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Precision Medicine Podcast, Season 6 Episode 69

#4 in the Series "Bringing Precision Medicine to Everyone"

Liquid Biopsy Part 1: Breaking Speed and Access Barriers in Precision Oncology with Dr. Kashyap Patel

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Dr. Kashyap Patel:

In some rapidly progressing cancer, time is of essence. For example, diffuse large B-cell lymphoma, or when you look into very aggressively spreading small cell lung cancer. These tumors which are also sometimes turbo cancers progress so fast that a difference of four days versus 30 days in turnaround time for reporting and finally not getting the right result can make a difference between life and death. So, liquid biopsy once again is a blood-based test. All one has to do is to draw the blood according to specification for the procurement, ship it the same day, and typically we get result back within 5 to 7 days.

Karan Cushman:

In today's episode, we begin a two-part focus on liquid biopsy — a blood-based test that delivers faster results and helps extend the reach of precision diagnostics.

Welcome to Season 6 of the Precision Medicine Podcast proudly sponsored by Trapelo. This is the podcast where leading voices in cancer explore how to bring Precision Medicine to patients everywhere. Welcome back to the Precision Medicine podcast, I'm Karen Cushman, your founder, host, and producer. And if you've been listening, then you know that we are in the midst of a series titled Bringing Precision Medicine to Everyone. Which is grounded in a powerful idea that Precision Medicine shouldn't be a privilege, it should be a promise that's extended to every patient no matter their zip code, background, or access to care. Few people embody that mission more than my guest today. He is CEO of Carolina Blood and Cancer Care Associates, and author and a national leader in value-based oncology. And he's co-sponsor of this series with me. He is a tireless advocate for closing the gaps that prevent too many patients, especially in the community and resource-limited settings from receiving timely personalized treatment. And as evidence of that, he founded No One Left Alone, an organization that is addressing health disparities in cancer care head on. Dr. Kashyap Patel, welcome back.

Dr. Kashyap Patel:

Thank you very much, Karen. And I'm really honored to work with you on this journey because I chose medicine, I chose oncology to make a difference in lives of people that put their faith in me, to allow me to inject poisons into their body. And I've seen evolution of cancer care going back from days of very limited options of chemotherapy beginning from… into paclitaxel and docetaxel and platinums to the MAPS, the monoclonal antibodies. And we are moving into the space for now, the T-cell engagement therapies, the bispecific, the radioligands, and the CAR T-cell

therapy. At the same time, there has been leapfrog movement in the diagnostic space. And it would be inappropriate for us to be comfortable, to be cozy, not dive deep into that, and ensure that every patient with a potential cancer or who actually has a cancer should have fundamental right, not privilege, to access the latest and greatest in diagnostic technology. And I'm glad that we are able to share our views on the different modes, and now we'll focus today on the liquid biopsy. Thank you.

Karan Cushman:

Thank you, Dr. Patel, I am really honored to have you be part of this series with us as someone who has spent 25 years working directly with patients in the community. We talked I think in our kickoff episode that at that time, Precision Medicine was just being introduced in the world. And here we are today at this place where I love that you described, let's not get cozy and comfortable because we're probably at a time where we all are feeling like we need to move faster and faster because there is so much opportunity in so many new developments in precision oncology. And so, with that, today's conversation is going to kick off at two-part on liquid biopsy. And like we just said, it's a technology that is really changing how and where precision care is delivered. And I know this opportunity is really far-reaching and as you just described, particularly meaningful to you Dr. Patel.

So much that you laid out in a recent paper, a really compelling case for how liquid biopsy, which is a simple minimally invasive blood-based test, how it can help overcome some of the biggest challenges baked into our current system from, let's say, minimizing the need for invasive procedures to providing critical options when tumor tissue is scarce or maybe inaccessible, to enabling faster turnaround times. Who doesn't want that, faster testing turnaround times? And even bringing testing directly to patients through mobile phlebotomy.

Liquid biopsy isn't really just a scientific breakthrough, it is a practical and scalable tool that is really changing how and where cancer care happens. So, Dr. Patel, let's start off the episode with just some grounding for listeners who may be newer to the space. Can you just explain what liquid biopsy is and how it differs to traditional tissue biopsy?

