his cardiovascular disease risk.

MR. BUSKER: Are there other options might you consider?

DR. PETERS: Given the data from the EMPA-REG trial using empagliflozin in patients like this one who have already had a cardiovascular event, I'm pretty likely to choose empa over other agents. But we do have intriguing data that liraglutide also may help reduce cardiovascular events in patients like this one, but that data has yet to be published, so I'm waiting to see what that data shows.

In this patient, weight loss is not a key goal, so adding empagliflozin, which may cause some weight loss, may make the most sense compared to a GLP1 receptor agonist. But once we understand fully the cardiovascular benefits of liraglutide, that potentially may become another good second choice. But we'll figure that out as we know more in the future.

MR. BUSKER: What about the other medications he's on? If you start him on empagliflozin, what kind of adjustments would you need to make there?

DR. PETERS: This patient has a very normal blood pressure on his current treatment, and adding empagliflozin could lower his blood pressure further. In fact, it might reduce his blood pressure. So I might reduce his hydrochlorothiazide by 50% when I add the empagliflozin, or if not, at the very least, I'd tell him that he could become orthostatic and explain what that means. If he's a patient who is working with me, I'll have him test his blood pressure at home and let me know if it becomes too low. So I do consider the blood pressure-lowering effect of the empagliflozin, and depending on the patient I will have them either reduce their diuretic and/or follow blood pressures at home to make sure they don't become hypotensive.

MR. BUSKER: SGLT-2 inhibitor side effects — anything you'd need to discuss with this patient that you didn't already address in the previous case?

DR. PETERS: In addition to the usual potential side effects of an SGLT2 inhibitor, in men I need to discuss the potential risk of balanitis. This is very uncommon in men who are circumcised and more common in uncircumcised men, but it can happen in every man.

So I basically explain it and I tell them that keeping up with good hygiene is important and just as with a woman, if they develop any irritation at the tip of the penis, anything that makes me think they might be developing a mycotic infection, I make sure that they treat it topically first and then will treat it more aggressively if necessary. This is known as a potential side effect and he needs to be aware of it.

MR. BUSKER: Thank you for that case and discussion, Dr. Peters. We've got time for one more patient scenario, so doctor if you would, please.

DR. PETERS: This patient is a 61 year old female who's had type 2 diabetes for 15 years. She's on metformin, a sulfonylurea and a basal insulin. Her A1C is 7.6%, her BMI 32, and blood pressure 148/86. She's tried many other medications. She was on a daily GLP1 receptor agonist in the past and stopped it because of GI side effects. She's not that engaged in her treatment; she rarely tests her blood sugar, and she'll go low if she forgets to eat lunch. She wants to have her A1C below 7% because she's seen family members who have developed significant diabetic complications, but she's not been willing to put in the effort to reach or maintain that kind of A1C target. She also wants to lose weight and just feels chronically discouraged. She's frustrated about everything. She's frustrated about her diabetes, and she's had a lot of trouble reaching the targets that she wishes to achieve.

MR. BUSKER: She wants her A1C to get below 7%, but she's not willing to take control of her diabetes to get there. I think you've described a type of patient that virtually all of our listeners have found in their exam rooms at one time or another. Tell us, how would you first approach this patient?

DR. PETERS: This is the very patient that I want to fix immediately, but this is the very patient where time will help you. In particular, I want her to know that unless we're working together I can't provide any magic.

I first would screen her for depression, because if she is depressed, I would want to address that and treat it appropriately. In addition, I would ask her about goals she stated initially but would want to drill down to learn how difficult is it for her to test her blood sugars, how hard is it for her to think of her family members who've had diabetic complications; I'd try to get a feel

for her. I'd just let her talk, I'd want to understand her, and I wouldn't change too much the first time we met, because I think it could overwhelm her. She's had side effects in the past, and I would just want her to know I would be her partner in this journey to get her healthy.

I would let her guide me, but I'd want to make her feel empowered. This is someone who doesn't feel empowered; she feels sort of lost in this whole thing, she doesn't feel like she has control but, in fact, she does. If I can give that back to her, that would be the most important therapeutic thing I can do initially.

MR. BUSKER: That's a lot to try to accomplish in a 15 minute primary care appointment.

DR. PETERS: I think you can. I say these specific words: I can't do everything now, but this is a process over time and we're going to get to know each other and I'm going to help you. What are your goals? That's all you have to say; four things, so easy.

MR. BUSKER: In your description, you said "she rarely tests her blood sugar, she'll go low if she forgets to eat lunch." How important is it to address her occasional hypoglycemia?

DR. PETERS: When treating people with diabetes, the most important thing we can do is help them avoid hypoglycemia. Hypoglycemia in the short-term can hurt a patient. Hyperglycemia can also hurt in the long-term, but right now I'd want to avoid her hypoglycemic episodes. So I'd explain to her that both the sulfonylurea agent and the insulin can cause a low blood sugar reaction. I'd talk with her to try to get her to start doing more blood sugar testing in the morning and evening, before breakfast and before dinner.

I would probably have her see a dietitian if she is willing to go. A lot of times people like this don't want to see a dietitian because they feel they've been diet failures. But I would obviously offer it to her and would discuss the need to eat lunch regularly.

