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## Primary Care's Role in SLE: Treating, Monitoring, & Consulting

Dr. Birnholz: Although the prognosis for patients with systemic lupus erythematosus has improved dramatically in recent years, the disease is often refractory to treatment, and preventing or mitigating flares and multisystem damage remains challenging. But are there ways we can help reduce side-effects and improve treatment adherence for our patients and understanding how to get there will be the focus of today's discussion.

From the ReachMD Studios in Fort Washington, Pennsylvania, this is CME on ReachMD. I'm Dr. Matt Birnholz, and today I'll be discussing the treatment of systemic lupus erythematosus with two experts who actually partner together to care for these patients: Dr. Robin Dore, practicing rheumatologist and professor at the school of medicine at UCLD, and Dr. Louis Kuritzky, a family physician and Assistant Professor Emeritus with The University of Florida School of Medicine.

Doctors, welcome to you both.

Dr. Dore: Thank you very much. Glad to be with you.

Dr. Kuritzky: Good morning. Glad to be here.

Dr. Birnholz: So, I'd like to frame our discussion around a patient case. And I'll introduce Trina. She's a 38-year-old, Asian-American woman with a history of lupus. She was diagnosed one year ago, and started on hydroxychloroquine, at 200 mg/dL. She was doing well on that regimen, but today she is presenting with multiple new spots of a raised, scaly rash on her face and back. She reports extreme fatigue and intermittent sharp inspiratory right-sided chest pain. There is a friction rub heard on auscultation. She is otherwise afebrile, and not in acute distress. So, Dr. Kuritzky, as someone who would be uncovering these details in your primary care practice, what would you do for Trina at this point?

Dr. Kuritzky: Well, first, apparently she has done reasonably well for the substantial amount of time that we anticipate that lupus is a disease with waning and waxing and flares, and her new symptoms would be indicative of a flare. The likelihood of flare versus other issue like perhaps not being compliant with medication has to be weighed, or perhaps she needs a bigger dose of her medicine. But I'm glad she's back and reporting what her symptoms are so we can possibly modulate what her regimen is. Even though the symptoms are pretty typical, of course we have to make sure there is no other disorder going on, and perhaps some monitoring of the lab data would help us to ascertain if this was a flare, things like complement levels or sedimentation rate.

Dr. Birnholz: And, just to stay with you for a moment, Dr. Kuritzky, let's advance the timeline about a week later. So Trina comes back to your office for follow-up. Her rash is improved, but she is still experiencing fatigue and pleuritic chest pain. And on top of that, she is now having joint pain. So what's next for Trina?

Dr. Kuritzky: Well, I'm sorry she hasn't improved enough with intervention, and I'm going to consult a local rheumatologist who has been involved in her care in the past because she may need to step up in her care.

Dr. Birnholz: Excellent. So it's a perfect segue. Dr. Dore, what are your thoughts here? Do you agree about possibly starting any particular medications; a biologic, for instance? Would you want to see Trina at this point?

Dr. Dore: Well, certainly the first thing I'd want to do is measure the hydroxychloroquine levels. That can tell us if the patient is on the appropriate dose of hydroxychloroquine, but it also can tell us whether the patient is taking the medication as prescribed. If her blood level shows it's in the therapeutic range, then I'm going to talk to her about other options. One option would be adding azathioprine. Another option would be adding mycophenylate. Most patients, before considering biologic therapy, would have taken mycophenylate and azathioprine. And then if she doesn't tolerate those, or they are not effective, then I go ahead and think about switching her to biologic therapy. And that switch and trial of medication; the timeline can really depend on how well she is doing to each medication I've tried. Unfortunately, we do not have any blood test that's going to tell us exactly how she is doing in this short period of time, so I will really go by her clinical symptoms to tell me whether the medicine is effective or not.

Dr. Birnholz: For those just tuning in, you're listening to CME on ReachMD. I'm Dr. Matt Birnholz, and I'm speaking with Dr. Robin Dore and Dr. Louis Kuritzky about management strategies for patients with SLE.

So, earlier, we got a sense of the treatment progression for our patient case, and I want to dive into her current treatment plan in more detail. So, Dr. Dore, can you tell us a little bit more about the role of biologic agents for patients like Trina? What have the clinical trials shown with regards to their efficacy and safety?

Dr. Dore: Well, when we look at systemic lupus, as I mentioned earlier, what we typically do is go from the hydroxychloroquine and maybe low doses of prednisone, to a non-biologic therapy like azathioprine or mycophenylate. The good news is that most patients respond to the four conventional therapies. But for those few patients that don't, the good news is that we have two different new biologic therapies that the rheumatologists can recommend for these patients, but these are not medications that most of the primary care clinicians are familiar with, and those include belimumab and rituximab.

If we look at the belimumab efficacy data, there are two BLISS trials, and the primary endpoint—that means the goal of what we want patients to reach—is something called SLE Responder Index, and this looks at many different aspects of their systemic lupus. So when we look here at the data from the BLISS-52, what we see there is that there are two different doses of 10 mg/kg, and 1 mg/kg compared to placebo. And here we have a 44% placebo response rate. And that's one reason that it is so difficult to meet primary endpoints in lupus because it's such a complex condition, and certainly this is a high placebo response, where normally we'd expect about a 30% placebo response. We see that with belimumab, patients start responding between 12 and 16 weeks, and usually their response levels off after that, but certainly the dose response is better with the 10 mg/kg. Then we look at the BLISS-76 data.. Here, we see that the placebo response was a little bit lower at 32.4%, but the response rate to the two doses of 1 mg/kg and 10 mg/kg were very similar.. And someone would look at these and say, 'Well, that's not really a very good response.' But we have, as I mentioned, so few choices in lupus, that if I can improve the patient's disease by about 40%, I'm happy, and then I should be able to taper down their dose of steroids.