Dr. Kashyap Patel:

Absolutely. So liquid biopsy is essentially blood-based testing that can help us look for identifiable mutations that are known to be responsible for triggering some types of cancer. We go back and look at the cell-free DNA fragment. I remember the days when we had the cell search technology where they were looking for free-floating TNA in the blood and then came the wave. There was a pause for about 10 years or so. And for last five years, there's a whole new invention and innovation that is happening where you can identify cell-free DNA, RNA fragments, multiple different tissue fragments that can be identified in the blood.

The most important significance of this is it has high positive predictive value, number one. Second is when we compare with the solid tumor biopsy, which is done from an invasive procedure either into the lungs or into liver or into pancreas or sometimes very difficult to exercise, does its own complications. When we look into solid tumor biopsy is associated with post-operative risk of infection, bleeding depending on the location of the tumor. Liquid is a simple

blood-based testing. You draw set amount of blood, and based on the type of testing that's done, the medical assistant separates the plasma fragment whatever the requirements are, and they're shipped to the lab. The turnaround time is a huge difference.

Typically, when we look into procuring solid tumor biopsy specimen, first of all, sending a request to the site that did pathology. So, there's a lot of archaic process involved where my team will send a form filled with appropriate data set for the patient that will be sent to a pathology where the tissue sample is held. Now, if there's a Thursday that I saw the patient, by the time the pathologist ends up in seeing the request, it probably could be Monday. And then they'll go back and look into the archival tissues, and then they'll identify the viable fragments and sent to the tertiary lab. And then, once it reaches tertiary lab in the transit time, it could be anywhere between 3 to 5 days. And then three out of 10 times, depending on the viability of the tissue left on the slide, there is something called QNS, quality not sufficient, quantity not sufficient.

So, three out of 10 times the whole exercise goes in vain, but it takes about four weeks. In some rapidly progressing cancer, time is of essence. For example, diffuse large B-cell lymphoma, or when you look into very aggressively spreading small cell lung cancer. These tumors which are also sometimes turbo cancers progress so fast that a difference of four days versus 30 days in turnaround time for reporting and finally not getting the right result can make a difference between life and death. So, liquid biopsy once again is a blood-based test. All one has to do is to draw the blood according to specification for the procurement, ship it the same day, and typically we get result back within 5 to 7 days. And second thing is you can repeat the test as often as you need. So once again, compared to invasive tumor biopsy from deep-seated tissue in the lungs or a liver or pancreas, this is a relatively lot more effective and a lot more efficient.

Karan Cushman:

That's really helpful. Thank you, Dr. Patel. And before we move on, I want to make sure that we're not projecting liquid biopsy as the end all be all methodology for testing. This is not a replacement for tissue testing.

Dr. Kashyap Patel:

Correct.

Karan Cushman:

Can you talk about some of the pros and cons of liquid there in that perspective, and maybe even get into some of the, as you just did with large B cell? Maybe get into some of specific disease areas where it is particularly effective or not.

Dr. Kashyap Patel:

So that's very important point. Once again, full disclaimer, I'm not trying to say that we'll stop doing solid tumor biopsy. For initial diagnosis for the tissue is required. It gives us idea about what kind of tumor are we dealing with. Liquid biopsy enables us in few different ways. Number one is it can help us identify tail TNA or RNA fragments floating in the blood and possibility of the treatment choice. Now since the whole process in evolution, when we look into there are tests

that you can do from the blood for predicting risk of recurrence for breast cancer, for colon cancer. You can quantify the fragments of the TNA abnormality, RNA abnormality into the blood, and that is also called minimal residual disease. So, there are three main applications I can see right now after the solid tumor diagnosis has been made or after the tissue diagnosis has been made. Number one, identify actionable mutations. And there are multiple labs of the tests that developed. Identifying the quantity of the test, quantity of the mutations so that you can monitor the response. It's also known as MRD Minimal Residual Disease.