I'd also go through signs and symptoms of hypoglycemia and make sure she was carrying a simple carbohydrate with her in case she went low during the day. Then I would talk about the benefits of either reducing or stopping the sulfonylurea agent and potentially replacing it with a drug that doesn't cause hypoglycemia, such as an SGLT2 inhibitor.

MR. BUSKER: So let's say that she takes your advice. She's testing her blood glucose regularly, and she reports it's around 150 in the morning, and it varies from 90 to 190 before dinner, depending on what she's eaten and the physical activity she's undertaken. And she agrees to try adding an SGLT2 inhibitor.

DR. PETERS: When you add an SGLT2 inhibitor to the regimen of a patient who is on a sulfonylurea agent and/or insulin, you have to reduce the dose of the drug that can cause hypoglycemia. An SGLT2 inhibitor won't cause hypoglycemia, but the sulfonylurea agent might if you lower the blood sugars with the SGLT2 inhibitor. So I always reduce the dose of the sulfonylurea agent by half when I add the SGLT2 inhibitor. That way you won't precipitate more hypoglycemia, which might make a patient less willing to work with you.

I would also have her continue self-monitoring her blood glucose so we can see if her blood sugar goes down even more than I would expect. I would discuss with her the goal of eliminating the sulfonylurea agent. As we taper these people off the sulfonylurea agent, I see even more weight loss than just using the SGLT2 inhibitor alone, because they are no longer getting hypoglycemic, and I think it may help her feel better. So I discuss all of these benefits, and I'm always going to encourage her to eat in a healthier way, as well as to exercise.

MR. BUSKER: Thank you, Dr. Peters, for today's cases and discussion. Before we wrap things up, I'd like to get your thoughts on a more general question about these SGLT2 inhibitor agents. There's been a lot of excitement over the positive cardiovascular results of the EMPA-REG trial — you reported on it in your newsletter issue, and you've mentioned it today in our discussion. One idea that's come up, and that's what I'd like to get your opinion on, is this: do you think the SGLT2 inhibitors should be considered cardiovascular drugs instead of antihyperglycemic agents?

DR. PETERS: That is an incredibly intriguing question, and as a diabetologist I'm incredibly happy that now I have a drug that also reduces cardiovascular disease risk in my patients with diabetes. But we only know this is true from data from one of these agents, empagliflozin. So first, we need to know if this is a class effect.

Other cardiovascular outcomes are ongoing, and a lot of research needs to be done to understand the mechanisms, but I think this could be an important role for these agents. It is currently only true for empagliflozin in patients who have already had a cardiovascular event, and even more intriguing to me is whether these drugs will work as primary prevention in these high risk patients to prevent cardiovascular disease.

MR. BUSKER: Thank you, Dr. Peters. So now let's wrap things up by reviewing what we've talked about today in light of our learning objectives. So to begin: the glucose lowering effects of SGLT2 inhibitors.

DR. PETERS: SGLT2 inhibitors are likely to reduce the A1C by somewhere between 0.6% and 1%. They could be used alone or when added to any other therapy because they have a unique mechanism of action. In addition to glucose lowering, there also is some potential for weight loss, as well as a lack of hypoglycemia when these agents are used alone.

MR. BUSKER: And our second objective: cardiovascular outcome data on the impact on patient care of the SGLT-2 inhibitor empagliflozin with regard to its effect on patient care.

DR. PETERS: Empagliflozin, which is an SGLT2 inhibitor, has been shown to reduce cardiovascular events in patients with type 2 diabetes and known cardiovascular disease, and this is unique among the agents we have for the treatment of type 2 diabetes. Overall, the SGLT2 inhibitors are diuretics, which may help reduce cardiovascular events, but it should also be considered when a patient's blood pressure is lower and/or they are on a diuretic at the same time.

MR. BUSKER: And finally: the common side effects of SGLT2 inhibitors and how to avoid them.

DR. PETERS: SGLT2 inhibitors are likely to cause some side effects, but the key is to have patients aware that this can happen. The first thing you should tell a patient is that they will notice they urinate more frequently. If you describe it as part of the effect of the drug, they probably won't worry about it. But make sure patients don't become dehydrated, drink enough fluid, and know this is an effect of the drug.

Patients are also at increased risk for mycotic genital infections and urinary tract infections. I warn patients

that this is a risk and I teach them how to treat it. So if a patient has had, say, vaginal mycotic infections before, I make sure they have some sort of topical antiyeast treatment at home so they can treat early. Men can also get mycotic genital infections, and I make sure they know what it is and they could develop a balanitis, and I want to treat early if they have any signs or symptoms.

Finally, there's a risk for fracture with canagliflozin, so I don't use these agents in patients who have active osteoporosis. There is a very slight risk of diabetic ketoacidosis in patients on SGLT2 inhibitors, and this needs to be considered.

MR. BUSKER: Dr. Anne Peters from the Keck School of Medicine at the University of Southern California, thank you for participating in this eDiabetes Review Podcast.

DR. PETERS: I really enjoyed it. Thank you very much for having me.

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