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ReachMD

www.reachmd.com

info@reachmd.com

(866) 423-7849

Can HCV be Treated in Primary Care?

Dr. Caudle:

Chronic hepatitis C is a major cause of liver cirrhosis and hepatocellular carcinoma worldwide. Some 130 million to 170 million people, or about 3% of the world's population, are chronically infected with the hepatitis C virus. Dr. Reau, welcome to the program.

Dr. Reau:

Thank you so much.

Dr. Caudle:

So, let's get started. Dr. Reau, why is it important to consider treatment for patients with hepatitis C virus?

Dr. Reau:

Well, I think that hepatitis C can be viewed from two different directions. It's obviously a liver disease and early identification allows us to treat someone and then prevent cirrhosis as well as liver cancer; however, hepatitis C has also been more recently associated with many extrahepatic manifestations or, in other words, a lot of injuries that are not necessarily liver associated. There was a very large Taiwanese database called REVEAL hepatitis C and that was the first time that they highlighted things such as a lot of cancers, prostate cancer, thyroid cancer, cardiovascular disease, renal disease, these other diseases that we would normally have not linked to hepatitis C, as having a higher prevalence. This has then been validated by other large databases including one through the VA, so that we not only want to identify and then treat or eradicate hep C so that we prevent liver progression, we also do this because we think we can decrease all cause mortality linked to things that go well beyond the liver. The third reason that we identify hep C is transmission, and hepatitis C is often an asymptomatic disease so that if you identify it in a person who doesn't know they have it and doesn't have symptoms, you can decrease the risk of them sharing it with close contacts. It's a challenge to share; it usually is blood borne, but we do recommend not using razors, not sharing a toothbrush, there's a small but real sexual transmission risk, and a small but real transmission risk in women who deliver babies when they have hepatitis C and then probably the most impactful is if you have someone who's using IV drugs or intranasal cocaine and they have hepatitis C. You can do a lot with risk reduction and even if it's through needle exchange programs or the awareness that they might share their liver disease, or their hepatitis, with another one of their associates, then you can prevent horizontal transmission.

Dr. Caudle:

And what can primary care providers do to improve hepatitis C prevention and care?

Dr. Reau:

Well, our primary care providers are really our first line, right? I only see a patient once that patient is known to have hepatitis C or, rarely, I will have a patient who comes because they have a friend who recommended they come and they make it directly to my office. So, primary care providers are tasked with a lot of things, I mean, the last time I went to see my primary care doctor they were recommending boosters I didn't even realize existed and the importance of wearing my seatbelt and my helmet when I was riding my

bike, so that if you try to task them with more things, it really is a daunting task to be a primary care provider. But that might be the only interaction with a person who doesn't have any symptoms and they have that bond with their primary care provider so they're more likely to agree to testing, to have that link to followup on the results of that test. It doesn't do us any good to screen a person if we can't communicate the results back to that person. So, screenings -- I know you have hep C -- isn't very useful unless I can find you, tell you you have hep C, educate you as to what that disease means, which means that a person's not going to care about the disease, unless they really think it's important to them and that there might be a therapy out there that's able to change their prognosis with a long term opportunity, and that's really where our primary care links are most important.

Dr. Caudle:

Can you talk a little bit about the assessments that primary care providers can do prior to treatment?

Dr. Reau:

So, beyond just screening, so knowing the patients that you need to identify that are at high risk that need to be screened, after that, our primary care doctors are wonderful resources for educating a person on transmission as well as progression, so that it's really nice to know that that person already has some basic information about their hepatitis. But, it goes beyond that. We know that hepatitis and obesity don't get along. Extra fat in the liver increases the risk of fibrosis. So our overweight individuals, or patients who have uncontrolled diabetes, these are additional liver insults that increase the risk of having complications from both liver diseases. We also know that alcohol does the same thing, so that our primary care providers can do a lot, even if the patient never chooses to get treatment with preventative measures through these other reductions in risk.

Dr. Caudle:

And, Dr. Reau, can you discuss how liver disease severity is assessed and really why is it important to know the extent of fibrosis?

Dr. Reau:

