LEUKEMIA & LYMPHOMA SOCIETY®

THE BLOODLINE WITH LLS

A PODCAST FOR PATIENTS AND CAREGIVERS

Episode: 'CAR T-cell Therapy: Your Questions Answered'

Description:

Curious about CAR T-cell therapy? We went straight to the source for answers.

In this episode, the LLS Patient Education team visited The University of Miami Sylvester Cancer Center to meet with Dr. Trent Wang. He answered some of the most frequently asked questions from our patients and caregivers about this innovative cancer treatment - from who's eligible and what to expect, to side effects, caregiver roles, and exciting future developments.

Transcript:

Elissa: Welcome to *The Bloodline with LLS*. I'm Elissa.

Lizette: And I'm Lizette. Thank you so much for joining us on this episode.

Elissa: Today, we will be speaking with Dr. Trent Wang, a hematologist/oncologist and Associate Professor of Clinical Medicine within the Division of Transplantation and Cellular Therapy at the University of Miami, Sylvester Comprehensive Cancer Center in Miami, Florida.

Dr. Wang's research focuses on complications of allogeneic stem cell transplantation, including studies of graft-versus-host disease, infectious transplant complications, and transplant survivorship. He also studies the outcomes of immune effector cell therapies such as CAR T cells for various cancers. Welcome, Dr. Wang.

Trent Wang, MD: Thank you so much. It's my pleasure.

Elissa: So, our episode today is on CAR T-cell therapy; and we have had a lot of questions from patients and caregivers come into our Information Specialists and LLS Community. So, we thought we'd ask some of the more common questions. But first, let's start with the basics. Could you tell our listeners what CAR T-cell therapy is and how it is different from other standard therapies like chemotherapy or stem cell transplant.

Dr. Wang: Of course. CAR T-cells are totally different and there's something very new over the last five to ten years. They've really exploded onto the scene. CAR T stands for chimeric antigen receptor T cells, and these are basically reprogrammed T cells. T cells are immune system fighting cells, and these technologies that have been developed allow us to teach these immune system cells how to target cancer based on some of the hats that the cancer cells wear. These are the antigens, and through this reprogramming, we have been able to direct them specifically to try to kill the cancer cells.

Now, these are very new; and they're being developed in many different cancers, as well as indications. They're different than chemotherapy and stem cell transplants because they're currently used in cases where chemotherapy and transplants aren't effective. So, they're used when there's active disease that is not responding to current treatment.

Lizette: I know that they're not approved yet for all of our blood cancers. So, which blood cancers does CAR T work for, and are approved for?

Dr. Wang: Yeah, of course. It began its approval process with the lymphomas, diffuse large B-cell lymphoma (DLBCL), the primary mediastinal B-cell lymphomas (PMBCL). Thereafter, it was also approved in the acute lymphoblastic leukemia (ALL) setting, initially in people who were 25 years and younger; and now we have it available for adults, as well. Subsequent to that, we've had a few more lymphoma approvals, different types of indolent lymphomas, including recently the CLL, the

chronic lymphocytic leukemia indication; and huge on the scene has been the multiple myeloma. Those patients have been able to benefit from CAR Ts very recently.

Lizette: So, why does it work on some blood cancers and not all?

Dr. Wang: Yeah, that's a great question. The main reason is because we're trying to identify safe targets that are present on the cancer cell and are generally not present anywhere else because you don't want to attack normal cells that also bear that same hat, as I call it. So, when you identify one of those targets, you have to make sure that the CAR T that's designed to attack the target is able to eliminate it and grow itself to certain levels and also, be safe enough without those off-target damages or without being too hyperactive that it causes too much inflammation and immune system problems in addition to that.

Elissa: Okay, so with the myeloid cancers, for instance, it seems to be difficult to find a target that's also not on healthy cells.

Dr. Wang: That's a very good summary of it, yes. A lot of times when you select a target that is on other cells, you're causing way too much off-target damage; and that can cause things such as very low blood counts or organ damage, for example.

Lizette: And many of our blood cancers have different treatment options. Why would somebody choose CAR T cell over another treatment option of stem cell transplantation or other treatments?

