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Treating Barrett's Esophagus: Time To End the Double Standard

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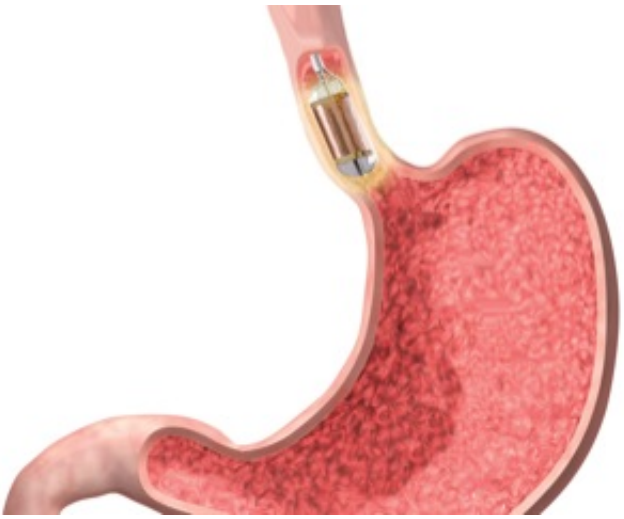
The way we have approached most cancers in the practice of evidence-based medicine has been to remove the precursor lesion before the onset of cancer, thus preventing or minimizing the risk that cancer will develop. We do that for actinic keratosis, cervical dysplasia and colon polyps. We have not done it for Barrett's esophagus, which is the immediate precursor to esophageal adenocarcinoma (EAC). The reason is that we did not have a safe or effective means of doing so—until now!

Gastroenterologists have long had a double standard. We approach colon polyps aggressively, but despite data suggesting that nondysplastic Barrett's is two to three times more likely to progress to high-grade dysplasia (HGD) or EAC than is an adenomatous colon polyp left in place, we are content to use a "watch and wait" strategy for Barrett's.

We have followed a policy of surveillance with little or no data to support its utility. In the interest of cost-effectiveness, we have spaced out surveillance intervals based on little more than whim and expert opinion. Fortunately, most of us haven't gotten into too much trouble with surveillance because most Barrett's patients have a relatively low risk for progression.



However, the risk for progression from nondysplastic Barrett's to EAC is not as low as some experts may purvey. A meta-analysis of 25 studies by Shaheen et al, in 2000, estimated the annual risk for EAC to be 0.5% per patient per year of follow-up, after correction for study bias (*Gastroenterology* 2000;119:333-338). Wani et al, in 2009, estimated the risk for progression at 5.98 per 1,000 patient-years (about 0.6% per patient per year; *Am J Gastroenterol* 2009;104:502-513). To

suggest that the rate of progression has
somehow decreased, when the incidence of this disease over the past three decades has soared, seems to defy logic.

One explanation for this lower rate may be that publishers of natural history studies have generally excluded patients from the data pool if they were noted to progress from nondysplastic Barrett's to EAC in the first year of the study. It is assumed that the endoscopist must have missed dysplasia at the time of inclusion.

Not only is this requirement an admission of the failure of surveillance as a policy, it is potentially removing a highly important subset from the data—and falsely underestimating risk. No matter how you look at this issue, the first and generally only time you sit down with a patient and explain the risk from this disease is the first time you diagnose it. The risk for patients during that first year includes the risk for that subset of patients with prevalent cancers who have been cut out of the data.

Even when excluding that subset in 1,376 patients with a first-time diagnosis of Barrett's esophagus, Sharma at al reported data showing that 53% of the patients who developed HGD or EAC had at least two consecutive initial endoscopic surveillances showing only nondysplastic Barrett's (*Clin Gastroenterol Hepatol* 2006;4:566-572). This disease is variable and unpredictable. It also carries one of the worst prognoses of any human malignancy, and patients know this. A diagnosis of Barrett's is highly anxiety-provoking, and this subsequently affects the quality of a patient's life (*Clin Gastroenterol Hepatol* 2009;7:613-623).

The average patient doesn't care if the risk for progression to EAC is 0.1% per year or 0.6%. Any risk is too much, especially when there is a safe, effective, cost-effective and durable way to deal with it. Many of my patients are already survivors of another cancer, or they know someone close to them (other than a blood relative) who suffered or died from the treatment of EAC. They feel the need to be proactive.

In 2010, Shaheen et al reported that radiofrequency ablation (RFA) improved health-related quality of life for patients with dysplastic Barrett's, apparently due to a perceived reduction in the risk for cancer (*Endoscopy* 2010;42:790-799). At this year's Digestive Disease Week, Li et al reported similar observations from more than 4,000 patients in the United States RFA Registry (abstract Sa1077). Treatment of Barrett's with RFA markedly improved health-related quality of life specific to the disease in these patients, especially when clearance of all intestinal metaplasia was achieved. Surprisingly, nondysplastic Barrett's had a significantly greater negative impact on life than dysplasia. Treatment significantly improved this impact to a similar degree. Although that effect at that time may have been due to a perception of improved survival, we now have data, pending publication, from the U.S. RFA Registry that supports a 10-fold risk reduction for nondysplastic Barrett's patients receiving RFA (compared with historical controls).

Anxiety about one's health is real. It has its own billing code. On Jan. 17, 2014, a Federal Appeals Court in Boston upheld the ruling of a lower court, granting consent for a taxpayer-

funded gender change procedure for an inmate serving a life sentence for a murder conviction. The essence of the ruling was that “medically necessary treatment is a constitutional right that must be protected, even if that treatment strikes some as odd or unorthodox.”

In 2010, Fleischer et al outlined the opinion of 16 of the nation’s most respected Barrett’s experts, including gastroenterologists, pathologists and surgeons, in an elegant treatise on why we should offer RFA to those with nondysplastic Barrett’s and low-grade dysplasia. Their conclusion: This treatment is “medically necessary.” The anxiety of an individual with Barrett’s is real, and even surveillance, no matter how frequent or lax, produces anxiety. This anxiety may or may not be comparable to an individual plagued by the perception that they have been born of the wrong sex, and that the only relief is a medical procedure to correct this. Yet, that is not the message of the court’s opinion. What the court implied is that no matter what the circumstance—whether RFA for the patient with nondysplastic Barrett’s, propofol for a colonoscopy patient or a sex change operation for an inmate serving a life sentence—if there is support for medical necessity, a patient has a constitutional right to receive the treatment in question. To withhold treatment from someone desiring RFA is unconscionable.

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