The Blood Test That Can Detect Cancer at Stage Zero Transcript

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Introduction and Guest Welcome

Hello everyone, welcome to the Future of Menopause Summit. I'm your co-host, Doctor Ben, and I'm very excited. Today we have a very special guest for you guys.

Sumit Rai Sumit is the CEO, founder and Chairman of Cancer Check Labs and is also directly involved in the development of the technology underlying his company's state of the art circulating tumor cell, or CTC test, which will help revolutionize the early detection of cancer.

Welcome, Sumit. We're very grateful to have you here today. How are you doing? Having me, I appreciate it. Happy to be here. Awesome, awesome. Well, we are so grateful to have you here with us today.

So, Sumit, I was wondering, could you tell us how you got into this field and what pushed you to work on developing this technology for cancer detection?

Sure. It's actually a second career driven by a personal passion. My first career was in venture capital, private equity, and being a Silicon Valley tech entrepreneur.

Fortunately, after I sold my my last company about three months later, my only sibling, my younger sister, got diagnosed with cancer and a year and a half later passed away.

And that's why and how I got into cancer 16 years ago, back in 2010. And since then, I've sort of made a life mission to try to figure out how to move the needle on cancer, look for ways to detect it early, where survival rates are extremely high.

For instance, at stage zero, survival rates 99% and or find ways to eradicate cancer through various technologies. Awesome. Awesome. We are very grateful for the work that you do.

All right, so let's jump in.

Why Sumit Rai Entered Cancer Detection

So just general question for those who may be unaware, what is a CTC or circulating tumor cell test? Sure. So a circulating tumor cell if you have a solid tumor and that means any organ tumor lung cancer, breast cancer, colorectal, pancreatic, liver, bladder, skin, thyroid, adrenal, whatever the case may be, the primary tumor itself, the lump generally does not kill you.

What kills you is the tumor sheds tumor cells that circulate through your bloodstream that are known as circulating tumor cells, or CTCs, the acronym for short.

And the CTC spread the cancer in your body in a process known as metastasis. The cancer spreads into your other biological organs, makes them dysfunctional.

They shut down, and eventually you die. That's how you died from cancer. Generally speaking, you don't generally die from the lump. And so these circulating tumor cells are shed from that primary tumor from a very early stage.

Because in order to go from stage zero to stage one to stage two to stage three to stage four, that is a function of spread. It's a function of metastasis.

And the mechanism that underlies it is CTC dissemination that causes that spread. So tumors begin shedding as early as stage zero. And that's why if these circulating tumor cells can be detected in a blood sample early on, you

could detect a solid tumor as early as stage zero.

That's awesome. So what are some of the shortcomings of other CTC tests that are out there compared to yours? So there's a few different categories of tests you have to look at.

There's one other, a couple other CTC tests. One of the big problems right now with those is they use something known as flow cytometry. Flow cytometry is a is a great instrument for characterizing cells, is actually the gold standard for cellular characterization with one very prominent known exception CTCs.

What CTC Testing Is and Why It Matters

And and the reason for that is because circulating tumor cells are effectively mutants. They're mutated cells right there apparatus. And as a result, you cannot accurately characterize them with a full cytometry because you don't have the ability to program all the parameters that would represent them.

There's too much heterogeneity in circulating tumor cells, whereas with healthy cells, in order the white blood cells or red blood cells, where the case might be, you can predict what the surface protein should look like.

You can predict what parameters to look for because they behave, they're contained. They're they're very homogenous and they're representations. And so the heterogeneity of CTCs makes it very difficult for flow cytometry to work on CTCs, which is why it's known that it's not accurate for CTCs.

So other tests are trying to use flow cytometry generally, or they're trying to use something called negative depletion, which is essentially taking a sample like a blood sample and putting it in a chemical bath.

And the theory being that the CTC are a little more resilient than the healthy cells, as it'll kill off everything except the CTCs. That's wonderful in theory, but in practice, CTCs, while they are a little bit more resilient than normal cells, they're not that much more resilient.

It's going to destroy a lot of them, which could destroy your sensitivity on the test. Really, the best way to do is to have mechanical filtration, which is what we use.

CTCs share characteristics size, structure, rigidity, lack of malleability, lack of deformable. They're big. The hard, the stiff that will bend those parameters enable us to selectively capture them on the proprietary filters that we developed over the last 15 or 16 years.

In order to do so, we use a very nuanced and very specific poor geometry that works, from which we have an issue patent one of our four patterns, and that allows us to remove the CTCs from the blood sample without having to use a flow cytometry, and without having to use any kind of chemical depletion that may destroy the CSI's and destroy the sensitivity of the test.

