



VOLUME 2 – ISSUE 8: TRANSCRIPT

Featured Cases: Vitamin D and Bone Health

At the conclusion of this activity, participants will demonstrate the ability to:

- Discuss the basis of the current vitamin D recommendation for patients with cystic fibrosis,
- Describe the potential for success of various strategies for treatment of vitamin D insufficiency,
- Compare the potential benefits and risks of using bisphosphonates for the treatment of osteoporosis in patients with cystic fibrosis.

This audio activity has been developed for clinicians caring for patients with issues related to cystic fibrosis. You can also read the **companion newsletter**. In this edition Drs. Green and Mogayzel will help expand our understanding of the vitamin D and bone health in cystic fibrosis, with the discussion some typical case scenarios.

Unlabeled/Unapproved Uses

The authors have indicated that there will be no reference to unlabeled or unapproved uses of drugs or products in the presentation.

MEET THE AUTHORS



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Guest Faculty Disclosure

Dr. Green discloses that she has no financial relationship with commercial supporters.

Dr. Mogayzel discloses that he has no financial relationship with commercial supporters.

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LAUNCH DATE

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MR. BOB BUSKER: Welcome to this eCysticFibrosis Review podcast. eCysticFibrosis Review is presented by the Johns Hopkins University School of Medicine and the Institute for Johns Hopkins Nursing. This program is supported by an educational grant from Genentech, Eurand Pharmaceuticals, Vertex Pharmaceuticals, Axcan Pharma, and Gilead Sciences Medical Affairs. Today's program is a companion piece to our May, 2010, eCystic Fibrosis Review Newsletter, "Vitamin D and Bone Health."

Our guests are Drs. Deanna Green and Peter Mogayzel from the Johns Hopkins University School of Medicine in Baltimore, Maryland. This activity has been developed for physicians, nurses, respiratory therapists, dietitians, and physical therapists caring for patients with issues related to cystic fibrosis. There are no fees or prerequisites for this activity.

The accreditation and credit designation statements can be found at the end of this podcast. For additional information about accreditation, Hopkins' policies and expiration dates, and to take the post-test to receive credit online, please go to our website newsletter archive, www.ecysticfibrosisreview.org, and click on the July 2010 podcast link.

Learning objectives for this program are that at the conclusion of this audio activity, participants should be better able to discuss the basis of the current vitamin D recommendation for patients with cystic fibrosis, describe the potential for success of various strategies for treatment of vitamin D insufficiency, and compare the potential benefits and risks of using bisphosphonates for the treatment of osteoporosis in patients with cystic fibrosis.

I'm **BOB BUSKER**, managing editor of eCysticFibrosis Review. On the line we have with us the newsletter issue's authors Dr. Deanna Green, a Pediatric Pulmonary Fellow, and Dr. Peter Mogayzel, an Associate Professor of Pediatrics and Director of the Cystic Fibrosis Center. Both at the Johns Hopkins University School of Medicine

Both Drs. Green and Mogayzel have disclosed that they have no relationships with commercial supporters.

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MR. BUSKER: Vitamin D deficiency appears to be a popular topic in the media. Why do you think this is and how does it really relate to your CF patients?

DR. MOGAYZEL: You're right, Bob, there have been a number of publications recently on vitamin D related to cancer, heart disease, and improving health overall for both adults and children. Patients with cystic fibrosis are living longer, so they are developing more complications, such as bone disease, and ensuring that vitamin D supplementation is adequate and figuring out new ways to prevent bone disease are becoming more and more important for CF patients.

MR. BUSKER: Would these be some of the reasons that the CF Foundation issued guidelines for bone health?

DR. MOGAYZEL: Yes, in 2002, the CF Foundation convened a consensus conference. This consensus conference developed specific recommendations for the prevention of bone disease and the optimal supplementation of vitamin D for patients with cystic fibrosis.

MR. BUSKER: Dr. Greene, anything to add?

DR. GREEN: Yes, I would add that the original consensus guidelines did not have any actual demonstration in cystic fibrosis patients, and most of this was expert opinion. And at this time we are actually trying to test these guidelines to see if they hold true in those with cystic fibrosis.

