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Screening Modalities for Colon Cancer: What You Need to Know

Dr. Buch:
Welcome to *GI Insights* on ReachMD. I'm your host, Dr. Peter Buch. Today, we'll be discussing screening modalities for colon cancer. We're joined by Dr. Aasma Shaukat, who is the Robert M. and Mary H. Glickman Professor of Medicine at the NYU Grossman School of Medicine and the Co-Director of Translational Research, Education and Careers and the Director of Outcomes Research in the Division of Gastroenterology and Hepatology at NYU. Welcome back to the program, Dr. Shaukat.

Dr. Shaukat:
Thank you so much for having me back. It's a pleasure to be here.

Dr. Buch:
To start us off, Dr. Shaukat, why do we need more screening tests for colon cancer?

Dr. Shaukat:
That's a great question. We have plenty of screening modalities. Currently, the most common ones used in the US are screening colonoscopy and stool tests. We have a fecal immunochemical test, also known as the FIT test, and then we have a multitarget stool DNA test. So are those modalities enough? They should be. However, despite having those modalities, our colon cancer screening rates across the US are lower than our target. So currently, we stand at 59 percent for individuals ages 45 and older—both men and women—and our goal is 80 percent or higher, so you can see there's still room for improvement. And that begs the question: If we had additional modalities, could we potentially improve this colon cancer screening rate?

Dr. Buch:
Thank you for that. Now let's look more closely at these options. What are the sensitivity and specificity of fecal immunochemical testing and multitarget stool DNA testing?

Dr. Shaukat:
So the most commonly used modalities right now in the US for noninvasive testing are stool-based, and as we mentioned, there's two options: either a FIT, fecal immunochemical test, which is recommended annually by guidelines, or the multitarget stool DNA test, which checks for the FIT as well as certain other molecular markers for risk of colon cancer. And that test is currently approved for every three years.

And both these tests perform really well in the screening paradigm. We have much more robust data with FIT and its predecessor, which was the fecal occult blood test, because it's just been around very long. The largest trial was done in the US. That started in 1975 with this fecal occult blood done annually and showed a 33 percent reduction in colon cancer mortality. The modern-day FIT is more sensitive and specific. The sensitivity for a one-time FIT is about 74 percent for colorectal cancer, and its specificity is 94 to 96 percent for colorectal cancer, so a very specific test.

The one-time performance of the multitarget stool DNA test showed that it was more sensitive than the FIT and the specificity was lower at 89 percent. So few more false positives, but one-time sensitivity is higher. However, that test is done every three years, whereas a FIT is done every year. So you can imagine, comparing three FITs to one multitarget stool DNA is really apples to apples comparison, and that study just hasn't been done, but they're both guideline approved for colon cancer screening.

Dr. Buch:

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Here's a question that I have come across many times when I'm lecturing across the country, and I'd like your clarification for this. If I do a FIT test and it's positive, can I do then a multitarget stool DNA test to just confirm that result?

Dr. Shaukat:
The answer is absolutely not. These aren't to be done in sequence. And both these tests are recommended for average-risk individuals—both men and women 45 and older who are due for colon cancer screening. And once you do a stool test, and it's negative or positive, then essentially the next step is either, if the test is negative, waiting for the recommended interval, or if the test is positive or what we call abnormal, then scheduling a colonoscopy.

Dr. Buch:
Thank you very much for that clarification. What can you tell us about future multitarget stool DNA testing?

Dr. Shaukat:
So this is a very exciting time in the world of noninvasive colon cancer screening. And as we discussed, there's still a gap of individuals not being up-to-date, and obviously, we'd like some of these tests to be even more sensitive, not just for colon cancers, but also for these advanced polyps that we see at colonoscopy and we think are on the pathway to colon cancer. So in that regard, last year was extremely exciting because there were three new noninvasive tests that published their pivotal studies and have subsequently received FDA and Medicare approvals. The first study was done in 20,000 individuals ages 40 and older and has a slightly different molecular panel of the tumor markers that it studies. So the sensitivity for this test was 94 percent for colon cancer, the specificity was 91 percent, and the sensitivity for these advanced polyps was still at about 43 percent—so not great, but still decent. And I believe the test is, now that it's approved, going to start slowly getting phased into the market and will replace our current multitarget stool DNA test that we have.