The other area. Incredible. That's how differentiates from other CTC tests. I think the other category of tests are what are known as CT tests, and those have massive problems, although they're very prominent right now in the market. That will change.

You know, when a circulating tumor cell is a biological cell, it's a messed up, aberrant, malignant, dangerous mutated cancer cell. But it's a cell. It has the components of a cell.

It has a nucleus. It has a genome with the DNA sequence. It has cytoplasm, membrane and so on and so forth. When that circulating tumor cells dislodged from the primary tumor and starts circulating through the bloodstream, typically one of three events is going to occur.

A it's going to go through cell app Aptos which is programed cell death. B it's going to be eaten up by your white blood cells, which is your immune system, or C it's going to traverse your capillaries where the shear force is.

The physical stresses will destroy it. When any of those events occur, the cell and its components, including the genome, blow up in the little bits and pieces that are dispersed into your bloodstream.

And one of those components is the genome DNA sequence. So what ends up happening is little incomplete. Scripts and scraps and bits of DNA, these circulating tumor cells are being dispersed into the bloodstream.

What a lot of these ctDNA tests are trying to do is look at those little scripts and scraps of DNA from those destroyed tumor cells and then extrapolate and guess, and I emphasize guess whether or not they actually have a tumor cell.

They don't actually know. Now, there's many problems with that guess because that guess is highly erroneous.

How CTC Testing Differs From Other Methods

Problem number one is you're using incomplete scripts and scraps. You have very little signal. That's why the sensitivity of those tests suffers, because you don't have enough signal to detect. Because the signal is inadequate.

They often try to amplify the signal using techniques like PCR. PCR is fine to amplify viruses, like if you get pricked in a hospital, you need a rapid HIV test.

You need to amplify a whole, intact viral organism to be able to detect whether or not there or whether it was coronavirus or code. Whatever the case might be, PCR does not work well on highly unstable scraps of DNA.

If you try to apply PCR and highly unstable scraps of DNA, you will mutate them. So what ends up happening is healthy cells come in, they don't have signals to detect them.

They try to amplify it. And through that amplification, they mutate it in outcomes of false positive. That's why some of these tests have false positive rates at 56.9%, 57%.

And that's why these tests have recently been failing their primary endpoints on their clinical trials. Gotcha. So not sensitive and high false positive rate doesn't sound great.

No not at all. So yeah. No that sounds like the last thing I would want to use to screen for cancer. How early can your test detect cancer in the body?

We can and have detected stage zero cancer for example DCIs which is a breast cancer ductal carcinoma to on a blood draw. And so you're going to look one gram of tumor mass and say breast cancer for example, is known to shed up to 3.2 million CTCs a day.

And so there are millions and millions in one gram is nothing. One gram is not even palpable. You can't feel it. In fact, it's so small that many people refuse to biopsy because they will either miss or they will not procure enough tissue to actually do a diagnosis.

And so at stage zero gram, you're looking at millions of CTCs floating around the bloodstream. And that is the mechanism that allows us to be able to capture those CTCs and extract them.

And once we do, we can take those CTCs which are whole intact cells, not strips and scraps and diseases, place those whole intact cells onto glass slides because it is cellular tissue staining using standard gold standard pathology methodology using IFC, which is a host of chemistry to look at surface proteins and antigen markers.

Using histology scenes to look at the morphology of the cells shape, size, structure, which is dramatically different for kicks and healthy cells, and then hand them to a third party licensed pathologists to be able to evaluate and come up with a result.

And unlike ctDNA test, they can't do that because they don't have the actual cells. So that's all right. Are there any limitations to the results of your test?

You know, for example, any or particular types of cancer that could be missed or is your test able to, you know, if you do get a positive result, is it able to tell you, you know, where in the body that the CTC is coming from, can it locate the tumors?

So the today we only claim to detect solid tumors, solid tumors and their subtypes because the mechanism of metastasis is the same. It's dissemination of the CTCs from the primary underlying tumor.

We do not claim to detect blood cancers. I believe in the future we may be able to at least certain types, but some of them will be difficult with this mechanism because things like a lymphoma that is in the lymphatic system, that builds in the lymph nodes and spreads through lymphatic tissue, may or may not show up as commonly in the bloodstream.

And so that's why we only claim to do solid tumors at the moment. But solid tumors represent north of 90% of all cancers and blood cancers, you know, with some exceptions, typically are much easier to detect because you'll see them in a complete blood count.

You'll see them because they will mess up your your blood counts, your platelet counts, or white blood cell counts because they'll make the bone marrow dysfunctional.