MR. BUSKER: Based on what we've just been saying, it's got to be very difficult for clinicians to determine the best way to treat CF patients that will optimize their bone health.

So put that into a patient-oriented context for us if you would, Dr. Greene, give us a case scenario on this.

DR. GREEN: Sure, Bob, let's talk about a child with cystic fibrosis, let's say we have a five-year-old female. Her parents come to clinic routinely as they're supposed to. Overall, she is very healthy, and they state she has no lung problems. She seems to eat pretty well and has been gaining weight fairly well. They state having given her all of her prescribed medicines on a routine basis. She ends up getting both pancreatic enzyme, as well as her cystic fibrosis recommended vitamins. Her parents are therefore

very interested in continuing to keep her healthy and want to know what our recommendations would be for her future.

MR. BUSKER: So then what would your recommendations be at this point?

DR. GREENE: Well, our first recommendation to the parents would actually be kind of a reinforcing idea and encouraging them to keep doing what they're doing. If she, in fact, has good weight gain and seems to be appropriate for a five-year-old, then they seem to be doing what is needed.

We would definitely encourage them to keep using her pancreatic enzyme, and then the next most important thing would be working towards prevention of anything such as bone disease or things that these children may develop as they become adults.

The biggest problem we have right now with vitamin D deficiency is that we don't know exactly when it is going to start for patients. And so what we initially recommend is that everyone needs to be on vitamin D, which tends to be provided in their regular routine vitamins. Every patient with cystic fibrosis should be on a vitamin supplement, this is a multivitamin along with both vitamin A, E, D, and K.

The dose of vitamin D in these supplements depends on the actual dose that patients are getting, as well as the type of supplement that they're getting. The supplements can range in dosage in vitamin D, anywhere from 400 international units, up to approximately 1,000 international units, and therefore patients can get a variable range of doses that they're getting just in vitamin D.

Additionally, many parents that come to see us in clinic believe that their patients can actually get vitamin D in the foods that they get on a daily basis. And what's important to emphasize to these parents is that vitamin D is a fat soluble vitamin and if they are not also taking their pancreatic enzymes, they may not be able to absorb what they get in their food.

Additionally, most foods have a lower amount of vitamin D than most of us suspect, such as in milk you're only getting about 400 international units in a single 8 ounce cup of milk. So a lot of our patients with cystic fibrosis may actually need higher doses than what they have been provided in their vitamins or in their daily food.

MR. BUSKER: So Dr. Greene, what you've been saying here, these are obviously good general preventive mechanisms, is there a way to determine which patients are more likely to have problems with vitamin D deficiency? Dr. Mogayzel?

DR. MOGAYZEL: No, there isn't. Studies have shown that a vitamin D deficiency may be present as early as birth, and there is no way to really predict which patients are going to have low vitamin D levels. That's why we recommend testing children for vitamin D on a regular basis, and the most appropriate test to do is a 25-hydroxy vitamin D level.

So despite a good diet and routine vitamins and pancreatic enzymes, a child can be vitamin D deficient at any point.

MR. BUSKER: And Dr. Greene, anything else to add to that?

DR. GREENE: Yes, the only thing I would add is that it is important to know that patients may be sufficient at one point; however, they can become insufficient at another point. And therefore, it is very important to check vitamin D levels on at least an annual basis for cystic fibrosis patients.

MR. BUSKER: Are you talking about measuring levels on an annual level – on an annual basis? What would you consider to be a low vitamin D level?

DR. MOGAYZEL: Well, optimally you would measure vitamin D levels in the fall or winter when vitamin D levels are likely to be at their lowest because of the limited sun exposure. Most experts agree that a 25-hydroxy vitamin D level of 30 nanograms per milliliter or higher is adequate.

MR. BUSKER: What do we do with a patient who does show insufficient levels?

DR. MOGAYZEL: Well, if you think about a child or an adult who has a low vitamin D level, say a 12-year-old with a vitamin D level of 20, the first step is to make sure they are actually taking the pancreatic enzymes appropriately and using their vitamin supplements as prescribed. If that's the case, then their vitamin D intake should be supplemented and there are recommendations from the Cystic Fibrosis Consensus Guidelines of giving 50,000 units of ergocalciferol once a week for 8 weeks, and then to increase this amount should the level continue to be low.