Dr. Wang: Yeah. As it currently stands, March of 2025, CAR T cells are still mostly used when the other options aren't working well. So, for example, if chemotherapy is able to eliminate the cancer and the chance of the chemotherapy curing the cancer is fairly high, you probably don't need additional therapy at all. And an example of a blood cancer, if that chance of cure with chemotherapy is not that high, sometimes we offer a stem cell transplant to optimize those numbers of cure.

The CAR T cell is used if the cancer has already returned after therapy or if the therapy did not work and there's still a lot of active cancer. We are investigating different ways to use the CAR T cells as well, so there is also consolidation methods that are being assessed, how to improve a response that's already kind of worked.

The most recent example is in multiple myeloma after an auto transplant (autologous transplant). Some people who didn't have a great response with auto transplant, meaning they still had some levels of detectable myeloma in the blood, underwent a CAR T cell directed at the multiple myeloma; and that was able to reduce the protein further. So, that was just presented at the Tandem Meetings (Transplantation & Cellular Therapy Meetings of ASTCT(R) and CIBMTR(R)) in Hawaii last month. That's just one example of things that are happening there.

Elissa: Great. So, it sounds like it's not used right now as a first-line treatment and just for relapsed or refractory patients.

Dr. Wang: Right. Currently, it's not used in the first-line setting. With most cancer therapeutics, you generally try it to see if it's safe and effective in people who are the most sick. And then as it shows itself to be reliable, you starting moving it closer and closer to the people who are closer to the first line, I should say.

Elissa: Do you think it ever could be potentially used as a first line?

Dr. Wang: I do. It definitely has that potential. There's a lot of other factors involved in it such as the cost currently.

Lizette: So, are there considerations for where CAR T goes in the sequencing of treatments? Should it go prior to a stem cell transplant? Or if there's newer treatments, like we're hearing a lot of bispecifics as new treatments, should it go prior to trying another therapy or behind another therapy?

Dr. Wang: Yeah, I think that's a question that is great for discussion, but there's no right answer to that for the most part. Every CAR T has been FDA approved at a

certain line of therapy. So, to be eligible for it, you might have had to fail one or two or some certain specific drug, for example.

So, the FDA already defines when we can use the CAR T. But in terms of the optimal timing, when we think it'd be most effective, there are going to be six different opinions among five different physicians; and it depends a lot on the cancer that we're treating. It depends a lot on the other options for that specific cancer and the patient preferences.

One of the most important things about CAR T is that it's a fairly high-risk procedure in certain cases, especially if there's a lot of tumor burden. We always think that the less tumor we have going in the safer and possibly more effective it will be. So, all of those things kind of play into the decision-making process.

Elissa: Okay. So, for our listeners who are new to CAR T-cell therapy, can you give us a basic description of the full process of CAR T-cell therapy from preparation to remove the T-cells through after care?

Dr. Wang: Sure. I'll give the example with the B-cell lymphomas since that's the one that's been around the longest. Generally, if a patient is diagnosed with a B-cell lymphoma, they'll undergo chemotherapy treatment and then they'll have assessments using usually PET scans or CT scans to make sure that the chemotherapy is working, that the lymphoma is shrinking. If the lymphoma goes away and then it returns very early, one of the indications for one of the CAR T cells is if the cancer comes back within 12 months, that's a very aggressive subtype of it. So, they become eligible for CAR T.

Let's say that did happen in this example case, then, the cancer doctor would refer the patient to a CAR T center or they would do it themselves if they're already at the center. And then, upon meeting the CAR T physician one of the first steps that happens, other than explaining this whole process, is to obtain insurance approval.

This insurance approval often takes between one to four weeks, depending on the complications that we run into. Usually, closer to one, we hope.

And as we're doing that, we're also doing some tests to make sure that the patient is eligible in terms of their comorbidities, to make sure that their body is strong enough for the procedure upcoming. So, we have some tests such as an echocardiogram (EKG) or pulmonary function tests (PFT), and we check the liver and the kidney numbers out. All of those things.

We would then set up a date to collect the blood. This is an apheresis procedure where it kind of is like a blood donation or plasma donation if anyone's ever done that. You get two IVs, one in each arm – one to take the blood out of the body. It goes into a machine. The machine spins the blood. Based on density, it takes out a layer of the lymphocytes, which are the fighting cells that we're after. And then you get the rest of the blood back the other side.