I'm also looking into proposing a study where we could do what we call a concordance between the MRD and the radiological appearance. Typically, when we have a stage four disease patient or lymphoma patient, we typically follow them doing the imaging studies, either a CT scan or a PET scan at three, four, five months interval depending on each individual case. MRD has a potential of predicting resistance earlier. And I just saw a paper about two weeks back that showed that doing the minimal residual disease assessment by liquid biopsy can predict resistance development in lymphoma, we can change the treatment effectively there and then, rather than waiting for the radiological appearance to show us the progression of disease. So, we may not waste any resources in treating patients with ineffective therapy, we can try and find out what's going to work in that patient.

And once again, it does reduce the risk of toxicity from unwanted treatment and possibility of substituting the effective treatment based on liquid biopsy testing. So that is a third application. And the fourth one, which actually has been developed right now for certain tumor type, for example, MCED Multi-Cancer Early Detection tests. There are companies that have developed tests for detecting colon cancer early on, even before you can see that on symptoms or even on the colonoscopy. At the same time, there are also tests, they're looking into prostate cancer early detection tests. So, if I categorize the role of liquid biopsy in management of cancer patient, number one is early detection, which may eventually replace the invasive testing, which could be either colonoscopy or I'm not sure about mammography as yet, but a time will come. Second one is the therapy selection, once the tumor is diagnosed based on a solid tumor biopsy. Third is minimal residual disease monitoring, and fourth is changing the treatment according to the MRD assay.

So, these are the four categories I feel that in the next 10 years there will be leaps and bounds progress that will change the cancer patient's management to a whole new different level. But I also want to emphasize one more thing. If a time comes where in certain tumor types, we are able to establish that the liquid biopsy and the MRD testing in accordance with the radiological imaging, if it's proven to be same or has better positive predictive value, then in those situations we may not need to either expose patient to more radiation or they may not have to travel a whole lot back and forth. The mobile phlebotomy can go to patient home, draw the blood, send the sample for testing, and may change into the true patient centered cancer care where patients are able to live with their loved ones as long as they can rather than spending three, four, five hours waiting for imaging studies. So, I can see a huge potential revolution that may happen in next decade or so.

Karan Cushman:

So, Dr. Patel, I think that's a great place to ask. What might be a couple or just one patient example of what you just described of how liquid biopsy using mobile phlebotomy is really opening doors earlier for cancer detection, but also just a more precise treatment decision for a patient who might not otherwise have access to that.

Dr. Kashyap Patel:

Excellent suggestion. So, I have a young patient, he's about 44 now. He was diagnosed four years back with stage four melanoma. We started treating him, and he heard something that was in the bones. Now, it's very difficult to assess the response to the treatment in the bones. His condition is very stable even now, and we started doing MRD monitoring once the test was approved and is being covered by the payers. And obviously, he's been on treatment for 18 months and we don't know how long do we have to continue treatment in stage four melanoma, there are no clear guidelines about that.

Some papers say up to two years is appropriate, then you end up developing side effects. So, in this particular case, we started checking for MRD and has been MRD negative for over a year now. So, we are gently increasing interval between the successive treatment, and maybe in six months or so we'll stop treatment altogether. So, while his radiological appearance is stable, so bone metastasis particularly are extremely hard to evaluate in terms of the responses. And he has some scar tissue from previous lung lesions as well. So once again, the tissue diagnosis based on the radiological imaging was less clear and more ambiguous about when to stop, when to start. But now this patient is playing golf, he's doing full-time job, is enjoying his life to the fullest, traveling across the world with his MRD being negative. We actually reported his case in one of the journals as well.

Karan Cushman:

The Precision Medicine Podcast will return right after this.

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Karan Cushman:

Amazing. So, moving over into maybe the other side of using liquid biopsy, say in the diagnostic realm and in deciding in what that perhaps first line of therapy will be. We're seeing, like I mentioned earlier, a rise in the use of liquid biopsy, just purely liquid tests. But what are you seeing even in the reflex and concurrent testing is rising? What are you seeing on your end?

