MEDICAL TECHNOLOGY

REUTERS/BRENDAN MCDERMID

Putting cancer screening to the test

A prominent New York doctor wants everyone over 50 to have their gullets checked, though there's no evidence that doing so saves people from a deadly malignancy

BY FREDERIK JOELVING

CONTRARIAN VIEW: Dr. Jonathan Aviv says he flouts mainstream thinking on esophageal cancer screening "because of what I have seen with this disease."
REUTERS/BRENDAN MCDERMID

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Cancer was on Gritley Henry's mind when Dr. Jonathan Aviv treated her for a cough that had bested other doctors for a decade. "But I was too nervous to mention it," says the grandmother of three.

She didn't have to.

The vocal-fold disorder Aviv had diagnosed as the cause of the cough was already responding to treatment when, during a follow-up visit, the doctor threaded a thin flexible tube tipped with a camera into Henry's nose and down her throat. She sat wide awake as Aviv checked out her voice box. Then, though Henry had no symptoms of esophageal cancer, Aviv pushed the tube farther down her gullet, used the device to take a biopsy, and looked for signs of the precancerous cells known as Barrett's esophagus.

Screening for rare but deadly esophageal cancer is typically a laborious and costly procedure, requiring sedation and a day off from work. The new technology Aviv uses makes it a cinch.

That's why the few minutes he spent on Henry's screening threatens to open a new front in the fight over the costs and benefits of looking for disease in patients who aren't sick.

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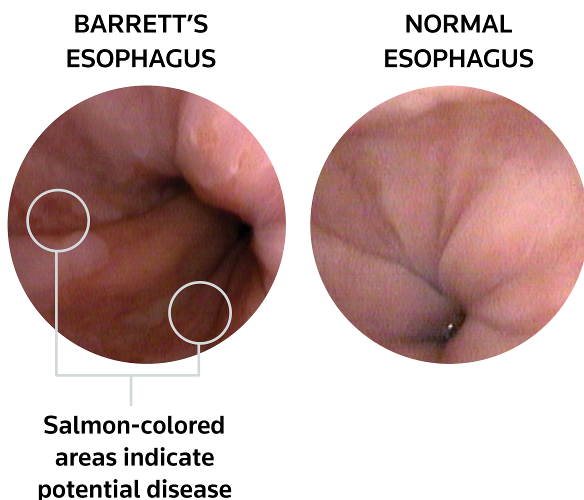
>
> **Dr. Jonathan Aviv**
> ENT Allergy and Associates LLP

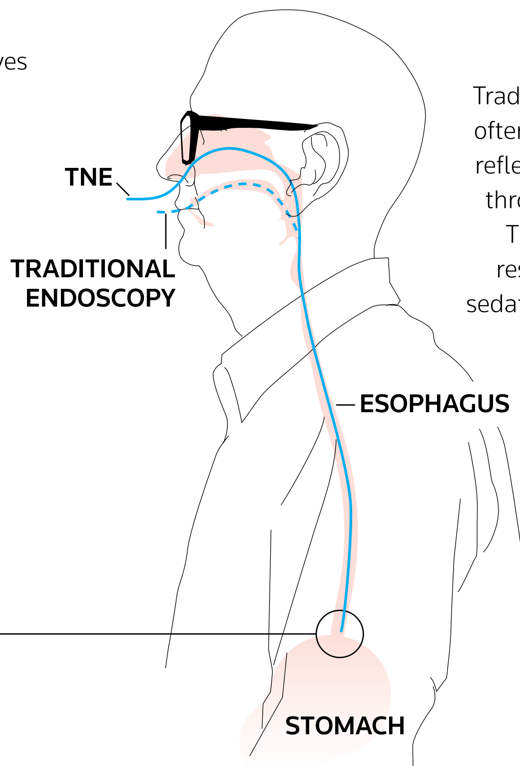
Aviv and his partners at Tarrytown, New York-based ENT and Allergy Associates LLP, which advertises itself as the largest ear, nose and throat practice in the United States, want everyone age 50 or older to undergo esophageal cancer screening. And they are working the media to promote transnasal esophagoscopy, or TNE, as the new technique is called. Aviv's radio and TV appearances have included a spot on ABC News's "Good Morning America."

Early detection, Aviv and other proponents say, could dramatically reduce the number of deaths from esophageal cancer, and at lower cost than traditional endoscopy. "The disease is devastating … and it's very easy to stop," Aviv says. "Everyone over 50, just like they have a screen-

Gullet-cam

Cancer screening with transnasal esophagoscopy, or TNE, involves threading an endoscope into a patient's nose and down to the junction of the esophagus and the stomach.





Traditional endoscopy often triggers the gag reflex because it goes through the mouth. TNE avoids that response, making sedation unneccessary.

Doctors look for signs of Barrett's esophagus, a condition that may turn into esophageal cancer.

PHOTOS: Dr. Jamie Koufman, Director, Voice Institute of New York

ing colonoscopy, should have a screening esophagoscopy."

