The American Society for Gastrointestinal Endoscopy PIVI (Preservation and Incorporation of Valuable Endoscopic Innovations) on real-time endoscopic assessment of the histology of diminutive colorectal polyps

The PIVI (Preservation and Incorporation of Valuable endoscopic Innovations) initiative is an ASGE program whose objectives are to identify important clinical questions related to endoscopy and to establish a priori diagnostic and/or therapeutic thresholds for endoscopic technologies designed to resolve these clinical questions. Additionally, PIVIs may also outline the data and or the research study design required for proving an established threshold is met. Once endoscopic technologies meet an established PIVI threshold, those technologies are appropriate to incorporate into clinical practice presuming the appropriate training in that endoscopic technology has been achieved. The ASGE encourages and supports the appropriate use of technologies that meet its established PIVI thresholds.

The PIVI initiative was developed primarily to direct endoscopic technology development toward resolving important clinical issues in endoscopy. The PIVI initiative is also designed to minimize the possibility that potentially valuable innovations are prematurely abandoned due to lack of utilization and to avoid widespread use of an endoscopic technology before clinical studies documenting their effectiveness have been performed. The following document, or PIVI, is one of a series of statements defining the diagnostic or therapeutic threshold that must be met for a technique or device to become considered appropriate for incorporation into clinical practice. It is also meant to serve as a guide for researchers or those seeking to develop technologies that are designed to improve digestive health outcomes.

An ad hoc committee under the auspices of the existing ASGE Technology and Standards of Practice Committees Chairs develops PIVIs. An expert in the subject area chairs the PIVI, with additional committee members chosen for their individual expertise. In preparing this document, evidence-based methodology was employed, using a MEDLINE and PubMed literature search to identify pertinent clinical studies on the topic. PIVIs are ultimately submitted to the ASGE Governing Board for approval, as is done for all Technology and Standards of Practice documents. This document is provided solely for educational and informational purposes and to support incorporating these endoscopic technologies into clinical practice. It should not be construed as establishing a legal standard of care.

PIVI on Real-Time Endoscopic Assessment of the Histology of Diminutive Colorectal Polyps statements:

1. In order for colorectal polyps \( \leq 5 \) mm in size to be resected and discarded without pathologic assessment, endoscopic technology (when used with high confidence*) used to determine histology of polyps \( \leq 5 \) mm in size, when combined with the histopathologic assessment of polyps \( > 5 \) mm in size, should provide a \( \geq 90\% \) agreement in assignment of post-polypectomy surveillance intervals when compared to decisions based on pathology assessment of all identified polyps†.

2. In order for a technology to be used to guide the decision to leave suspected rectosigmoid hyperplastic polyps \( \leq 5 \) mm in size in place (without resection), the technology should provide \( \geq 90\% \) negative predictive value (when used with high confidence*) for adenomatous histology†.

RATIONALE FOR THIS PIVI

This PIVI was developed to assist in the development of new paradigms for colonoscopic management of diminutive \( \leq 5 \) mm in size) colorectal polyps that may reduce costs and improve patient safety compared to current paradigm. An additional benefit of the new paradigm is

*The term “when used with high confidence” indicates that clinical judgment can be used deciding whether the histology of a given polyp can be assessed accurately using an endoscopic technology. Thus, if a polyp lacks features associated with confident endoscopic assignment of histology, it could still be resected and submitted for pathologic assessment. This occurrence does not diminish the potential benefits of endoscopic assessment of histology when there is high confidence in the endoscopic assessment.

†The use of endoscopic technologies to determine real-time histology must be accompanied by technology that allows permanent storage of polyp images that are of sufficient resolution to support the endoscopists’ assessment and clinical decisions when subjected to quality review.
the elimination of delay in recommending the next surveillance in many cases. Diminutive polyps are extremely common, with recent studies employing high definition colonoscopes identifying diminutive adenomas in about half and diminutive polyps in more than half of the U.S. screening population. A much smaller fraction (5%) of the U.S. population develops colorectal cancer, and polyps larger than 5 mm in size are more likely than diminutive polyps to harbor cancer or advanced neoplasia (see full PIVI document, www.asge.org) or to eventually develop into colorectal cancer. The current paradigm of colonscopic management of diminutive polyps is generally to resect and submit them for pathologic assessment (except in the case of multiple tiny polyps in the rectosigmoid colon that appear hyperplastic, for which sampling of a few lesions is widely considered adequate). However, the routine pathological assessment of all resected diminutive colonic polyps results in substantial costs to patients and society for management of a group of lesions with limited clinical importance. Pathologic assessment also causes a delay informing patients of the histology of their polyps and in recommending the next colonoscopy surveillance interval.

The purpose of this PIVI is to focus efforts by clinicians and industry toward development of new paradigms for the colonscopic management of diminutive polyps that minimize risk and unnecessary delay of information transfer to patients while improving the cost-effectiveness of colonoscopy. The PIVI statements rest on two general assumptions. First, all polyps in the proximal colon (proximal to the sigmoid colon) should be endoscopically resected, and all adenomas should be resected regardless of their location in the colon. Thus, to maximize the benefits of colonoscopy and polypectomy, the current paradigm of resecting all colorectal polyps except diminutive polyps in the rectosigmoid, which appear endoscopically to be hyperplastic, should be preserved in the new paradigm. The second assumption is that there is a group of colorectal polyps that have a sufficiently low prevalence of advanced histology including cancer such that the only value offered by their pathologic assessment is to guide assignment of the post-polypectomy surveillance interval. A detailed review of the literature indicates that polyps ≤5 mm in size have an extremely low prevalence of invasive cancer and a very low prevalence of advanced histology, and therefore constitute such a group of polyps.