When we look at the data with rituximab, this is data from what is called the EXPLORER trial, and unfortunately, again as I mentioned, lupus studies are very difficult to reach that primary endpoint. That primary endpoint in this study was not met. There was, however, a reduced risk of subsequent first severe flare, a lowered mean severe flare rate, and there were definitely efficacy signals in certain patient subsets, including African-Americans and Hispanics. Many of these patients with more severe disease are African-American or Hispanic. Similar to belimumab, what we see with the rituximab is also playing a potential role in reducing the dose of steroids. If we can get them on a lower dose of steroids, and then these patients should have a better quality of life and less

morbidity and mortality.

Dr. Birnholz: Thank you, Dr. Dore, that's excellent information to help ground us on the current treatment options that you're considering. But let me come back to our patient, Trina, then. Since you're considering belimumab for this patient, what would she need to know?

Dr. Dore: Again, in looking at her, I would assume that her hydroxychloroquine levels were therapeutic. I would have tried either azathioprine or mycophenylate. Again, she is 38 years old, if she wants to attempt pregnancy, mycophenylate would not be an option and, therefore, I would have given her probably an 8-week trial of azathioprine, monitoring her labs for side effects, looking at the blood count and liver, and whether she has abnormalities on the labs, or does not respond to the azathioprine with regards to the multiple complaints that she has, including joint pain and pleuritic chest pain, and just not feeling well. I would certainly consider adding belimumab to the therapy that she is already on, and then send her back to the primary care doctor, as I mentioned, to monitor her. But then I'd like to see her back in three months to assess her therapy and see how she is doing.

It's really important that she follow up with her primary care doctor. Again, I'm always concerned about pregnancy in the lupus patients to make sure she is taking the medicine like she's supposed to. Also, if she is on background therapy; let's say with steroids or with the azathioprine, that she's not having side effects from those medications. She also needs to get her flu vaccination in time because of the increased risk of infection with azathioprine, the steroids, and the belimumab.

Dr. Birnholz: Thank you, Dr. Dore. And unfortunately, we are almost out of time, but before we close, I want to explore what's next for patients like Trina, once her current treatment is under way. And Dr. Kuritzky, starting with you, what's the follow-up plan, such as how you'll help her manage any side effects, what situations might compel your outreach to a rheumatologist, and so forth? Can you give us some sense of that?

Dr. Kuritzky: Well, hopefully the patient will feel enthusiastic about taking a next-step therapy that will improve her symptoms, and has been documented to improve quality of life. We can also celebrate the fact that maybe she won't be having to use bursts of steroids. Sometimes patients want to reach for steroids because they're so promptly effective, and patients feel immediately better and they don't see the underlying occult things that are happening to their bone mineral density that they're going to have to pay a price for down the road unless we restrict the use of steroids. Once she's stabilized and feeling the improvements that are likely to occur with the belimumab, we want to make sure that she doesn't forget that there are a lot of other issues that need to be addressed. Even in young women like this, there is a dramatic increased risk for cardiovascular disease, so we want to make sure that we are monitoring any of her cardiovascular risk factors and then making sure that the patient isn't engaging in self-destructive activities like cigarette smoking, which could increase her risk for cardiovascular disease, and make sure she's on the right path about following routine healthcare issues so that it's not just the story of lupus as her only healthcare issue.

Dr. Birnholz: Excellent takeaways, Dr. Kuritzky. And Dr. Dore, let me come back to you for the final word. You mentioned the timeline in which you'd want to see Trina again, but is there anything else you'd like to add here?

Dr. Dore: I think that the two important things, is that there is that line of communication open, so if Trina has any problems, she can, will contact the primary care clinician, and if the clinician has any uncertainty or concern about some of Trina's complaints, you know, again picking up the phone and asking the rheumatologist, 'Is this a side effect of the medicine? Is this part of the disease? What laboratory tests should I order?' in order to determine whether it's her disease or a side effect to the medicine. And again making certain that the primary care clinician and the rheumatologist have that communication, but that the patient feels very comfortable with the primary care/rheumatology relationship, and that she will feel comfortable if she is not feeling well, to pick up that phone or send us a message on the portal so that we know how she's doing, instead of waiting until her next appointment to let us know that.

Dr. Kuritzky: I want to echo what Dr. Dore was just speaking about, because you remember when we first encountered the discussion about this patient, fatigue was one of her symptoms. Patients with lupus often feel like the fatigue aspect of their life is not respected and validated. And our patient needs to know that this is going to be a long-term relationship, that the fatigue can be a cardinal sign of the disease, even though it may not be graphic like a swollen joint or something that you can prove on a laboratory

test, like protein in her urine. It's sometimes incapacitating or reduces a person's quality of life in a dramatic fashion. So she needs to know we're there to listen to her complaints, and even things like fatigue may be important disease markers; we really want to know how she's doing. We're open to hear about all aspects of her health for the future.

Dr. Birnholz: Well, those are fantastic takeaways. As we come to the end of today's program, I want to thank my guests, Dr. Louis Kuritzky, and Dr. Robin Dore, for helping walk through current treatment strategies for patients with SLE. Doctors, it was great having you both on the program today.

Dr. Dore: Thank you very much.

Dr. Kuritzky: Thank you.