So, it's a circuit. It lasts about two or three hours on the machine. It's not painful. It's rather boring. And then, the cells that are collected are shipped off to one of several companies these days that are approved to manufacture the CAR T.

The manufacturing process generally takes between 17 days to generally a month, if that. Closer to the lower end. And then, during that manufacturing, the company will make sure that the cells are growing, that they're recognizing the bad guy when they're exposed to it, and a series of other quality checks.

So, from the time that you meet the CAR T physician, a lot of dates are getting scheduled. You're getting some tests also scheduled. The apheresis collection day will be put a couple weeks in the future, generally. And we have to make sure that there is a pause of therapy if you are on therapy because too much chemo or immunotherapy can actually reduce the number of circulating lymphocytes that can make the collection more difficult to complete successfully.

Once that patient gets to that collection, they finish the collection. They're waiting for the cells to manufacture. Like I said, another two to four weeks, usually. And then, they may or may not need treatment during that wait, and this is called bridging treatment because we don't want to hit it too hard but we don't want the cancer to grow too much either during this process. Like I said, the less cancer probably the better the outcome.

And then, we get a phone call from the CAR T manufacturing company saying Ms. X's cells are ready. Great. Then we can start scheduling a few more dates, including something called lymphodepleting chemotherapy dates. These are generally three doses of chemotherapy that are given to the patient before CAR T, and these chemotherapy doses are not so much to hit the cancer hard but to kind of make space in the immune system so that when the new T cells are infused, they can grow.

It's moderate-strength chemotherapy. Most patients don't feel too ill from this. It's done as an outpatient. And then, at the University of Miami, we usually admit the patients for a 1- to 2-week hospital stay for the infusion of the cells and monitoring of the side effects. Many CAR T products can be done as an outpatient, depending on where the cancer center is though. So, that's not always inpatient.

Lizette: So, people have to stay near the cancer center in case anything happens after the treatment or for observation.

Dr. Wang: So, if the CAR T were to be done as an outpatient, meaning the infusion and the immediate days right after the infusion, you would have to stay very close to the cancer center. The question we always get is after your discharge from the hospital – let's say you did the CAR T inpatient – you still have to stay very close to the cancer center, but probably not as close. Usually, we like within 45 minutes to an hour. And that's just in case complications pop up. You don't want to end up in the local emergency room that doesn't have any familiarity with the CAR T side effects. They are somewhat unique, yeah.

Elissa: Right, yeah, we'll talk about side effects a little bit later. So, I'm sure patients that are listening heard the word chemotherapy and moderate dosage of chemotherapy. I'm sure they were wondering are they going to lose their hair.

Dr. Wang: You know, I used to say no, but I've seen enough cases where there's such patchy loss of hair that, in the last several months I say yes. You'll probably lose enough hair that you're not going to be happy with me.

Elissa: Okay, it's good to know right off the bat. So, now we're going to ask some common questions that have come in to our Information Specialists and the LLS Community. Our first question that patients and caregivers often want to know is how long the reinfused T cells remain active.

Dr. Wang: Yeah, that's a great question, we don't exactly know the answer to it. There are cases where we've assessed for the CAR T cells to be checked in the body years later, and we can still detect them. But, I guess, the bigger point is are CAR T cells curative? Do they do enough to keep the cancer away forever? And the answer is we believe so. In many cases, there are patients who can be cured of their lymphomas or leukemias with just the CAR T cells alone. Generally, it's a fraction of patients. It's not every patient. And those patients that are cured have some degree of high levels of CAR T expansion early on. And, like I said, limited disease but, yes, the answer is these are a potentially curative therapy.

Elissa: So, the CAR T expansion, is that them essentially replicating themselves?

Dr. Wang: Yes, early on when they're put into the body, the CAR T cells look for the bad guy. Once they see them, they call for help and they release these signals. These signals cause other helper cells to come but also, cause themselves to grow and replicate, as you mentioned. And the degree of expansion has been associated in some studies with long-term, cancer-free survival risk.

Lizette: Well, our next question from our patients is, what's the difference in getting CAR T-cell therapy versus monoclonal antibody treatment, bispecifics, a transplant?

Dr. Wang: With regards to CAR T versus bispecific, it's a discussion between the physician and the patient. Bispecifics have been approved in many of the same indications that CAR T has. They have some more data showing that they can work when CAR T has failed already, so that's obviously one reason to use them if CAR T has already been tried.

