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Total Prostate-Specific Antigen (PSA) Testing in Capillary Samples: Proof-of-Principle and Feasibility Study for Home Self-Testing for Prostate Cancer.

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Guest: Dr. Rav Sodi from the Department of Clinical Biochemistry at the Mid and South Essex NHS Foundation Trust based in Essex, England.

Randye Kaye:

Hello and welcome to this edition of *JALM Talk* from *The Journal of Applied Laboratory Medicine*, a publication of the Association for Diagnostics & Laboratory Medicine. I'm your host, Randye Kaye.

While much of clinical laboratory testing is performed from venous blood collections, there are some patient populations for whom venous blood collection can be difficult or impractical. These populations may include neonatal and pediatric patients, elderly patients, and patients with disabilities. In these circumstances, capillary blood sampling may offer a more convenient alternative. However, laboratory tests from capillary samples are not widely available owing to the need for analytes to be specifically validated in this sample type.

In particular, there is a lack of evidence regarding the measurement of cancer markers and capillary blood. If valid and feasible, capillary sampling could allow for increased cancer screening by allowing for home self-collection. The March 2025 issue of *JALM* features a study that assessed capillary blood sampling for total prostate-specific antigen, or TPSA. The authors compared TPSA results in finger prick samples to those in venous blood collected by traditional venipuncture. Today, we are joined by the article's corresponding author, Dr. Rav Sodi.

Dr. Sodi is a Consultant Clinical Biochemist in the Department of Clinical Biochemistry at the Mid and South Essex NHS Foundation Trust based in Essex, England. His current research interests are home self-testing, particularly with regards to monitoring cancer with tumor markers, vitamins in health and disease, and applying artificial intelligence in medicine.

Welcome, Dr. Sodi. Rav, let's start with this: Following the COVID-19 pandemic, there appears to have been a growing interest in the use of capillary blood samples for testing many biomarkers. Why do you think that is?

Rav Sodi:

Well first of all Randye, thank you for inviting me to give this podcast about our work and yes, capillary blood sampling increased significantly around the world after the pandemic. The pandemic, obviously as you remember, many people couldn't go out. You couldn't go and get your bloods done, you couldn't attend hospitals, and so, many services around the world introduced capillary blood sampling as a way of getting patients to send their bloods in remotely so they could test it. Now, why is capillary blood sampling important and why is it offering us a new avenue to explore?

Well first of all, capillary blood samples are less invasive to take. All you need to do is a finger prick using a lancet or other device. It's also convenient. This is where the pandemic showed that you could use capillary blood samples in the comfort of your own home. You don't need to go to a phlebotomy or venipuncture center or such. There's pros and cons to it and one of the advantages is although it's convenient and invasive, it's a much smaller sample and being a smaller sample avoids wastage of such. It also means that you have a smaller container, which also means that it's more environmentally friendlier, so it's more green and as we all know, that's an important thing to consider these days.

Capillary samples are also amenable to collecting samples from specific patient groups where the standard venipuncture or phlebotomy may not be possible or may be a challenge. So for example, in pediatric patients, the elderly, those with mental health conditions or learning disabilities, those with severe needle phobias, and those with poor venous access. In this situation, capillary samples using a finger prick offers a good alternative. Now, an important area of capillary blood samples, which this study addresses, is home self-testing or remote testing. Many direct-to-consumer testing companies you'll be aware of online use this as a mode for sample collection.

Now, I have to say the quality of these companies are varied. Some are very high quality because they access very well-accredited, well-known laboratories for testing, others perhaps less so. When it comes to home-self testing to screen for or monitor chronic conditions such as cancer, we think using this testing mode, i.e., capillary blood samples, has huge advantages. It opens up access and for example, if you live in a remote area, it's easy to send in a sample rather than try and get transportation to the main lab. So, I think they offer advantages but there are some limitations to capillary samples.

Randye Kaye:

All right, thank you. Now, your article in *JALM*, it describes a proof of principle study to measure total prostate-specific antigen, or TPSA, in capillary blood from men with prostate

disease, so can you expand on that study for our audience and what were your objectives and what did you find?