Right. That's an excellent question because, like I already alluded, hepatitis is silent, but advanced liver disease is also silent. I'll have patients that find that they have cirrhosis and they're devastated because no one ever recognized any liver injury at all and they don't feel bad, so that when you look at a patient in front of you and you recognize the disease that is a liver disease, you have hepatitis C, in addition to the educational effort, the next thing that we know impacts urgency of treatment is the stage of the liver injury. I gave plenty of reasons to treat and eradicate hepatitis C independent of liver disease, but our patients with cirrhosis are at risk for symptoms of cirrhosis, variceal bleeding, liver cancer, development of ascites, and if you recognize that risk early, we can do, again, a lot of risk reduction. So that there are some subtle blood tests in getting the standard labs, your CBC and your CMP. If you see the AST higher than the ALT, that flip often will occur when a person is developing more fibrosis. Usually you look at that pattern and you're suspicious that the person's drinking alcohol, but there are other things that cause the AST to predominate over just ALT, other than just alcohol use, and so that's a very subtle, but important, thing that we can recognize on otherwise routine labs. The other thing that we use is your platelet count. It tends to be a very good litmus test for what we describe as portal hypertension. As the liver becomes stiffer, the pressure in the portal vein or the blood vasculature that is in front of or proximal to the liver is really going to increase and that causes the spleen to swell or extra pressure in the spleen and that decreases the platelets. They're just sequestered there in the spleen. So if the platelet count is lower than 150 that's something that I use to identify someone who is at much higher risk for cirrhosis. Now, there are plenty of legitimate reasons to have platelets lower than 150 that are not all liver disease. So you can't stop there, but those two tests are very easy ways to look at a person and say that we need to go a little bit beyond and make sure that you don't have advanced liver disease. Certainly things like low albumin, high bilirubin, these are much more accurate flags to help looking at someone who's got more severe liver disease, but the subtle things are really the ones that are most important. After that, there's innumerable ways of trying to decide if a person's got advanced disease. There are blood tests that can be indirect, which means that it's kind of a panel of things that you put together and equations to estimate the risk of advanced liver disease, and examples of that are like your APRI score and there are excellent calculators online, so you can just Google calculator for test X and you can often plug these values in from routine labs. There are blood tests that are more direct markers of fibrosis, so that you can order a blood test that gets a panel of things that includes things like metalloproteinases or collagenase, things that are more associated with fibrosis development, and that panel will then estimate the risk of advanced disease. And then, there are plenty of x-ray tests. Ultrasound, if it shows nodularity or signs of portal hypertension is very accurate; not very sensitive, but accurate when you see these abnormalities. And then, obviously, CAT scan would be a little bit more accurate, MRI, and then we have things that are directed towards fibrosis alone such as magnetic elastography or a plethysmography test; that's looking at sound wave through stiffness. An example of that would be something like FibroScan or you can have ultrasound technique that looks at sound wave production through the liver. So, there are many, many tests that don't always end

up in a biopsy; however, the gold standard, still, for fibrosis assessment is a liver biopsy and occasionally we are still challenged by a patient that the clinical scenario doesn't make sense and we still will obtain a biopsy to accurately determine the amount of scarring in that person's liver.

Dr. Caudle:

During treatment, what should patients be evaluated for?

Dr. Reau:

Well, I think that one of the things that we know is most important on a person who's on therapy is just adherence. So, the first and foremost thing is, as you see a person make sure they're not skipping pills, make sure that they're taking them in the way that they're prescribed. There are a lot of drug-drug interactions and some of them can be kind of subtle. They can also be different between the different hepatitis regimens so that we might know that two regimens affect proton pumps, but one regimen might be because you need the acidic environment in order to absorb your medicine. The other medicine might be that it lowers or increases the amount of the other drug, so that it might change the effectiveness of the proton pump inhibitor, so it's a drug-drug interaction, but a very different one, based on the different therapies. And there are many drug-drug interactions, so that if you see a person who's on hepatitis C treatment, as a primary care doctor, and they have, even like an upper respiratory infection, you always want to make sure that the medicine you're going to give them doesn't interact or isn't influenced by the hepatitis C treatment. And then, they do have side effects, but they're uncommon. Their severe side effects are uncommon, so just being aware of the most common complaints that the patient might have so that you don't think a person has an upper respiratory infection or a migraine when it's just a side effect of the medication that was started by the person managing the hepatitis C.

Dr. Caudle:

If you're just tuning in, you're listening to CME on ReachMD. I'm your host, Dr. Jennifer Caudle, and today I'm speaking with Dr. Nancy Reau, Associate Director of Solid Organ Transplantation and Section Chief of Hepatology at Rush University Medical Center and we are speaking about the role of primary care providers in hepatitis C management.

Dr. Reau, let's say a patient is recently diagnosed with hepatitis C but does not want to see a specialist because he's scared and he's simply more comfortable with his primary care provider. What do you recommend in this case?

Dr. Reau:

Well, to some extent, that drives at the fact that we feel that we probably don't have enough providers for hepatitis C therapy, or care management, as we do patients with hepatitis C. So that if that primary care doctor is in a location where there are a lot of individuals with hepatitis C, often primary care providers may treat hep C. These medicines are a challenge to get access to, but they're not necessarily a challenge to give. And there are excellent examples of innovative ways to get hepatitis C treatment to the patients that have hepatitis C. If the primary care provider isn't interested in trying to manage that patient, then a lot of what can be done focuses really just on education. Your patient isn't going to take the drug you want them to take unless they believe the disease you're treating is important and that the medicine you've just prescribed is going to impact the importance of that disease. So, in that patient who may not be ready for treatment because they're scared and they're nervous, it's just a continual reminder that they have something that's curable, but they also have something that is important. We just don't want to get rid of it because we can, we want to get rid of it because we believe it has long-lasting and important effects on their overall mortality and morbidity, and when that person's ready, then maybe they'll be a little more willing to go and visit a provider that can link them to hepatitis C treatment.