Dr. Kashyap Patel:

We are seeing a lot more helpful information coming from patients who have difficulty in getting re-biopsy because once again, going back to the original question of, we definitely need a solid tumor piece to diagnose, and frequently the genomic sequence testing from the solid tumor biopsy specimen is frequently difficult because of the availability of the tissue. In the same patients when we do the blood-based liquid biopsy, I would say, we have been able to identify close to five out of 10 patients with actionable mutations. I'm seeing a huge role in some of the hematological malignancies that a couple of companies have developed the liquid biopsy for heme malignancy, and there were patients who used to come and see us for non-specific leukopenia, thrombocytopenia, or anemia for two, three years.

We did bone marrow on them earlier and that didn't do anything. And then doing liquid biopsy, we are able to identify about 40% of them having some sort of actionable mutation either for myeloproliferative disorder or from MDS. And treating them with appropriate treatment, for example, luspatercept for early MDS, we've seen huge difference. So, our case once again, I will share. There's a lady I'd been following for about two years for anemia and thrombocytopenia and leukopenia. She had bone marrow tests done year and a halfback that showed non-specific changes, not sufficient to conclude shared myelodysplastic syndrome. And her reflex testing didn't show a whole lot in terms of mutations.

Second time we repeated the bone marrow, and we sent the liquid biopsy for heme malignancy panel. And while the bone marrow had shown slight devolution in the changes, there were not enough to classify as classical MDS, but she had a mutation that goes with myelodysplastic syndrome. We put her on appropriate treatment, and within two weeks her hemoglobin came up from 8.9 to 13, her white count came up, and she's living normal life. So, I can see that there's a massive potential of the test implications for multiple disorders, but heme malignancy is one where I think there has been no progress for last several decades. And now we are seeing significant access to liquid biopsy testing, which will change management of patients with early MDS myeloproliferative disorders and other, even myeloma and lymphomas.

Karan Cushman:

So, if we're able to get a patient in the community a liquid test, so then it gives them access to some treatment, it may not be the most precise treatment for them because we might miss something. Do you know where I'm driving towards?

Dr. Kashyap Patel:

Yeah, yeah, yeah. I think the evolution of testing and access to multiple mutations probably will allow access everywhere. So yes, I mean, I think when we look into the immunohistochemistry, the traditional testing where most of the labs do PD-L1, and now there are tests that can actually help you detect the likelihood of response to even the immunotherapy. So, there are companies that are developing multiple tests based on neutrophil folding pattern, based on the mitochondrion.

So, there are tests being evolved, even that with a quick turnaround time that can help us identify would immunotherapy as a role or not. But also, word of caution is, there is some situation where

certain mutations like MDM2 when they get checkpoint inhibitors or immunotherapy, there's a risk of them becoming hyperprogressor. Also, there's a risk of having the autoimmune disease following immunotherapy. And we all know that hypersensitive pneumonitis, they all are side effects. So, I think accuracy in diagnosis and choosing right intervention is probably the best way going forward to explore and implement liquid biopsy so that every patient gets what they deserve, what they get, and they don't get any harm from the treatment.

Karan Cushman:

What do you think are the biggest barriers for physicians say, technically, operationally, or policy related that still really limit the broader adoption of liquid biopsy in clinical practice?

Dr. Kashyap Patel:

So, number one is there is such a wide divergent test available, and there is no comparable standards. Number one, because it's evolving field, awareness, education, and guidelines are probably very important part of bringing liquid biopsy some sort of standardization.

Second is the peer coverage because depending on what geographic area do you leave, what kind of policies are involved is second big barrier because many peers may not have the in-depth understanding of what this liquid biopsy means, so they may or may not cover. Number three is the standardization. So, I still feel that there's a need for developing standardized prospective study criteria to look at the validity. So about 15 years back I was involved with MolDX, which is the CMS entity that evaluates the test's validity. And we'd come up with the idea of developing, first of all, the analytical validity was number one, to make sure that there is a standard reproducibility of the results. Second, we decided to work was the clinical validity and a clinical validity. So, if every lab follows this track and then looking at the positive predictive value and negative predictive value.