Rav Sodi:

Yes. So Randye, in this proof of principal study, we wanted to explore whether we could test for PSA in men with prostate cancer using capillary blood samples because until now, there is no good evidence that capillary samples will give you the same results as venous. So that was the first step, and the question was is the venous and capillary samples results are they correlated and is there a bias? Now, obviously our long-term objective is to screen for diseases remotely in the same way as we screen for colorectal cancer using fecal hemoglobin in the UK. Now, I know screening is a very loaded topic and Randye, we won't go into that today, it's beyond the scope of today's podcast.

But in this study, we recruited men for a urology clinic at Broomfield Hospital in Essex United Kingdom. Now, let's take a step back. Why is prostate cancer an important clinical problem? First of all, now the Lancet Commission on prostate cancer estimates that by 2040, there will be a doubling of cases, and this is due to the increasing lifespan and changing demographics. And the important thing to note at the outset is that prostate cancer can be treated if it's caught earlier. It's very important to detect the condition sooner and this was the premise of our study, that using home self-testing, we can aid the detection of prostate cancer. We can provide access to those difficult-to-test groups. Now, there's evidence that men are less likely to get tested for diseases. I'm sure, Randye, you will agree. You'll agree with me -- probably will agree with that.

Randye Kaye:

Yes, getting my husband even to the doctor is quite a feat.

Rav Sodi:

Yeah, so not only men. In addition, there is good evidence that the prevalence of cancer is higher in Black men, and these are the very people who are less likely to access health systems. One of the main premises of this study is to not only provide a convenient suitable modality but also to increase access to healthcare.

Randye Kaye:

All right. Thank you. Certainly, early detection is always an effective tool. So, now that you have completed this study and it was successful, what are the next steps to move it forward to implement the TPSA testing from capillary samples?

Rav Sodi:

To date, there is no recognized prostate cancer screening program, anywhere in the world as we're aware, and given the pressures on existing health services, there needs to be a better way to screen for and then monitor diseases, but we hope our study provides an impetus in this respect. So as I said, in the first phase of study, we want to confirm that the

venous and capillary samples were highly correlated, and we ended up sampling 64 men aged 24 to 64 years of age who had the mark of a prostate cancer known as total prostate-specific antigen, TPSA that is, to distinguish it from other forms, the free forms. And the concentration we obtained was 0.3, which is deemed normal, to 314 micrograms per liter, which is pathological. So, once we ascertained there was no significant bias that were correlated, the next step is then to extend the study to an unselected population and screen for prostate disease. Importantly, this can be applied to other markers for other conditions and other cancers, so we hope this study is an example for other conditions as well.

Randye Kaye: All right, thank you. So finally, you may have already addressed this a little bit but can you describe some challenges with using these capillary blood samples?

Rav Sodi: Yes. So given the nature of collection using a finger prick, the failure rate is often very high but thankfully, there are new sample collection devices that can make collection easier and painless and more successful. You probably heard the term patient-centric testing. This is an emerging area in our field and you could probably hear more about this, the new devices that collect samples painlessly and easily. Also, given the smaller volumes of collection, many automated laboratory instrumentations have not been adapted to deal with this kind of samples.

This has hampered wide spread adaption but this has to change as manufacturers introduce print article sample handling devices. The other thing to note is Randye, there is no reference intervals for capillary samples at the moment. We used data extrapolated from serum samples but there's actively work going on to address this. The biological variation and the analytical performance specification also largely remains unknown. But all these issues as I said are being actively addressed, but we believe capillary samples offer a good alternative to venous sampling, allowing for home self-health testing, and we believe they're here to stay and will only develop with time.

Randye Kaye: That was Dr. Rav Sodi from the Mid and South Essex NHS Foundation Trust describing the *JALM* article "Total Prostate-Specific Antigen (PSA) Testing in Capillary Samples: Proof-of-Principle and Feasibility Study for Home Self-Testing for Prostate Cancer." Thanks for tuning into this episode of *JALM* Talk. See you next time and don't forget to submit something for us to talk about.