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### Blood-Based Colorectal Cancer Screening: Where Do We Stand?

#### Dr. Buch:

This is *Clinician's Roundtable* on ReachMD. I'm Dr. Peter Buch, and today I am joined by Dr. Aasma Shaukat to discuss a recent study that examined the age and sex-adjusted performance of a blood-based colorectal cancer screening test. Dr. Shaukat is the Robert M. and Mary H. Glickman Professor of Medicine at the NYU Grossman School of Medicine and the Director of Outcomes Research in Gastroenterology.

Dr. Shaukat, welcome back to the program. We always learn so much from you.

#### Dr. Shaukat:

Thanks so much for having me. The pleasure is mine.

#### Dr. Buch:

Let's start with some background, Dr. Shaukat. Why is there a low adherence to colorectal screening guidelines?

#### Dr. Shaukat:

The low adherence to colorectal cancer screening guidelines is because one, we recently dropped the screening age to 45, and people still aren't up to date on that information. So screening is not on anybody's radar—not individuals who are screen eligible, and not the providers or the healthcare system.

And even for people that know about colorectal cancer screening and the fact that they're eligible, some just aren't very interested because of the modalities that we currently use or having other constraints.

#### Dr. Buch:

When patients think about colorectal cancer screening, they're always thinking about colonoscopy. Could you comment on that please?

#### Dr. Shaukat:

Absolutely. So colonoscopy is the most commonly used modality in the US for screening. And again, it's not a procedure that people are excited to sign up for, because it requires preparation the day before and taking time off. People are worried about the procedure itself, because it has a small possibility of complications, there's usually sedation or a light anesthesia that's administered. And people are always worried about that, also.

#### Dr. Buch:

So the other question I just wanted to ask you is, are there regional differences to adhering to these guidelines?

#### Dr. Shaukat:

There are regional differences. In fact, there are differences, even within states, within cities, and within neighborhoods. And a lot of these differences fall along the lines of access. So, as you know, there are vast areas in the US where there is just no colonoscopy availability, or the nearest gastroenterologist or colonoscopy facility might be, say, 60 to 100 miles away.

So that's definitely a barrier. Second, individuals that tend to be in neighborhoods with high population density or lower number of facilities near them also tend to have lower screening rates.

#### Dr. Buch:

Thank you so much. And what are the most common barriers you encounter?

#### Dr. Shaukat:

We like to divide them into patient level, provider level, and then health system level. At the patient level, the main barriers are, again, lack of education or knowledge that somebody is screen eligible or they have options for screening. Or they have worry, fear, or other cultural beliefs about colon cancer screening. Or they're just not making it a priority in their busy lives.

At the provider level, the barriers we see are providers get so busy that sometimes they forget to mention to their patients who are screen-eligible that they should undergo screening, recommend a test, or order it.

And at the health system level, we see problems with access when there isn't a facility near the patients where screening can be completed. Or there might be either cost or other delays in scheduling, and those can lead to delays and are barriers to screening.

**Dr. Buch:**

Let's get into the details of your research. Why did you decide to perform this study?

**Dr. Shaukat:**

We decided to perform this study because we thought perhaps introducing another modality of colorectal cancer screening—such as something as convenient as a blood draw—would perhaps entice individuals to take up screening in higher numbers than they are currently.

And we just talked about the barriers to colonoscopy and how a lot of patients aren't excited to sign up for it. The other option is a stool test. Again, people aren't excited about having to handle stool and collect things and mail them in. So the convenience of a blood draw that can be done at the doctor's visit or coupled with other blood tests and other labs that they could be getting for preventative measures—such as checking one's cholesterol—seems appealing.

So, if we could actually develop a blood-based test, that might improve people's interest, enthusiasm, and ability to complete screening.

**Dr. Buch:**

Thank you. So let's move on and talk about what the risks and benefits of doing this study that you have already performed are.

**Dr. Shaukat:**

So the benefit is that there's more interest and higher uptake of blood-based tests compared to, say, colonoscopy or even stool-based testing. Again, the convenience is something that is definitely of benefit in improving screening rates.

The limitations are that the study's results—and this is why we do these studies—essentially told us that it's a good test for detecting colorectal cancer and it has good sensitivity and specificity for colorectal cancer, but the sensitivity for detecting these advanced precursor lesions—or these types of polyps and lesions that we worry about are on the pathway to turning into cancer—is low for this test. So that kind of dampens a bit of enthusiasm for adopting this test as a first-line modality.

**Dr. Buch:**

Thank you. For those just joining us, you're listening to *Clinician's Roundtable* on ReachMD. I'm Dr. Peter Buch, and I'm speaking with Dr. Aasma Shaukat about her study, which evaluated the age and sex-adjusted performance of a blood-based colorectal cancer screening test.

Dr. Shaukat, what do the results of your research show and what is the take-home message for clinicians?