Yet there is no research showing that routine screening for esophageal cancer lowers the risk of dying from the disease. Specialist medical groups recommend against it, as does the American Cancer Society.

The situation is similar in other countries, where TNE is available but not widespread. In Europe, the British Society of Gastroenterology says it can't recommend screening even for people with heartburn, considered a risk factor for esophageal cancer, because there is no evidence that doing so "is worthwhile and benefit is so unlikely."

While the cost of TNE is lower on a per-patient basis than traditional endoscopy, critics say testing millions of people would needlessly add billions of dollars to the already bloated U.S. national health bill and lead to lifelong follow-up testing for many people who would never get the disease.

"You are going to end up hurting a lot of people, and it's not clear to me you're going to help very many," says Dr. Otis Brawley, chief medical officer of the American Cancer Society and author of "How We Do Harm: A Doctor Breaks Ranks About Being Sick in America." "The simple, 'Let's find it early, let's not pay any attention to the potential for harm' – that same thought process is what started prostate cancer screening."

COSTLY LESSONS

When the blood test for prostate-specific antigen, or PSA, emerged two decades ago, it represented a simpler and cheaper alternative to the standard at the time – ultrasound and a biopsy of the prostate done through the rectum.

Promoted by urologists and patient-advocacy groups, the test quickly took off. Doctors began finding tumors early enough to destroy them with surgery and radiation. Some men experienced treatment side effects such as impotence, incontinence and severe infections, but these seemed a tolerable price to pay for thwarting a potentially deadly disease.

In the ensuing years, the picture grew muddy. Reports mounted that many men were submitting to treatments for slow-growing cancers that would never have bothered them in the first place. Scientific evidence showed that the millions of screenings and treatments performed hadn't significantly lowered death rates from prostate cancer.

In a 2010 op-ed article in the New York Times, Richard Ablin, one of the discoverers of PSA, noted that 30 million American men were getting the test every year, racking up a $3 billion bill. "The test's popularity," Ablin wrote, "has led to a hugely expensive public health disaster."

Last year, the U.S. Preventive Services Task Force, a federally funded panel of independent experts that makes recommen-

dations on preventive care, caused an uproar with a draft recommendation against prostate cancer screening.

"Looking hard for asymptomatic cancers will always result in overdiagnosis and overtreatment," says Dr. Michael LeFevre, a member of the task force. The panel does recommend routine screening beyond certain ages for breast, cervical and colo-rectal cancers and other diseases where research has shown that screening reduces deaths.

THE FEAR FACTOR

Whether TNE screening for esophageal cancer becomes as popular as the PSA test will depend largely on the attitudes of patients like Gritley Henry. To her, it doesn't matter that Aviv didn't discuss the pros and cons of screening before he did the test. She is just glad he took the initiative. Thanks to her negative biopsy result, says the Westchester County resident, "I can finally breathe a sigh of relief."

Esophageal cancer is particularly lethal, killing four out of five patients within five years of diagnosis. And as Aviv points out, the incidence of the esophageal cancer that doctors can screen for, called adenocarcinoma, has been rising – 2 percent to 3 percent a year between 1992 and 2008, according to the latest U.S. data, reported March 28 in the journal Cancer.

Still, the disease remains uncommon among cancers. About 10,500 Americans are diagnosed with esophageal adenocarcinoma each year, according to the American Cancer Society. The number for tumors of the colon and rectum – the No. 2 killer cancer, after lung cancer – is 143,000. White men over 50 have an elevated risk for esophageal cancer. Smoking, obesity and chronic acid reflux add to the danger.

The American College of Gastroenterology and other relevant specialist groups unanimously recommend against routine screening but are split over screening for people with multiple risk factors. All stress the need to discuss the pros and cons first. Aviv says he was prompted to screen Henry, a slim African-American woman with no known history of reflux disease, because her cough suggested to him she might have had reflux. (Henry won't specify her age beyond saying she is over 50.)

People diagnosed with Barrett's esophagus – a symptomless condition that experts say affects some 5 percent of Americans – are typically retested every few years to see if it has developed into something more dangerous. Follow-up tests usually involve traditional endoscopy, still the gold standard. Some patients also submit to invasive treatments in hopes of preventing the condition from developing into cancer, including a procedure to burn away the abnormal cells in the esophageal lining.

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> Chief Medical Officer, the American Cancer Society

Barrett's patients often liken their condition to living with a ticking time bomb in their throats. Laura Schmidt, a 43-year-old in Gardner, Massachusetts, was diagnosed last year during a traditional endoscopy for a stomach disorder.

"The doctor did tell me that, no matter what, I have to have an endoscopy every year, because usually, nine times out of 10, it turns into cancer," she says. "So I'm pretty scared."

The perception that Barrett's esophagus usually leads to cancer is a common one. It's also wrong. According to data published in the New England Journal of Medicine in 2011, the risk that Barrett's will turn into cancer in any given year is five in 10,000 for women and 15 in 10,000 for men. Some experts question the value of monitoring the condition at all, given the absence of any evidence that doing so protects against esophageal cancer.

