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INVITED COMMENTARY

Real-Time Endoscopic Pathology Assessment of Colorectal Polyps

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Determining the pathology of colorectal polyps in real-time has been the subject of many studies. Polyp pathology has been estimated using white light endoscopy, narrow band imaging with and without optical magnification, the Fujinon Intelligent Chromo Endoscopy system, the Pentax i-scan, confocal laser microscopy, autofluorescence, and the endocytoscopy system. Nearly all the technologies have had a substantial degree of success, with the largest number of studies performed using narrow band imaging. The persistent and nagging question is whether the use of these technologies can have an impact on everyday clinical practice, because, although they have been available in some cases for more than a decade, they currently do not have a meaningful role in routine endoscopic practice.

Numerous obstacles to the implementation of real-time pathology in practice are still present. These include lack of reimbursement, and consequently a lack of motivation for many endoscopists. Second, in many locations, all surgically removed tissue must be sent for pathologic evaluation. Finally, the recent development of endoscopist-owned pathology laboratories incentivizes the current paradigm of submitting all resected tissue for pathology.

Two cost-saving clinical uses for real-time determination of polyp pathology have been proposed [1]. The easiest to achieve is leaving diminutive rectosigmoid polyps that appear hyperplastic in place without resection. The second has been referred to as "resect and discard," in which polyp pathology is determined endoscopically and then polyps are resected but not submitted to pathology [2, 3]. The target group for resect and discard in the United States is diminutive polyps, i.e., lesions ≤5 mm in size [2], but in the UK the target is ≤9 mm in size [3]. This difference is based on the UK post-polypectomy surveillance guidelines, which (unlike those in the US) make no reference to villous elements or high-grade dysplasia in determining surveillance intervals [4]. Villosity and dysplasia grade are histologic features that cannot be reliably identified endoscopically. Because these features are more common in 6- to 9-mm polyps compared to diminutive polyps, 6–9 mm polyps are not a target for resect and discard in the United States. To facilitate the actual clinical use of real-time pathology, the American Society for Gastrointestinal Endoscopy proposed through its PIVI process that a technology could be endorsed for use in leaving distal hyperplastic polyps in place if its use allowed a negative predictive value for adenoma histology of 90 % or higher [1]. For resect and discard, decisions based on real-time pathology made with a particular technology should lead to agreement in surveillance intervals determined by endoscopy versus pathology in ≥90 % of patients.

To summarize what has been seen thus far in clinical trials with regard to meeting the thresholds established by the ASGE PIVI, it is fair to summarize that academic centers have consistently met the targets and that community-based centers have not. Two recent publications nicely demonstrate this discrepancy. In a meta-analysis of narrow band imaging, the investigators identified 28 studies involving 62,80 polyps in 4,053 patients [5]. The overall sensitivity for identifying adenomas was 91 %, and specificity 82.6 %. In 8 studies involving 2,146 polyps utilizing high confidence diagnostic predictions, sensitivity was 93.8 % and specificity 83.3 %. When 60 % or less of all polyps were neoplastic, the negative predictive values exceeded 90 %. In addition, surveillance intervals

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based on endoscopic diagnosis agreed with those based on pathology in 92.6 % of patients. Thus, the meta-analysis suggests that the PIVI thresholds are met in published studies. On the other hand, individual reports continue to describe low-level performance in community practice [6, 7]. For example, a recent German study using Pentax i-scan technology evaluated 675 polyps seen by 10 experienced private practice endoscopists performing screening colonoscopy [6]. Accuracy, sensitivity, and specificity of in vivo diagnoses were 76.6, 78.1, and 73.4 %, respectively. Recommendations for post-polypectomy surveillance based on endoscopic estimation of pathology were correct in only 69.5 % of cases. An important question is whether the endoscopists in this study were adequately trained in making real-time pathology determinations. Not using confidence measurements also contributed to poor performance. Beyond these factors, the issue of whether community practitioners are really interested in the entire process (given that it takes some time and there is no reimbursement) worries many observers, as we see consistently good results from academic centers.

To make real-time endoscopic pathology determination a game changer in clinical practice, several steps will need to take place. First, the ASGE will conduct evidence reviews and determine whether in some settings and from some technologies, the PIVI thresholds have been met. This will establish real-time histology from a standard of care and medical–legal perspective. Second, endoscopic image storage systems must allow storage of photographs that are of the same quality as the real-time image, so that these photographs can support an endoscopist's decision about pathology and also permit documentation of an individual endoscopist's adenoma detection rate. Third, we need effective training tools that adequately prepare endoscopists to have high rates of success and to use confidence rankings effectively. Finally, there should be a realignment of reimbursement toward the goal of incentivizing cost-savings policies such as resect and discard, which could substantially improve the cost-effectiveness of colonoscopy [8, 9]. Bundled payments for colonoscopy, particularly if they include the pathology component, would also incentivize resect and discard. Actual payment to endoscopists for the performance of real-time pathology by insurance companies would be the most direct and effective incentive.

The concept of saving billions of dollars on the pathologic assessment of diminutive lesions that have almost no risk of cancer, and which are encountered in enormous numbers during routine colonoscopy, remains very attractive. Hopefully, we can overcome the few remaining obstacles and establish real-time pathology as a valuable clinical tool.

Compliance with Ethics Guidelines

Conflict of Interest Douglas K. Rex is a consultant for and receives research support from Olympus America Inc. (Center Valley, PA).

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