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Implementation of Optical Diagnosis for Colorectal Polyps: Standardization of Studies Is Needed

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Roadmap to the FUTURE of PRACTICE

In 1993, the National Polyp Study (NPS) was published in the New England Journal of Medicine and demonstrated the power of colonoscopy and polypectomy to reduce subsequent risk of colorectal cancer (CRC). The protocol for NPS included removal of all visible lesions and all were sent for pathological review. This process became standard practice in gastroenterology. Recently, the concept of "optical biopsy", where hyperplastic polyps can be accurately identified and discarded in lieu of pathologic analysis might be safely accomplished, thus reducing costs without compromising patient health outcomes. Issues related to accuracy of optical biopsies, potential liability and practice reimbursement have all been barriers to widespread implementation. In this month's column, Dr Kaltenbach and colleagues outline a process to standardize studies, training, and classification of optical biopsies; a needed step in the evolution of our colonoscopy practice.

The potential application of optical diagnosis for diminutive colorectal polyp is at a crossroads. Recent studies have shown its feasibility; the diagnostic operating characteristics for the real-time diagnosis of diminutive colorectal polyps are similar to those of pathologists. These studies showed 93% concordance between the surveillance interval recommendations that are based on optical and pathologic diagnoses and ≥90% negative predictive value for polyps in the rectosigmoid colon.[1] These findings may open the applications of optical diagnosis for diminutive colorectal polyps in practice, which in turn may lead to improved cost-effectiveness of colonoscopy for colorectal cancer screening.[2]

However, some recent reports of optical diagnosis conducted beyond the academic setting did not reproduce the high levels of accuracy, eliciting reservation on the generalizability of optical diagnosis in practice. A variety of explanations could account for or contribute to these results. These studies (as well as some studies from academia) have not followed the key steps for a system redesign, the underlying basis for implementation of optical diagnosis. Because of the recent pattern of results, we propose a set of recommendations to be considered by investigators in the design of future studies. Our objective is to share the lessons learned from successful optical diagnosis studies[1] and thereby to suggest a framework in which to conduct and report such studies.

Designing an Optical Diagnosis Study

General Framework

The implementation of optical diagnosis, a system redesign, should be evidence-based and adopt a quality improvement model. It requires participants to recognize that learning is experiential: "a cyclic process of doing, noticing, questioning, reflecting, exploring concepts and models (evidence), and then doing again – only doing it better the next time (PDSA cycle)" (Supplementary Figure 1).[3] The iterative process of "checking" the correlation of endoscopic diagnosis to pathology findings is important. Without it, the study participants miss a

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Abbreviations used in this paper: **ADR, adenoma detection rate; ASGE, American Society for Gastrointestinal Endoscopy; NBI, narrow band imaging; NICE, Narrow Band Imaging International Colorectal Endoscopic.**

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significant opportunity to continuously improve the quality of their optical diagnoses.

Studies should commence once there is consistency in the ability to provide optical and pathology diagnoses, and this ability should be periodically checked, following the Plan-Do-Study-Act cycle. A study can only be successful when the participants remain interested in learning, engaged, and committed to the process. Published guidelines on the general framework for study conduct and standards for the reporting of results can be very useful. As such, the research team should be deliberate to include the key elements of diagnostic studies before, during, and after the study (Supplementary Table 1). These standards are necessary to minimize biased results from incompletely designed, conducted, or analyzed diagnostic studies.

Optical Diagnosis Specific Framework

Training

The knowledge and skills required to perform optical diagnosis are not innate but can be learned by people with varying levels of expertise. As such, training modules have been developed and studied. In an early report of training of a short teaching session on optical diagnosis for the endoscopic differentiation of colorectal polyp histology, Raghavendra et al[4] showed attainment of high accuracy (90.8%) and good interobserver agreement ($k = 0.69$) by using high-definition still photographs of polyps. Ignjatovic et al[5] assessed the construct and content validity of a still image–based teaching module on the basic principles of narrow band imaging (NBI), the microvessel patterns, and the role of NBI in differentiating between adenomas and hyperplastic polyps. After training, they found improved accuracy and specificity of optical diagnosis in novices, trainees, and experts with moderate agreement ($k = 0.56$, 0.70, and 0.54, respectively). Rastogi et al[6] showed the importance of active feedback to achieve high performance. After a 20-minute training module, community and academic practitioners reviewed 80 short clips of diminutive polyps, with feedback provided after each video. They made significant improvements in accuracy and the proportion of high confidence predictions as they progressed through consecutive video blocks of 20. Although none of the studies used consecutively collected images or video content and none assessed durability of performance after the training in real-time in vivo setting, their findings underscore the importance of learning before engagement in a formal study or the practice of optical diagnosis.

A teaching video entitled "Optical Diagnosis of Colorectal Polyps" is available through the American Society for Gastrointestinal Endoscopy On-line Learning Center. The program outlines the steps necessary to practice the technique. It provides a review of the concepts of optical diagnosis and numerous illustrative case examples.

Documentation of Competence

The documentation of successful completion of training is important. The formal training should be based on a validated tool, should be periodic, and should include an in vivo component. Ex vivo competency should be assessed before evaluation of clinical performance. After achievement of ex vivo performance thresholds, study participants should then be evaluated in real time to ensure sustained performance before study initiation. Finally, and consistent with the Plan-Do-Study-Act quality improvement model, participants should undergo additional ex vivo testing periodically throughout the study to ensure sustained performance and evaluate the need for further training. By using this approach of regular self-training and a robust teaching tool, we observed no significant difference in a group of experienced endoscopists between performance in the first and second halves of the study. Agreement in surveillance interval recommendations between optical-based and pathology-based strategies exceeded 95% in both halves of the study.[7,8]

Standardized Optical Diagnostic Criteria

When feasible, investigators should use validated criteria for the endoscopic diagnosis of colorectal polyps. An example is the Narrow Band Imaging International Colorectal Endoscopic (NICE) classification by using NBI, which describes real-time differentiation of non-neoplastic (type 1) and neoplastic (type 2) colorectal polyps,[9] as well as for lesions with deep submucosal invasion (type 3). Other endoscopic classifications of colorectal polyps by using NBI, i-Scan, or chromoendoscopy have been described with and without optical magnification but have not yet been validated.

Although sessile serrated adenoma/polyps exhibit features of non-neoplastic lesions, their distinction from hyperplastic polyps is challenging because of the variations in pathologic diagnoses. Until such endoscopic and pathologic distinctions are further described, investigated, and reproducible, it may be necessary to remove and submit to pathology all proximal and/or large NICE type 1 polyps.