And so the problem really has been more around the tumor detection, things like pancreatic cancer. Pancreatic cancer is considered to be a death sentence.

Pancreatic cancer is not a death sentence. Stage for pancreatic cancer might be a death sentence. Stage one pancreatic cancer is generally curable. You'll just never find it. There's no symptoms.

It's difficult to detect when they do fight it. It's typically by accident.

Early Detection, Cancer Types, and Screening Gaps

It's because they're doing some kind of procedure in an adjacent organ, and they notice an abnormality and they biopsy it and they go, oh my gosh, we found pancreatic cancer.

But when they do, pancreatic cancer is broken into. Even stage one is broken into one A and one B. Survival at one B for pancreatic is 85%. Survival at one A is 92%, survival zero is 99%.

And so it really just comes down to early detection. But being able to pick up those types of cancers was been very difficult historically. The other problem in the industry right now is we have very limited screening.

There are only five primary screens, right? Most of them are knocked on and those include mammogram for breast cancer, colonoscopy for colorectal, PSA for prostate, pap smear for cervical and lung CT for long.

Now, most people will not have a lung CT ordered unless they're 20 years smokers or have some genetic history or symptomatic. You're down to four. And then depending on your gender, you're not going to do all four.

If you're female, you're not doing a PSA. If you're a male, you're not doing a mammogram and a pop smear. So so if you're a female, you're generally going to do a mammogram for breast cancer, you're going to do a colonoscopy for colorectal, and you do a pop smear for cervical, you to do nothing for ovarian, you do nothing for thyroid, pancreatic, liver, bladder, stomach, esophageal, gastric, brain, all these sorts of things.

And if you're male, it's probably going to do a PSA for prostate. And you're going to do a colonoscopy. Just two for colorectal. And that's it. And so one of the issues has been historically that there just isn't sufficient screening methodology out there to detect the vast majority of cancers.

Today. We don't screen for them. That's part of why we developed this test. Absolutely. That's such a good point because it's important, like, you know, again, I'll emphasize that the correction is where you move the needle on outcomes.

Like you pick up early cancer. You have a really great chance of survival. So are you able to go into any more detail on the the technology of the filter that you were describing earlier or the test in general?

The, you know, the capture apparatus, just to give us any more of a clearer idea, more information on how this test actually works. It's fascinating stuff, really is.

Well, it took about $80 million in 14 years to develop the technology. And so removing circulating tumor cells from whole blood is very challenging. There's a dozen technologies in the world today, generally that are known to be able to do it.

They're very well understood. They're very well studied. They're competitive analyzes and medical journals like the Journal of Hematology blood and the Journal of Oncology Cancer.

And depending on which of those we're talking about, they can process between half a milliliter of blood to nine milliliters of blood. And that's the range.

And on the high end nine milliliters is two teaspoons. That's not a lot. The human body is 500ml of blood. That's arguably not even statistically significant at the size.

And the mechanisms they use are generally twofold. One is something called EPC which is looking for a surface protein marker. Cam stands for epithelial cat hair and Indian molecule.

And the second is using something as a microfluidic, which is a custom designed circuit that's very slow. One of the problems with microfluidics is that it takes a long, long time.

And so by the time you actually process the sample, the white blood cells might actually eat up all the seats in the blood because it's 24 to 48 hours.

So what you need is a rapid way to be able to extract those CTCs before that occurs, in a way to get scale. And so where this started actually was because we were thinking about a principle where if the primary tumor is shedding CTCs to spread the cancer, and the problem is generally not the primary tumor, it's the metastasis, can we remove those CTCs from the bloodstream in order to slow down, inhibit metastasis, to extend life?

And so we began by creating very large scale filters that could process over 10,000ml of blood. The human body has about five liters, 5000ml of blood depending on body weight, 4600 to 2400 generally.

And so what we're trying to do is build a cancer dialysis machine, which we built. We have prototypes of those machines. Those machines are medical devices.

They will need to go through the FDA. That will take some time. But in doing so we built these very large scale filters that in real time essentially could remove CTCs.

And what we realized was the difference between a 10,000 milliliter filter, a 1000 milliliter filter, 100ml filter, or a ten millimeter filter is a scissor.

Just cut the sheet smaller. And so what we did was we built all scale, you know, consoles that could essentially deal with smaller sample sizes for the purposes of screening to go to market first.

And in order to do that, there's no equipment out there today in the world that standardized that can build us. So first you have to build actually custom manufacturing equipment, which is custom lasers, custom optics, custom housing, custom systems that will take you three, four years.