But if neither of them have been used and they're up for consideration, one thing to keep in mind is that the CAR T is a one-time infusion, and then you watch for what happens. The bispecifics generally are given every other week or some iteration of that. Much like chemotherapy, they're a therapy that we have to continue on. There is some risk of infection that might be a little bit higher with the bispecifics, but CAR Ts certainly have their own risk as well.

So, I think we don't know the answer to that just yet. If there's urgent cancer need for treatment, as we mentioned earlier, there's a lot of start-up time to get the CAR T cells up and ready and able to be infused, so bispecifics may be more useful in those situations where we can just infuse a patient within a week or less, whereas the CAR Ts will need, you know, two to six weeks of setup.

Elissa: So, what happens when CAR T therapy fails? Can it be given twice?

Dr. Wang: Yeah. CAR T failure is a huge area of need still. It's a new therapy. We're still kind of navigating our way around it. But we definitely don't like to see that.

When it fails, we look for clinical trials as our first option because those are the next generation of treatment. So, whenever possible, that'd be our first recommendation. The bispecifics, as we mentioned, has data in the setting of CAR T failure. And there is data saying that stem cell transplant can still help many patients who have CAR T failure. So, there still are many options. We just don't know the best ones yet.

Elissa: That's good to know. So, just because it fails doesn't mean that a patient is out of options.

Dr. Wang: Correct. And the answer to the second CAR T is, for most patients, a second CAR T is not easy to obtain, largely because of insurance approvals. But at the University of Miami, we've been able to do it here and there in the setting of a clinical trial because clinical trial CAR Ts are usually not done through insurance.

Lizette: And are patients at risk of developing a secondary cancer after CAR T-cell therapy?

Dr. Wang: I think anytime you're exposed to more chemotherapy, that secondary cancer becomes a higher risk. The answer is yes. You're at slightly more risk just because you're subjecting yourself to that additional chemotherapy, but also the additional inflammation that comes with CAR T. But as with any decision in hematology/oncology, we have to weigh the benefit versus the risk of therapy. And the majority of cases, the benefits will be potentially much higher.

Elissa: Are there certain cancers that are more prevalent after therapy?

Dr. Wang: Yeah, so, the more common ones are the skin cancers and the ones that aren't life-threatening. The dangerous ones that are not as common are the ones that might include secondary bone marrow cancers like myelodysplastic syndromes (MDS). There are these very few reported cases where the CAR T cells themselves can cause cancer. Not so much a secondary cancer, but a CAR T-related cancer just from the genetic modification. These are extremely rare. I would not worry about these, no.

Elissa: Good to know. So, we've had a lot of questions come in from caregivers. Can you tell us what the caregiver can expect and what their responsibilities might look like?

Dr. Wang: Yeah. Caregivers are very, very important for CAR T success. If the CAR T is being done as an inpatient, they don't need to do much there. They're there for

moral support. But upon discharge, once you're out of the hospital, you don't have a nurse within a minute of you all times, then the caregiver's job is to be our second set of eyes. They're supposed to see when the patient might not be acting themselves. If they're more tired, sleeping more than usual, they should give us a call. If obviously, there's a change in the behavior of the patient, that's something they need to look out for. But in general, just the second set of eyes and be someone who can advocate for the patient when they might not feel like getting themselves driven into the cancer center. Someone needs to help you.

Elissa: Yeah. So, it's good that caregivers don't have to do a whole lot while the patient is in the hospital, but at home are they really expected to provide that 24-hour care on their own or is it just really monitoring symptoms, monitoring any signs that may look off?

Dr. Wang: Yeah. Before CAR T, we usually say they don't have to be a 24-hour caregiver, more of a person who can check in on you. If they live with you, that's definitely better than if they don't. But it's not mandatory that they're there next year for the entire day. Mostly so just as that check-in.

Lizette: So, caregivers have to take a lot of precautions after like a stem cell transplantation. Do they have to still take the same types of precautions so the patient doesn't get any type of infection, you know, cleaning the house differently, things like that?