"You're basically surveying a huge amount of patients for very little endpoint, so it's a big problem," said Dr. Lauren Gerson, a gastroenterologist at Stanford University in California.

'EXTREME POSITION'

Aviv is aware that his campaign for routine screening places him outside the mainstream. "I'm taking an extreme position because of what I have seen with this disease," he says. To underline his point, he ticks off a list of high-profile victims: baseball great Harmon Killebrew, architect Charles Gwathmey, actor Ron Silver, Texas Governor Ann Richards.

In 2009, ENT and Allergy Associates recruited Aviv, then a professor at Columbia University in New York City, to found and run its voice and swallowing center.

At different times over the past decade, he was a paid consultant to three companies that make or sell TNE scopes and related equipment: Minneapolis-based Medtronic Inc., Pentax – now known as KayPentax, based in Montvale, New Jersey – and Vision-Sciences Inc., of Orangeburg, New York. Aviv says he is no longer a paid consultant to any of the companies, though he owns several thousand shares in Vision-Sciences and uses its equipment. The company's systems cost between $30,000 and $60,000.

Vision-Sciences says that while it "may not have the marketing power of a larger corporation who might be able to take the promotion directly to the patient," it has supported research on the use of TNE and plans to offer training to teach doctors "about the merits of our TNE product offering."

Nicholas Tsaclas, who has worked in marketing for Pentax and Vision-Sciences, says input from Aviv and Dr. Jamie Koufman, another prominent New York-area ENT, was critical to the development of TNE devices. Among other things, the new cameras have given ENT doctors easier access to parts of the human anatomy

– the esophagus and stomach – that have typically been out of reach.

In 2009, it was Tsaclas who played the "patient" on "Good Morning America" while Aviv demonstrated TNE screening and host Diane Sawyer told viewers, "It's not painful, you can do it fast, and it can save your life." Since then, Aviv has appeared on "The Dr. Oz Show" and Bloomberg TV and on radio to promote TNE screening.

Many of his critics are worried about the history between doctor and equipment maker – not a rarity in the medical profession – as well as the sheer number of people who would be screened if Aviv had his way.

"The unfortunate thing is … this is something that will be a money-maker for the people who offer it," says Brawley of the American Cancer Society. In the absence of research showing that routine screening yields clear benefits, it's premature to be doing it, "especially if they are charging for the procedure," he says.

"This is marketing, that is all that is," says Dr. H. Gilbert Welch, an internist at the Dartmouth Institute for Health Policy and Clinical Practice in Hanover, New Hampshire, and author of "Overdiagnosed: Making People Sick in the Pursuit of Health."

Aviv bristles at that. "This is not about money," he says. "I mean, we don't get paid a lot of money for these procedures."

IT'S A CINCH: Screening for esophageal cancer using transnasal esophagoscopy, or TNE, takes just a few minutes, and the patient can remain wide awake. **REUTERS/BRENDAN McDERMID**

'I'VE SAVED THEIR LIFE'

Because the device does not trigger a gag reflex, and thus eliminates the need for sedation, it shaves about $1,000 off the cost of a traditional endoscopy and trims an hour-long exam to just a couple of minutes. The main physical risk is a nose bleed, and experts warn that a false-positive test result is another.

Labs charge between $250 and $350 to analyze a biopsy like the one Henry had, and insurers reimburse similar amounts to doctors for the procedure. Follow-up tests and preventive treatments can be more expensive.

When one of Aviv's biopsies turns out positive, he sends his patient to Mount Sinai Medical Center, which is affiliated with Aviv's practice. There, gastroenterologists perform an in-depth exam with sedation to determine whether the patient should be treated immediately or undergo follow-up testing. At that point, Aviv says, "in my mind, I've saved their life. And in the patient's mind, I've saved their ass."

The hospital's endoscopy suite says it receives eight or so such referrals a month from Aviv's practice. Yet the suite's director doesn't support Aviv's campaign. "I am not recommending [routine] screening," says Dr. Sharmila Anandasabapathy, a gastroenterologist. She does think all people over 40 with chronic reflux symptoms should be checked.

Dr. Gaelyn Garrett, who heads the voice center at Vanderbilt University in Nashville, Tennessee, says Aviv is "a visionary guy," but that "it is overstepping what the evidence is telling us to suggest that everybody over 50 get esophagoscopy."

Signs are emerging that Aviv's message is gaining traction. One advocacy group, the Esophageal Cancer Action Network, has begun promoting the message that "early detection saves lives." And while TNE isn't widespread yet – Vision-Sciences puts the total number of systems in use in the low hundreds – some family practices are already advertising TNE services on their websites.

Koufman, the onetime Aviv collaborator, says she hopes to open 26 clinics over the next three years with the primary goal of screening more people for esophageal cancer. "This is the disease of our country," Koufman says. In her view, as many as 100 million Americans may need to be screened.

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