If you could successfully build that, which is very difficult, you still have a major first filter. Then you have to solve, you know, poor geometry problems, laser physics problems, optical training problems, material science problems.

And maybe 5 or 6 years later you'll make your first filter. Once you make your first filter, you then have to figure out how do you make 101,000?

How the Filter Technology Was Built

How do you scale production? That's going to take you another year or two? Once you do that in every square foot of this filter sheet, there are 117 million pores of a specific geometry.

You cannot inspect that manually. You have to figure out how do you build automation to actually do the inspection and quality assurance of these filters.

That's going to take another couple of years. Eight. Ten years later, hopefully, if all goes well, you'll have a manufacturing system. You'll have the ability to make some filters, quality assure them.

And now you have a custom filter. What do you do with it? It doesn't plug into any standard piece of equipment. So now you have to build custom housings to hold it and assemblies.

You have to build custom tubing sets. You have to build custom consoles to pump blood through it. That's going to take you another couple of years, maybe 12 years later.

If you're successful, you'll have all this stuff. Thereafter, you have to go build the lad. You have to go get it federally certified. You have to get compliance.

You have to get every state in the country. There are six required in the US, California and New Jersey, Maryland, Pennsylvania, Rhode Island and New York.

If you do all that successfully 14, 15 years later, you'll have a lab that can screen and extract CTCs from whole blood and provide a test such as ours.

So that's kind of the pathway that it's been to build. No one's catching you guys, is what I'm hearing. No one is catching you guys if it can happen. But all right.

Likely. Yeah, definitely. You definitely make it sound that way. I'll say they're still going to. I don't know. If you did, they would have more patents.

Two pads with a fifth one pending right now. So there's also that issue. But gotcha. All right I don't know if you answered this earlier. So if you did I apologize.

But can your test results do anything as far as locating the tumor. And if not, you know, if the patient was to run your test and get a positive result.

So we say, okay, we pretty, pretty good bet that there's cancer somewhere in the body. How would we go about locating that if your chest doesn't do that on its own.

So we do not locate the tuner. It is a binary result positive or negative. You either have circling tumor cells or you don't. Healthy blood is known to not have circulating tumor cells.

So if you do detect a circulating tumor cell on a blood sample, it means it came from somewhere. There's a source, there's an origin, which means there's likely underlying tumor that is disseminating it. Otherwise, where did it come from?

And to identify the location? The next step is imaging. Now, is it possible to use circulating tumor cells to identify

location? Arguably, yes. We don't do it today.

It is more complexity involved in that. It may even require a much larger blood sample, the number of antigens and surface protein workers you need to look for, you know, to pinpoint it.

And it may become, you know, prohibitively large blood sample at scale. But today, if you get a positive, most physicians are going to tell you to go get imaging.

They're going to look for it on the image. Interestingly, you know, they may find it. They may not. We have instances where we detect it earlier than imaging.

We've had instances where, you know, because we detected a cellular level we detected earlier than imaging. Can you have billions of cells, you don't have billions of pixels in an image.

And so you have a constraint with the pollution. And you know, while imaging may improve in the future and you may be able to get more resolution, there's probably a hard limit as to how far you can go because of radiation exposure.

I don't think you can get to the resolution need to for cellular detection without endangering the patient. And so there's going to be circumstances where and there have been where we picked it up early.

For instance, we we had one person recently that we had a positive. They went and did a pet CT with contrast. It was stone cold negative. There was nothing on it.

They did a repeat six months later. They had a one centimeter lump in their throat. They had another lump in their lymph, you know, suspected squamous cell carcinoma of the throat.

These types of things happened. And this is where, you know, medicine is really going to bifurcate today. And, you know, science is ahead of medicine.

Always takes a while for medicine to catch up because of how the systems are built regulatory wise. But, you know, you've got sort of traditional allopathic medicine, and then you've got this new a world of functional medicine and preventative medicine and longevity and wellness and, you know, look, your immune system knows how to kill cancer.

It does it every day, all day long. One of the questions I get asked often is doesn't everybody escalating tumor cells. Well, no they don't. It's a very nuanced question.

What happens is we are living biological beings, and as living biological beings and organisms, we constantly have cellular turnover. All cells died, new cells are formed, old cells die, new cells are formed.

And this cycle continues. As long as we are alive in making billions and trillions of replications, our body makes mistakes. It creates erroneous replications, i.e.

mutated precancerous cells. Fortunately, our immune system recognizes them, knows how to destroy them, and kills them. That is why everyone on the planet is not dead from cancer.

Literally. However, unfortunately, once in a while our body makes mistakes and our immune system may be compromised. Those rodeo cells may evade the immune system.