So, we need to standardize the testing and the application so that we exactly know which lab has the best of the best of the best. I mean, right now, it's all based on the coverage policy. People determine whether they want to go for solid tumor or liquid biopsy or not. We actually started a pilot with our commercial pair, Blue Cross Blue Shield, to offer liquid biopsy to early state lung cancer patients. All stages to see, number one, what's the concordance between what we find in liquid biopsy and not. And number two is, how do we share our findings so that more and more practices got involved in implementing liquid biopsy as a standard of care. And third thing I want to share is I probably will be publishing data on about our experience of some 40 plus patients with heme liquid biopsy and how effective it is or concordant it is with the presumed clinical diagnosis.

Karan Cushman:

Wonderful. Well, so speaking of standardizing, how do you think we can best approach standardizing? What is a complicated process testing? There are many labs, many tests. Now, we're talking about more modalities coming into play. How do you look at standardizing this in practice for your oncologists, and how do you see others in other practices doing this?

Dr. Kashyap Patel:

I think, first of all, we need to elevate entity like MolDX, which is the probably one of the longest serving entity in assessing and judging the efficiency, the predictive value, the validity and utility of a test. So, we need to elevate their level almost to the level of FDA, because I personally feel that FDA does excellent job in drug development process. But because lab is totally separate entity, I think MolDX has the best bandwidth of promoting the adoption of the liquid biopsy. So, I think standardizing the evaluation and approval process would be first step. And once standardized, I think then something like NCCN guidelines can have a special lab division to ensure that the recommendations of their disease specific management include the minimum number of mutation that has to be tested for each type.

And then, when and how frequently you do MRD testing? How often do you screen for cancer? What kind of potential groups of patients we want to screen, because we can't screen everybody living on this earth. But if you identify, for example, high risk population, patients with family history of cancer, patients with autoimmune disease, patients with exposure to certain environment…So, these all would enable us to create almost like a glossary of recommendations.

Karan Cushman:

Wonderful. Thank you, Dr. Patel. So, you touched on something earlier right out of the gate, which is in hematological cancers you mentioned large B-cell lymphoma, which is exactly the type of cancer that I had. I consider myself one of the lucky who responded right away, but I actually do remember one of my good friends' physicians who put his arm around me, and in the beginning when you're diagnosed, you're debating. I was a fairly healthy person, had just had one child thinking, I'm still growing my family, yet I'm going to go and do something to save my life that may prevent... You're just going through all these different choices, right?

Dr. Kashyap Patel:

Mm-hmm.

Karan Cushman:

And I remember him saying to me, "You don't have any time to make the choice. You need to be there at your chemo appointment on Tuesday or you're not going to be here." Fortunately, I responded right away. But can you just give another example in lymphoma where, as you mentioned, it is an aggressive type. Another patient example perhaps of where that really came into play for a patient to be able to have this form of testing.

Dr. Kashyap Patel:

I had a patient, actually. So funny, her parents were both my patients that moved up from Florida to Rock Hill to retire, and her wife came to see me first because she had a breast cancer in 2002 or '03. She was with me for about five years. And then in the same duration, her husband developed lymphoma, and I treated him, and they both are deceased now, and they were so kind that they donated $5,000 to me and said, "You give it to any charity of your choice." So, I got so close to them. I got an email from their daughter back in, I think fall of 2017 saying that she's

been diagnosed with lymphoma that's gone to the brain, and she's been advised to undergo bone marrow transplant, high-dose intrathecal chemotherapy. And without that, she has no chance. And obviously, she had meningeal lymphoma, but she used to leave probably about 150 miles away from here.

So, I actually asked her, "Why don't you send me all the records?" And I saw the records, and I said, "Correct. I think whatever has been recommended by the tertiary care center probably standard of care. But there's a drug that's been developed that crosses blood brain barrier called Ibrutinib, and there are some case reports. I think it's worth looking at that." Now, the question was how do we monitor that? So, she had a full faith in me, so she moved physically from where she was to Rock Hill, the same place that her parents used to live, and then she started coming for treatment. Her symptoms got better, but we could not objectively measure the response until the test. The clonoSEQ was approved for MRD monitoring for lymphoma, and we've been monitoring that. And it's been so helpful and so inspiring to her because we started at certain level and now, she's so happy that we are able to objectively quantify response. And so far, almost eight years out now, she's doing so well with MRD almost negative.