Dr. Buch:
That's great. Thank you. For those just tuning in, you're listening to *GI Insights* on ReachMD. I'm Dr. Peter Buch, and I'm speaking with Dr. Shaukat about the latest updates on screening for colon cancer.

So, Dr. Shaukat, now that we have talked about stool-based screening methods, let's talk about blood testing. What are the options, and how effective are they?

Dr. Shaukat:
There is one new blood test approved by the FDA and also Medicare, and the pivotal study was published last year, so it's very, very new. This is based on a cell-free DNA technology in peripheral blood. So the idea is that as polyps grow larger, become more advanced, and start turning into cancer, they, perhaps, shed small amounts of cells, which have this tumor DNA that is shed into the blood. And now, with pretty sophisticated platforms, we can actually detect even very small amounts of tumor DNA in the circulating blood. So a straightforward blood test—it tests for a whole panel of markers and looks for signatures associated with colon cancer.

And the pivotal study included validation in 7,800 individuals that were average risk. So they had the blood test, and then they had a colonoscopy as the gold standard to see the accuracy of the blood test results compared to what was found at colonoscopy, and the test showed that the sensitivity for colon cancer was 83 percent with this blood test, and the specificity was 89 percent for colon cancer. What was disappointing was the advanced polyp detection was pretty low at 13 percent, but nonetheless, it's a screening test that meets the bar that Medicare had set for national coverage decisions. And once it got FDA approval, Medicare approved it also. So the test is probably either available or very soon to be available in your lab also, and I imagine patients will start asking about getting the test.

Dr. Buch:
So moving on and thinking about future uses, is there any benefit in performing colon cancer blood tests on a yearly basis? And how about combining blood and stool testing? Do we have any data yet?

Dr. Shaukat:
Great questions. So in in terms of stool testing every year, we just don't know what the interval should be. Right now, Medicare has approved to pay for the test every three years, but that doesn't mean it's the right interval for the test. And there's ongoing modeling studies because while waiting for this information or data to accrue because we've never had this test, now we have to rely on modeling studies and projecting if the test is done annually versus every three years. Do we have differences in outcome? And sure enough, the modelling studies do suggest that there is more benefit if it's done annually. However, then the issue becomes who's going to pay for the test because out of pocket, it's quite expensive. So that all will get sorted out, and once guidelines look at that more closely and provide guidance on the interval.

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And there are also studies going on to combine stool and blood test. The only issue there is it'll probably add a layer of complexity to the screening process, and it might deter individuals from undergoing screening because our whole purpose to have these additional options is to increase or make it easy for individuals to get screened, so we definitely don't want to add additional barriers. The blood test is pretty appealing because it can be done in the doctor's office; it can be bundled with other labs. And patients are used to getting preventative labs for high cholesterol or other things, so this can be coupled in that blood draw. So that's the appeal, and we're hoping that it's enough to boost adherence and bring those individuals that currently have not opted for either colonoscopy or stool-based tests to sign up and get screening done.

Dr. Buch:
And, Dr. Shaukat, in the last few minutes of our conversation, do you have any key takeaways you'd like to share?

Dr. Shaukat:
Yeah, absolutely. So colon cancer screening is both effective and cost-effective. Screening is the most effective way to prevent colorectal cancer as well as death from colorectal cancer. We want to get to a screening rate of 80 percent or higher, so again, for all our physicians listening, make sure you have a good idea where your patient population in terms of their screening rates and make sure that if they are eligible for screening that they are up-to-date. And if not, then the best advice is that the best test is the one that gets done. And that may vary for every patient population and clinical resource setting, so see what works in your setting for your patients, even for yourself, be it colonoscopy, a stool test, or, in the future, a blood test. But get screening done because any screening is better than no screening.

Dr. Buch:
I want to thank my guest, Dr. Aasma Shaukat, for this very important update on screening modalities for colon cancer. Dr. Shaukat, it was a pleasure speaking with you today.

Dr. Shaukat:
Yes, absolutely. Same here.

Dr. Buch:
For ReachMD, I'm Dr. Peter Buch. To access this and other episodes in the series, visit *GI Insights* on ReachMD.com, where you can Be Part of the Knowledge. Thanks for listening, and looking forward to learning with you next time.

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