There's some mechanisms by which that can happen. And when that occurs, that erroneous precancerous mutated cell gets the chance to multiply and grow.

And that's when the tumor is born. And when she was born, the first thing it wants to do is spread its essentially alien civilization, a mutant that has taken birth inside your body, and it wants to do what every civilization wants to

do.

It wants to expand its territory. And the way it does that is it sends its little soldiers out to sea. And those soldiers are CTCs and the seas your bloodstream.

And it looks to set up camp in other lands. Which are your other organs, which are what metastases are secondary tertiary tumors. And so as this all occurs, you're seeing a massive spread and birth of these precancerous cells.

Locating Tumors, Imaging, and Immune Response

Now, your immune system before that happens throughout your life has been killing these cells. If you catch it really early before it can successfully spread.

And it's very nascent and it's very small, oftentimes you may be able to do things like optimize your immune system and have your immune system actually kill it.

It's possible tumors regress. Tumors do disappear at times. It's not extremely well understood, but a lot of that gets into sort of preventative medicine and functional medicine as opposed to traditional allopathic medicine.

You know, radiation, it's not chemo. It's not surgery, especially if you can't see the tumor yet. If you've caught it so early that you know you're not even showing up on imaging, you've got a shot with your immune system, you want to take that shot.

They're not surgery to cut out something they can't see. They're not going to be raised. And when they don't know where it is not going to prescribe chemo when they don't know where it is.

So, you know, immunotherapy is interesting in this because immunotherapy is the one where I think there's a ton of potential. I think if you can figure out and you can do this actually with CTCs we don't do today, we plan to do it in the future at some point.

But if you can, because the CTCs that are shed from the primary tumor are homologous of the primary tumor, their cells of the primary tumor are the same. They're just moving around, that's all.

And so if you take those CTCs and you can sequence them to see what the mutation is, you may be able to learn what the best therapeutic target is. Is this triple negative answer is this Her2 breast cancer?

If it's hard to use receptive and if it's triple negative different protocol. Is this V7 mutated cancer. If so hormone therapy is not going to work. It's a different so on and so forth.

And so if you can get that information you may be able to avail of immunotherapies actually very early in the course, which works in conjunction with your immune system is significantly really incredible stuff.

How often would you recommend running your test as a routine screen for, you know, we can say for menopausal women or just in general, if the answer is the same.

Generally, we say once a year, you know, it's kind of three answers to that you answer will typically give is once a year unless you have risk factors.

If you have risk factors, you have a genetic history. You're a smoker. You have a high risk occupation. You're a firefighter, something of that nature.

Then I would say every six months the real answer is is every three months. But I don't say that because that will just sound like we're selling tests.

Like, you know, the reason it's every three months is you have a turnover every three months. So if you're negative

today and all cells die and turn over and you cells are formed three months from now, there is a chance you could develop a cancer.

It could be negative now and it could be positive in three months. Because if you have an erroneous replication once again that evade the immune system somehow, now what is the probability that you're going to develop cancer in three months?

And it's going to be so aggressive that if you wait at another three months until six months and it's going to take off, it cause all kinds of problems very low, like most cancers are not that aggressive.

Generally, tumors are known to be slow and indolent.

Testing Frequency and Closing Remarks

In fact, the recent research is now showing that they can tumors start forming at least three years before we start seeing them in current diagnosis. And so they don't overnight, generally speaking.

So I think if people did this or maybe six months, if they have high risk factors, that should be adequately gotcha. Excellent, excellent. All right. Well soon that I wish we could keep talking.

This is such a fascinating conversation. I know I'm learning a lot. I'm sure audiences as well, but unfortunately we are out of time. I did want to mention to our audience that we do have this test available through our office.

Our number is 480407 6500. We have a special deal with submits company, which we are very, very grateful for. You can get the tests through us for $750, where it is normally $1,995 on their website.

So if you're, you know, at all worried or just, you know, looking for peace of mind, I would highly recommend this test as a screen. It is the best one available on the market.

I wouldn't recommend doing any other one in lieu of this one. In addition, you could also email us at support at Lasting Wellness Center. Sumit, I'd like to thank you again for taking the time to talk with us today.

Again, it was just so interesting, so fascinating. Always learn a lot hearing you talk. So just very grateful for your time. Thank you very much. And as always to our audience, anytime, anytime to our audience.

Once again, thank you for taking the time to join us and learn more about cancer, health, cancer screening, and just how to advocate for your own health.

We'll be back soon with another very interesting conversation. But until then, everyone take care and be well. Thank you.