This PIVI establishes two new paradigms for diminutive polyp management that address the clinical needs specified above, ie, minimizing risk and delay in transferring information to patients and improved cost-effectiveness. The first paradigm has been called the “resect and discard” strategy. This paradigm could be appropriately applied to diminutive polyps anywhere in the colorectum. In this paradigm the histology of a diminutive polyp is assessed by an appropriate endoscopic method, the assessment is recorded by means of a high-resolution photograph, and the polyp is then resected. However, rather than submitting the polyp for pathologic assessment, the polyp is discarded and the endoscopic assessment of histology is used to determine the impact of the polyp on the patient’s next post-polypectomy surveillance interval. The principal value of the “resect and discard” paradigm is a reduction in costs for pathologic assessment of diminutive polyps. In many cases, the resect and discard paradigm allows an immediate recommendation regarding the next colonoscopy interval.

The second new paradigm for diminutive polyp management applies only to diminutive hyperplastic appearing polyps in the rectosigmoid colon. This paradigm proposes that when multiple diminutive rectosigmoid hyperplastic polyps are suspected endoscopically, then the hyperplastic nature of these polyps can be established and documented by real-time endoscopic assessment and photography, without the need for sampling or resection of some or all of the polyps. The value of this second paradigm is a reduction in costs and risks associated with polypectomy, and a reduction in costs associated with pathologic assessment.

The PIVI is intended to guide technology developers and clinical investigators toward the design and testing of technologies that address these important clinical needs in diminutive polyp management. The PIVI’s recommended thresholds for performance standards of technologies should serve investigators by establishing the correct group of target lesions in which to examine technologies that purport to allow real-time determination of histology, to create clinical endpoints in trials that are meaningful and relevant (with the potential to change clinical practice), and to estimate the required sample sizes for adequately powered studies. In addition to meeting the performance thresholds recommended in the PIVI, other endpoints may need to be satisfied to establish that a technology can be used in the new paradigm in a manner that is feasible and accurate by community endoscopists. In turn, technologies that meet the recommended thresholds specified in the PIVI, and which satisfy other necessary endpoints, will be supported by the ASGE (as well as other interested professional societies choosing to do so) as technologies that can be used to operate in the new paradigm (and thereby substitute for the old paradigm), and that the use of these technologies in meeting the new paradigm meets the standard of medical care for management of diminutive colorectal polyps.

**METHODOLOGY OF THE PIVI**

The PIVI committee performed literature reviews of the following topics: (1) association of polyp size with cancer, high grade dysplasia, and villous elements; (2) the accuracy and interobserver variation of pathologic assessment of hyperplastic versus adenomatous histology; (3) histology of colorectal polyps by site within the colon; and (4)
performance characteristics of technologies currently under study for real-time assessment of colorectal polyp histology. The detailed results of these reviews are available online. Factors that were considered in reaching consensus regarding the recommended thresholds included the importance of the issue to clinical practice, the accuracy of the gold standard (pathology), and the impact of other factors that affect the clinical outcomes (eg, optimal or designated post-polypectomy surveillance intervals are influenced by missed lesions during colonoscopy, loss of polyps without retrieval, bowel preparation, and other factors that impact the endoscopist’s decision regarding surveillance interval.

Potential consequences of the new paradigms in diminutive polyp management

Cost analyses have found that the resect and discard paradigm is associated with substantial cost savings with negligible impact on patient cancer risk. The use of the resect and discard paradigm must preserve the ability of the endoscopist and the endoscopy center to accurately measure the adenoma detection rate (ADR) of individual endoscopists. The ADR is currently the most important measure of the quality of mucosal inspection during colonoscopy, and in one study the ADR of individual endoscopists strongly predicted patients’ subsequent risk of developing colorectal cancer. In the resect and discard paradigm, an endoscopic photograph, rather than a glass pathology slide, becomes the record of a diminutive polyp. As such, photographs must be stored to support an endoscopist’s claim of adenoma detection, and to allow measurement of endoscopists’ adenoma detection rates. The polyp detection rate, which is highly correlated with the adenoma detection rate in retrospective studies, provides fewer obstacles to measuring mucosal inspection quality in a resect and discard policy. However, the polyp detection rate may be more subjective to gaming than the ADR with prospective use; this issue requires further study.

In many settings there may be a requirement that all resected tissue be sent for pathologic assessment. The ASGE recommends that all state, local, and institutional rules be followed in this regard, but urges also that appropriate channels be pursued to present the evidence and rationale for clinical goals addressed in this PIVI.

In some settings, endoscopists have established laboratories that provide surgical pathology services for the tissue specimens generated by the endoscopy practice. In these settings there will be a financial disincentive to incorporate the new paradigms for diminutive polyp management outlined above. Financial disincentives can be major obstacles to incorporation of new medical practices. The ASGE believes the rationale for real-time histology with regard to cost savings and patient safety to society warrants creation of this PIVI and support of the new paradigms for diminutive polyp management. Once technologies have been validated as effective in community practice, the ASGE will lobby for and will recommend that other societies and endoscopists work toward appropriate reimbursement for cost-saving technologies such as real-time endoscopic assessment of histology of diminutive polyps.

(The full PIVI document on real-time histology of diminutive colorectal polyps is available on the ASGE website www.asge.org).

REFERENCES

1. Rex DK, Helbig CC. High yields of small and flat adenomas with high-definition colonoscopes using either white light or narrow band imaging. Gastroenterology 2007;133:42-7.
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