However, studies that we've done at Johns Hopkins have shown that this repletion strategy is not really adequate to improve vitamin D levels for an extended period of time. That giving up to 50,000 units of vitamin D once a day for a month can be effective in transiently improving vitamin D levels, but that this isn't necessarily sustained over time.

Based on these studies and other investigators who have looked at vitamin D supplementation, it's clear that the recommendations that are available don't really provide an optimal approach for replacing vitamin D or supplementing patients who are vitamin D insufficient. This is an area where future research is clearly warranted.

An alternative approach that may be more effective would be to increase the daily intake of vitamin D that patients receive routinely, and the approach of preventing vitamin D insufficiency by higher daily supplements rather than treating insufficiency when it occurs, may be more effective.

DR. GREENE: I completely agree with Dr. Mogayzel's last point. One of the biggest concerns we have is with the use of high-dose ergocalciferol, especially in the doses of 50,000 international units once a day for multiple days, there's a high risk that vitamin D toxicity may be developing in these patients. Many patients are not monitored for things such as high calcium, which may then lead to stones in their kidneys or other risk. Therefore, it is very difficult for us to determine when patients may actually be having vitamin D toxicity.

Additionally, the actual level of vitamin D in the 25-hydroxy vitamin D has not been determined what would be associated with toxicity. So I think it's very important that maybe a lower routine daily supplement would be appropriate for patients with cystic fibrosis as opposed to intermittent high dose therapies that they are currently receiving.

DR. MOGAYZEL: Now you bring up a very good point, it probably is more appropriate to increase the daily supplementation to try to prevent vitamin D insufficiency, than to take high-dose supplements knowing that there is a risk of toxicity and limited effectiveness of this approach. This is clearly an area where further research would be helpful.

MR. BUSKER: Well, with a potential toxicity and potential lack of effect here, are there other

alternatives a clinician might consider for increasing vitamin D levels?

DR. GREENE: Actually, Bob, there are multiple different forms of vitamin D that are available that could be used. The original consensus guidelines recommended use of ergocalciferol, which is vitamin D₂, mainly because this particular medication can be prescribed to patients and you can get it in fairly high concentrated doses.

There is another form of vitamin D that's available called cholecalciferol, which is vitamin D₃. This medication doesn't have as high a formulation usually as ergocalciferol.

Additionally, if you think about how vitamin D is absorbed, you can get it both in your food, as well as from the sun, and therefore, ultraviolet radiation through ultraviolet B provides vitamin D, as well.

Recent studies have actually compared the effectiveness of all three of those particular regimens, ergocalciferol, cholecalciferol, as well as ultraviolet B, and basically found that cholecalciferol seemed to be the most effective at increasing vitamin D levels in patients with cystic fibrosis.

Now the major concern is which is better for patients. Is ultraviolet radiation better, or would it be appropriate to continue with oral regimens? The study that looked at the comparative effectiveness of these three alternatives found that many patients with cystic fibrosis were noncompliant with the ultraviolet radiation, mainly because they were now requiring an additional ten minutes that they needed to provide themselves with some sort of treatment therapy.

Additionally, there is a concern from our dermatology colleagues that additional ultraviolet may lead to skin cancer, and therefore, further research in the area of using ultraviolet radiation needs to be done. So at this time, it seems probably the most likely alternative to what is listed in the consensus guidelines is to use cholecalciferol instead of ergocalciferol.

MR. BUSKER: And Dr. Mogayzel, anything to add to that?

DR. MOGAYZEL: Although exposure to sunlight is a wonderful way to produce vitamin D, one has to remember there is very little ultraviolet B radiation in northern latitudes, even in the summer. Therefore,

to use this therapy, patients living in northern latitudes would need use an ultraviolet light. And as Dr. Greene pointed out, this tends to have poor compliance because of the added burden of care.

MR. BUSKER: Would you tell us, please, how you are treating patients at the Johns Hopkins Hospital?