Dr. Wang: Yeah. For the most part, in the stem cell transplant field, we've been following COVID precautions, you know, before COVID precautions were a thing. And that, for the most part, is still what we follow. The risk of significant infections after CAR T is there. There's a lot of chemotherapy. Sometimes we have to give some corticosteroids for the treatment of CAR T-related side effects. So, simple infections can become not so simple in this patient population. The caregivers should, to the best of their ability, try to avoid going to concerts and putting themselves out there

when not necessary. We understand it's not always possible, but, yes, the less contact we have with potential respiratory viruses the better.

Elissa: Is that a conversation that then you're having with the caregiver?

Dr. Wang: Yeah. Trust me, they'll bring it up to me.

Elissa: Good. So, what if a patient doesn't have a caregiver? Are they still able to get CAR T-cell therapy?

Dr. Wang: It really depends on the, the whole picture here. At the University of Miami, a caregiver is a necessary part of the process. So, a caregiver doesn't have to be a family member or anyone specific. It can be a collection of friends or church members are often ones that I hear about. But they just need to identify a network that can help them get where they need to get.

Elissa: Good, so you can talk to them and say, "Hey, who in your life would be able to potentially stop by through the day or a few people stopping by through the day, so that they'd still be able to get this procedure?

Dr. Wang: Exactly, yeah.

Lizette: You said that we were going to speak about side effects. So, what are the potential side effects from CAR T-cell therapy?

Dr. Wang: Yeah. Well, I like to say the biggest side effect is that it doesn't work for the cancer. That's always the one I counsel, most importantly, that despite these being available, they still don't work all the time. In terms of what happens, in the hospital stay for a typical CAR T patient, after the CAR T infusion, when the cells are expanding and growing and causing inflammation, it causes release of these signals. They're called cytokines, and this is a cytokine release syndrome, which, in short, makes you feel like you have the flu, a really bad flu. You get back pains, you get

fevers, it might affect their other organs, affect their blood pressure, oxygen. For the most part, it's fevers though.

That has to be watched. It's treated with antibiotics generally, and just in case that there is an underlying infection as well. But sometimes, we have a special medicine that's FDA-approved for this specific syndrome called tocilizumab that we use. We have steroids that we use, and we have a couple other medications that aren't FDA-approved but that help a lot in these situations.

And then, the more scary side effect that we see in the hospital is the neurotoxicity. It's called ICANS or immune effector cell-associated neurotoxicity syndrome, and this is a neurocognitive thing. It's when the inflammation signals kind of start affecting the brain and the brain fluid, it can cause a whole spectrum of effects, including just maybe mild delayed speech or there's a little bit of difficulty with expression, to tremors, to difficulty in answering questions, all the way on the very severe and very rare side, it can cause seizures or in even swelling in the brain. So, these are the things that we really are looking for when we're doing the CAR T infusion in the hospital when there's fever; and these are the things that we generally observe less when there's less cancer going into the CAR T.

Lizette: And are those manageable?

Dr. Wang: Yes. The vast majority of these are resolvable very quickly with therapy, within a matter of days, yeah.

Lizette: Okay. We also had a patient ask about the side effect of B-cell aplasia. Can you talk a little bit about that and tell our listeners what that is?

Dr. Wang: Yeah. B-cell aplasia is when the CAR T-cells suppress the antibody producing cells that live in the bone marrow. So, B-cell aplasia is usually measured just by our antibody levels. You've heard of the IgG level, the immunoglobulin G, which is just one of the antibody sets that are produced. After CAR T, the B-cell

aplasia is generally noticed at a small amount for most patients. That the numbers of the antibodies decline in the first one to three months. You see that very commonly. It has to decline to a significant level or there have to be infections for us to really treat it aggressively with antibody replacement, which is called intravenous immunoglobulins, IVIG. We don't always do that, we watch the levels though. And usually within a matter of months, they tend to reconstitute and get better.

Now, the caveat is in B-cell ALL, the acute lymphoblastic leukemia population. Sometimes they can have very low B-cell levels for long periods of time. And this is usually a pediatric thing where they watch the B-cell aplasia and they like the B-cell aplasia. When they lose a B-cell aplasia, they don't like that. So, that's a setting that's more rare and we don't generally follow those guidelines in the adults, yeah.

Elissa: So, let's discuss the future of CAR T-cell therapy. Are there any emerging CAR T therapies or those still in trials that you're particularly excited about?