Karan Cushman:

Wow, that's amazing. Thanks for sharing that, Dr. Patel. Wonderful. Well, so one more question. As we look at cancer detection across many patient populations, and in particular we're striving to overcome some of those logistical barriers as we've talked about in underserved settings. What do you think is the greatest value for liquid biopsy here in terms of the screening side?

Dr. Kashyap Patel:

We have faced some challenges in screening. Number one is when you look at the mammography, patient has to go to place where it's being done. It cannot done at home, so that's number one. Second is lung cancer screening. You have to have low-dose CT scan. So when we look into all of these, if we are able to develop blood-based tests that can detect cancer from blood in a certain population, then all you have to do is to have a diagnostic camp somewhere at a church or a common places where people get together for fun and say, "We have the cancer test available." I think that will be a huge leap ahead because even now, less than half of the patients who need to be screened for multiple cancer get screened. And the number varies depending on the geographic location, access to testing, insurance status. So, we can address lots of these disparities by developing a test that can be applied on the mobile phlebotomy van that can go to different locations and bring parity for healthcare access.

Karan Cushman:

How far away do you think we are from seeing something like that in action?

Dr. Kashyap Patel:

Less than 2 to 3 years because the colon cancer and prostate cancer are almost there. We need to have one for the breast cancer and then lung cancer. I think we should be there pretty soon.

Karan Cushman:

Do you see organizations starting to implement the mobile units, if you will, in this case already?

Dr. Kashyap Patel:

Not as yet, but I'm trying to work with one international company to start that concept in India, so it may be a lot easier there. I'm going to work on that and see if that becomes a reality.

Karan Cushman:

Amazing. Awesome. So, Dr. Patel, I know that you are an avid traveler and photographer, and where are you headed next personally in your journey?

Dr. Kashyap Patel:

So, Patagonia one, but also, I'll be going somewhere to the Arctic Ocean sometime in next six months or so.

Karan Cushman:

Wow, that's awesome. I look forward to seeing those photos.

Dr. Kashyap Patel:

Absolutely.

Karan Cushman:

All right. Well, thank you for being with me today, and I'll be in touch with you, of course.

Dr. Kashyap Patel:

Thank you for giving me opportunity. You are very kind, gentle, and thanks for letting me have a platform to share my thoughts.

Karan Cushman:

Oh my gosh. Dr. Patel, of course. Thank you for being-

Dr. Kashyap Patel:

You're welcome.

Karan Cushman:

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About Our Guest

Kashyap Patel, MD
Hematologist & Medical Oncologist

Kashyap Patel is the CEO of Carolina Blood and Cancer Care Associates. Dr. Patel is a practicing medical oncologist, board certified in Hematology, Oncology, and Internal Medicine.

He is immediate past president for the Community Oncology Alliance (COA), He is past chair for the clinical affairs and trustee for the Association of Community Cancer Centers (ACCC). He has published/presented over 150 papers. He is frequently interviewed and cited in mainstream newspapers including NY times, Washington Post, NPR just to name a few. He has been an advisor for the large payers including DHHS (SC), Palmetto GBA, and serves on an advisory board for Medicaid HMOs. He has a special interest in end-of-life care, health care policy and economics, and he has expertise in Value Based Care and has successfully led Oncology Care Model pilots with two payers including with CMMI.

Additionally, Dr Patel has been working directly with cancer patients for the last twenty years. He has served as chairman of several committees in numerous South Carolina hospitals. Moreover, he has extensive research experience in oncology. Dr. Patel has extensive legislative experience both at the local and national level. He has testified in state senate as well as has carried out capitol hill briefing on precision medicine. He has been honored by the US Congress for his exceptional contribution to the healthcare. Multiple journals have written about his life. He is now working with multiple national entities on cancer health disparities. He has started his own foundation www.nooneleftalone.org to address disparities. In addition, he is an author and his book Between Life and Death is published by the Penguin Random House www.betweenlifeanddeath.org. He is a nominee for the Ellis Island Medal of Honor for 2024.