DR. GREENE: At Hopkins, what we've been doing based on the current evidence, is basically changing the routine daily care of our patients. And for all of our patients we are now giving them an additional 2,000 international units of cholecalciferol on top of what they are already receiving, and their vitamin A, D, E, and K.

MR. BUSKER: And we will return in a moment with Drs. Deanna Green and Peter Mogayzel from the Johns Hopkins University School of Medicine in Baltimore Maryland.

MS. MEGAN RAMSEY: Hello, I'm Megan Ramsey, nurse practitioner and clinical coordinator for adults at the Johns Hopkins Cystic Fibrosis Program at the Johns Hopkins University School of Medicine. I am one of the program directors of eCysticFibrosis Review. These podcast programs will be provided on a regular basis to enable you to receive additional current, concise, peer-reviewed information through podcasting, a medium that is gaining wide acceptance throughout the medical community. In fact, today there are over 5,000 medical podcasts.

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MR. BUSKER: Welcome back to our July, 2010, eCysticFibrosis Review Podcast. I'm Bob Busker, Managing Editor of eCystic Fibrosis Review. Our topic is Vitamin D and Bone Health and our guests are Dr. Deanna Green and Dr. Peter Mogayzel of the Johns Hopkins University School of Medicine.

And our topic is Vitamin D and Bone Health. We've been talking about helping CF patients achieve sufficient vitamin D levels to prevent lung disease but what about treating lung disease once it is present. Dr. Mogayzel?

DR. MOGAYZEL: Well, for instance, if you have a 32-year-old male who has had two vertebral fractures in the past and routinely has vitamin D levels of 25 nanograms per milliliter despite A, D, E, and K vitamin supplements and high dose ergocalciferol, which has been given repeatedly, there are several approaches one could take.

First of all would be to try to increase vitamin D supplementation to try to get the 25-hydroxy vitamin D level above 30 to prevent future problems and to help with bone remodeling. It's important to realize, though, that bone disease may actually have started early and that reversing bone disease can be very difficult. A significant proportion of bone is laid down during adolescence, and it may be difficult to reverse osteopenia, osteomalacia, or osteoporosis which has developed solely by increasing vitamin D and calcium supplementation.

One therapy that's now available is to use bisphosphonates which are a therapy recommended in the CF Foundation guidelines. This can help to improve bone mineral density.

MR. BUSKER: Dr. Greene, tell us more about the previously used IV forms and oral form for supplementation?

DR. GREENE: So in the past multiple different bisphosphonates have been studied for their use in patients with osteopenia and osteoporosis. There haven't been quite as many studied within the cystic fibrosis patients, and predominantly there's been two types used. One is alendronate, which is an oral form of bisphosphonate, and in a couple of small trials it

was found when used on a daily basis for approximately 12 weeks, that there was an improvement in bone mineral density which was studied in patients with cystic fibrosis.

This form seemed to be very easy to take in patients; however, it did need to be taken on a daily basis, and therefore, noncompliance began to be an issue for some patients.

An additional form which was studied was an IV form of bisphosphonate called pamidronate. This was also found to be very effective in increasing bone mineral density, however, there were significant side effects in that many patients reported very severe bone pain.

Most recently, alendronate has now been studied being used only once a week and in this form, compliance seemed to be less of an issue for patients with cystic fibrosis. And when alendronate was given in 70 milligrams once a week for 12 months, at the end of the treatment trial it was found that there was a significant improvement in bone mineral density in all patients with cystic fibrosis.

DR. MOGAYZEL: I think the think to add in here is this is an important advancement because intravenous bisphosphonates have been associated with significant side effects, including substantial pain following infusion, which has really limited their use in cystic fibrosis patients.

The hope is that oral bisphosphonates that can be given on a schedule that favors good compliance will be much more useful in the treatment of CF patients.

MR. BUSKER: You know, something that may be of concern here is that there is now this nationwide mandate for newborn screening, and what do we do, what do you recommend we do with a baby who is, a newborn who tests as vitamin D deficient?