Dr. Wang: Yeah, definitely, definitely. So, one of the things that you heard me talk about was a delay in getting CAR T care. So, we have been working with one or two companies about working on developing these off-the-shelf CAR Ts, these allogeneic CAR T-cells, essentially, one that you can just take out of the freezer and infuse it in the patient immediately, once you have certain matches that you identify. But these would be great in terms of facilitating access to CAR T and getting them in the patients when they need them the most because we still have many patients who become ineligible for CAR T just because of the delays that occur. So, these are called off-the-shelf CAR Ts.

There's also, of course, new antigens, new cancer indications trying to use the CAR Ts earlier or in newer, different types of targets for the same diseases sometimes. For B-cell lymphoma, for example, they've been looking at CD22 and CD20 in addition to CD19, which is the FDA-approved antigen target. And combinations of the CAR Ts with other therapies are important. Here at the University of Miami, Dr. Lekakis has a

study where we're trying to optimize the effectiveness of CAR T by adding two other agents to it during the CAR T, before and after. So, the commercial CAR T target, CD19, and then he's adding a CD20 target and a CD79b target to it to do a complete program, and it's not complete, but that's the rationale. If you target different antigens, you might be able to eliminate any hiding or resistant cancer cells.

Elissa: So, that would be a single infusion then of T cells, and they would just be programmed to look for all these different targets?

Dr. Wang: Not this study. Those, what you're mentioning is CAR Ts that have more than one target, bicistronic CAR Ts. But this is just including two other drugs to be given around the CAR T days before and then days and weeks after the CAR T.

Lizette: So, what are you most excited about with CAR T-cell therapy and the advances that are coming up, as well as other advances for our blood cancers?

Dr. Wang: Yeah, I mean we hope that CAR T will be able to be obtained very easily for affordable numbers. And eventually, safe enough that it'll replace chemotherapy. That's the goal. This is what personalized treatment is. I think we're still fairly far off from that goal. But the immediate goals are just making CAR T cells more accessible and making sure that people know that CAR T cells are available. You'd be surprised that, well, maybe not you guys, but many people would be surprised to see how few patients are still referred for CAR T, just because of referring physician bias that they might not be eligible because of their age or, their cancer type is too aggressive, those kinds of things.

Lizette: That's a good point. A lot of people ask us about the age limits. Is there an age limit for CAR T?

Dr. Wang: I think we treated like an 81-year-old, so it's a case-by-case basis. There's no absolute number cutoff.

Lizette: Sure.

Elissa: And there's really also some difficulty too with patients maybe living farther away from a major cancer center that offers CAR T-cell therapy, right?

Dr. Wang: Yeah, that's always been a tough one, especially with the requirements to stay locally. But, that's why we have organizations such as yours to help everyone and do what we can to bring them close.

Lizette: And you're looking for CAR T now more to be curative. I know when it first came out, sometimes we were looking for it to bridge to another therapy. But at this point, we are looking for the word cure, right?

Dr. Wang: We are. And we don't know that every CAR T has that option, but many of them do. The only way to know is to give the data time to mature once you see the five-year data. If you're seeing that 30, 40% of people are still in remission, then you can throw that word around. But if it's 10%, that's not a great, permanent solution. Then you have to look at other consolidation measures.

Elissa: So, our final question today, on our patient podcast home page, we have a quote that says, "After diagnosis comes hope." What would you say to patients and caregivers who may be eligible for CAR T-cell therapy or have recently had it to give them hope after being diagnosed with cancer?

Dr. Wang: I wouldn't have chosen this field if that wasn't the case. I'm all about the hope.

Elissa: That's wonderful. So, there is a lot of hope there with CAR T-cell therapy.

Dr. Wang: Yeah, there certainly is, yeah.

Elissa: Wonderful. Well, thank you so much, Dr. Wang, for joining us today and talking all about CAR T-cell therapy. I hope that you've answered a lot of questions that are on the minds of our patients and caregivers today and so they can feel much

better about going into potentially having this procedure done. And so, thank you again for joining us.

Dr. Wang: Thanks for having me.

Elissa: Thank you.

Lizette: Thank you.

Elissa: And thank you to everyone listening today. *The Bloodline with LLS* is one part of the mission of The Leukemia & Lymphoma Society to improve the quality of lives of patients and their families.

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