Dr. Caudle:

Can you discuss some of the programs that have been implemented to increase the primary care provider's capacity to treat, particularly among rural and under-served populations?

Dr. Reau:

Absolutely. There are excellent programs out there. I think a lot of this started with the concept of Project ECHO which is a very well-known academic mentoring program. So, ECHO does have some support/structure, but it links academic institution to a more rural area where the academic, the more experienced providers, can then help direct the care through either nurses, physician assistants, or primary care doctors who actually see the patient in front of them. The academic institution never sees that patient. That model has been expanded. The ECHO model has worked for many diseases, not just liver disease, and so it's not only just tried and true for hepatitis therapy, but it's tried and true for diabetes management, hypertensive management, but looking at that model and mirroring it

has occurred with many mentorship programs. There are examples where the primary care doctors who are interested in hep C therapy might have a WebEx on regular basis with a more experienced mentor and then that person answers questions when they get stuck, provides a link to newer data that they may not be aware of. It's hard to keep up to date in everything, and if you're a primary care provider trying to follow the hepatitis C literature, in addition to everything else, might be a challenge and this is a way of making sure that they remain credible and current.

Dr. Caudle:

Have these programs been successful and is there any data that shows that primary care physicians can effectively treat patients with hepatitis C?

Dr. Reau:

Absolutely. These are successful programs and even if you didn't believe the first one, when there are many examples of this, we know that the ability to treat hep C is not necessarily limited to just a subspecialist. Even within subspecialty clinics, most of our hepatitis C therapy is provided by nurse practitioners or physician assistants, usually under the auspice of a more experienced provider or of an attending liver specialist, but we wouldn't get our work done if we didn't have a lot of help. There are also examples where primary care providers are very successful, even without the back of a mentorship program, but part of that is going to depend on volume. So, even when we think of something like a surgeon's experience in doing a surgical procedure, we know that if they regularly do that surgical procedure they -- it's not that they make less mistakes -- but the outcomes tend to be better. It's just that they're repetitively doing the same thing you tend to get more experienced, more confident, and the outcomes show that. The same is going to be true with most management. If you have a lot of hepatitis C patients, and you are treating them, then you're certainly going to be more aware of the manifestations of side effects; you're going to be more confident in your decision-making tree; you're going to anticipate things and prevent them, as opposed to just reacting to them, and this is all volume-based. And places you can see very successful models also include FQHCs, where federally qualified healthcare clinics often have a lot of marginalized patients where hepatitis C might have a higher prevalence and they're doing a great job managing the hep C. That's important for the patients who might have limited ability to get access to providers outside of their FQHC, or may not feel comfortable going to a provider outside of the location that is convenient to them.

Dr. Caudle:

Which patients do you feel should still be referred, however?

Dr. Reau:

Well, no matter how experienced a treater is, there's always going to be a patient that's a challenge, and I think, if it's me, and I have a patient that I know has failed prior therapy, or I have someone who's got very advanced liver disease, this is an individual where treatment is not going to be straightforward and these individuals should probably be, at least, run by, or you should be in a mentoring program where you can discuss the management of that patient. So that in an inexperienced clinic where they're just trying to learn hep C, starting with the treatment naïve, that means they've never failed prior hepatitis C therapy, and those without advanced liver disease, non-cirrhotic patients, the expectations for current treatment are greater than 95% cure rates for most patients, especially easy-to-treat patients, and then you want to make sure that that provider has enough time to educate the patients and make sure that they're adherent. Even in a more experienced setting, if you've got a patient that's more challenging because they are co-infected with HIV, that is going to require a certain subset of providers; they've got advanced liver disease, they've had a kidney transplant, they've got a lot of medical comorbidities, they have a lot of drug-drug interactions. These are all individuals that take a lot more time and a lot more thought, and isn't, necessarily, going to have the primary care provider that may not have all the resources that an academic institution or someone with a bigger staff/support staff is able to accommodate.

Dr. Caudle:

Great. And finally, how do you see the role of the primary care provider evolving in the coming years with regards to hepatitis C treatment and management?

Dr. Reau:

Well, I think our biggest challenge is going to be identification. As our birth cohort, right now we know that individuals born between 1945 and 1965 have a higher risk for hepatitis C and that's a very easy thing to go by, right? Your birthday. As we treat the patients we are going to have to look harder to find those with hepatitis C, and that's a good thing. We want to have an impact on this disease, but

we are going to rely heavily on our primary care providers for identification. I also think that as we reach out into more challenging groups, so as you treat the easy patients that are already in your practice, now we're going to be looking at individuals that might be in opiate substitution therapy programs, people in those FQHCs, are populations where there may not be as many provider choices and our primary care providers might be the only link to a successful cure that that patient has. And so, we're going to lean heavily on them in those situations also.

Dr. Caudle:

Wonderful. I'd like to thank our guest, Dr. Reau, for helping us better understand the role of the primary care provider in hepatitis C management. I'm your host, Dr. Jennifer Caudle, and thank you for listening.