DR. MOGAYZEL: Well, you bring up a wonderful point: newborn screening is now universal in the United States and we have the opportunity to see patients in cystic fibrosis centers before they develop any symptoms. The approach to all therapy for cystic fibrosis care is prevention, and prevention of pulmonary disease, but also prevention of bone disease, moving forward.

We know from studies that vitamin D deficiency can occur right from birth so that monitoring for

vitamin D deficiency, even early in life before other problems like failure to thrive may be present, is vitally important.

So when seeing patients diagnosed by newborn screening, the CF Foundation has recommended early testing for vitamin D deficiency by monitoring 25-hydroxy vitamin D levels. If an infant is deficient then the optimal approach isn't quite known yet, but we know that supplementing with cholecalciferol or other vitamin D analogs is vitally important and achieving a level of greater than 30 nanograms per milliliter should be the goal. And it should not be unreasonable to accomplish that evening small infants.

DR. GREENE: The only thing I was going to add would be that there's also a great push for breast-feeding in the United States, and with that infants are not able to receive any vitamin D in breast milk. And so it's even more important in cystic fibrosis patients that they are receiving an adequate amount of vitamin D and, therefore, supplementing with a multivitamin with A, D, E and K is very important in patients with cystic fibrosis.

As it is with an other normal children, they should have a multivitamin, but especially in cystic fibrosis they're at greater risk, and especially if they're breast fed.

DR. MOGAYZEL: So to get back to when the level should be drawn, they should be drawn within the first three months and then again at a year. That's why the Cystic Fibrosis Foundation recommends testing 25-hydroxy vitamin D levels in infants before 3 months of age, and then repeating the level if the baby is found to be sufficient, when he or she turns a year old. Obviously, if the initial level is low, then it should be repeated after appropriate supplementation is given.

MR. BUSKER: These treatment regimens, are there any particular considerations with toxicities in newborns?

DR. MOGAYZEL: There is and the recommendations initially in the consensus guideline was at a much lower supplementation than you would be in a child. so that recommendations for children over the age of one were to supplement with ergocalciferol 50,000 international units once a week, for infants the recommendation was only 12,000 international units once a week, hoping that toxicity would not develop with the lower doses.

Unfortunately, the lower doses also have been found not to improve vitamin D levels as high as the higher doses of ergocalciferol, even in infants.

MR. BUSKER: So tell us if you would about future directions in addressing vitamin D in cystic fibrosis.

DR. MOGAYZEL: Well we know that vitamin D is very important in bone health in patients with cystic fibrosis, however, vitamin D may have a number of other roles in promoting lung health.

It's known that vitamin D sufficiency, having an adequate vitamin D level, is very important in asthma and maintaining lung function in asthma. There is also accumulating evidence that vitamin D is important in fighting off infections such as influenza and tuberculosis. So there may be a role for vitamin D in moderating or ameliorating the infections that are seen in cystic fibrosis.

Taken together, it implies that vitamin D may have important roles in cystic fibrosis patients beyond just bone health, and future studies addressing this possibility will be very important.

MR. BUSKER: Dr. Greene, same question.

DR. GREENE: I completely agree with Dr. Mogayzel. I find the research with vitamin D and lung function, in general, to be completely fascinating and I think that will be a great avenue. But addressing just vitamin D and bone health, I think there's still quite a few questions left to be answered. And one most important one is whether we actually know the correct vitamin D level that these patients need to achieve. Does it really need to be a vitamin D level of 30 nanograms per milliliter or does that level need to be higher to prevent bone loss?

Additionally, as we've been alluding to, it is still very unclear what the actual dose of vitamin D patients need on a routine basis. So further research into that particular avenue is also warranted at this time.

MR. BUSKER: Dr. Deanna Green and Dr. Peter Mogayzel of the Johns Hopkins University School of Medicine, thank you for participating in this eCysticFibrosis Review Podcast.

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to clinicians treating patients with cystic fibrosis. This activity has been planned and implemented in accordance with the essential areas and policies of the Accreditation Council for Continuing Medical Education, with a joint sponsorship of the Johns Hopkins University School of Medicine, and the Institute for Johns Hopkins Nursing.

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