**Dr. Shaukat:**

The result shows that the blood test performed well in being able to detect colorectal cancer. The sensitivity for a one-time test was about 80 percent. The specificity was about 90 percent. However, the sensitivity for detecting advanced precursor lesions was quite low, at 13 percent.

So the take-home message is that the blood test in its current version should be reserved for patients that are, at this time, unwilling to complete a colonoscopy or undergo a stool-based test, and should not be offered first line. It is better than no screening, but inferior to a screening colonoscopy or a stool-based test at this time.

**Dr. Buch:**

So let me just ask you this kind of out of left field: if, number one, the cost of these blood tests would be more reasonable and it could be done on a yearly basis, would that help with the sensitivity and specificity of the polyps and change the results of your study?

**Dr. Shaukat:**

Yes, very much so. So if the test could be a lot cheaper than they're currently positioned at and we could do it every year, it would actually improve its detection, because again, it's the repeat testing that will actually catch something, with colon cancer precursor lesions being slow growing. So we have a window of opportunity there.

**Dr. Buch:**

Let's move on. The important thing here is comparing these blood-based tests to the alternative tests that are out there. Can you just tell us a little bit about the sensitivity and specificity of the alternative tests that exist?

**Dr. Shaukat:**

So these blood tests compare favorably in terms of their sensitivity and specificity for detecting colorectal cancer compared to the other stool tests, providing caution that there are no head-to-head studies. So take this information with a grain of salt, knowing that these are from different patient populations, the comparisons that I'm making.

However, the sensitivity for detecting these advanced precursor lesions are higher for the stool tests. They're about 25 percent for the FIT test and about 43 to 48 percent for the multi-target stool DNA and the multi-target stool RNA test. However, for the blood test, it's only at 13 percent.

So that's where the predominant difference comes in. The FIT is recommended every year, so it kind of makes up for its lower sensitivity for advanced precursor lesions by being repeated every year. The multi-target stool DNA and RNA tests are recommended every three years, but we actually don't know if that's the right interval.

And for blood test, currently, Medicare's national coverage decision is to pay for them every three years, but perhaps a strategy of doing them more often might be more optimal.

**Dr. Buch:**

It just got me thinking about one other alternative. Tell me what the research environment is in combining non-invasive tests—is there any research?

**Dr. Shaukat:**

Yeah, there has been some work in that arena, and it is a promising strategy. The only caveat there is that it becomes really complicated, because we already have difficulty getting patients to complete either a blood test or a stool test. Now, when we add both, it adds a lot of complexity. So that could lead to poor uptake. It adds cost, and it's also more difficult to operationalize at a health system level.

**Dr. Buch:**

Thank you so much. So with all of that in mind, how do you frame conversations with patients about the options that are out there?

**Dr. Shaukat:**

So first and foremost, it's really important that we identify the screened eligible individuals and essentially bring up that they are due for colorectal cancer screening. Right now, that's men and women ages 45 and older. However, if somebody has a family history, particularly one first-degree relative with colorectal cancer, then screening should start at age 40.

So at age 40 or 45, it's important for us as clinicians to have this conversation about colorectal cancer screening, and then provide the patient with options. I would start with either a screening colonoscopy or a stool-based test as the primary option for the patient and see which one the patient is willing to complete and do in a timely manner. I'd also look at the resources of the clinic to understand which test might be best.

So start with one of those tests. Make sure it's ordered and completed. Then, if the patient is unwilling to undergo a screening colonoscopy at this time, or even a stool-based test, then I would offer them the possibility of a blood test as opposed to no screening. Modeling studies show that any screening is better than no screening, but colonoscopy and stool-based testing currently provides more benefit in terms of cancers prevented and colon cancer deaths prevented than the blood test at this time.

**Dr. Buch:**

Thank you so much for that. We are in the last few moments of our conversation, Dr. Shaukat. Do you have any additional thoughts you'd like to share?

**Dr. Shaukat:**

The thought I'd like to leave our audience with is that the best screening test is the one that gets done and done well. So look at your health system and also your patient population to figure out what might be the best strategy for screening for the population. And it's going to vary between different health systems and settings across the US.

So based on that, again, offering screening colonoscopy or a stool test are all good choices. And if a stool test or a blood test is offered, make sure that the health system has some kind of a tracking mechanism to follow up on individuals that have an abnormal stool test or abnormal blood test, and make sure that they get a colonoscopy to complete the loop.

**Dr. Buch:**

Thank you. I want to thank my guest, Dr. Aasma Shaukat, for joining me to discuss this very important topic of blood-based tests in colorectal cancer screening. Dr. Shaukat, thanks very much for this wonderful, very informative presentation.

**Dr. Shaukat:**

Thank you so much. Glad to be here.

**Dr. Buch:**

For ReachMD, I'm Dr. Peter Buch. To access this and other episodes in this series, visit *Clinician's Roundtable* on ReachMD.com, where you can Be Part of the Knowledge. Thanks for listening and looking forward to learning with you again very soon.