

# Should ESGE implement optical diagnosis in Europe?



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## Bibliography

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It is not the scientific relevance of endoscopic innovations *per se* that justifies an endorsement by an international society of endoscopy. Indeed, most innovations represent mere improvements in already established practices. On the other hand, when endoscopic innovations dramatically change the current *standard of care* – and risking uncertainty about the potential benefit and risks – that a scientific society should be expected to express its perspective about these advances.

The latter is clearly the case for new clinical strategies based on application of optical diagnosis of polyps  $\leq 5$  mm detected at colonoscopy. According to the “resect and discard” (R&D) strategy, all colorectal polyps  $\leq 5$  mm *in vivo* characterized with high confidence as either adenomatous or hyperplastic do not require post-polypectomy histological examination. In addition, as already widely accepted in clinical practice, recto-sigmoid polyps  $\leq 5$  mm characterized as hyperplastic by optical diagnosis can be left in place.

*Is it the right time for the European Society of Gastrointestinal Endoscopy (ESGE) to support the clinical implementation of optical diagnosis for diminutive polyps?* First, these strategies find their main field of application in settings of clinical relevance, such as ongoing colorectal cancer (CRC) screening programs that aim to reduce the second leading cause of cancer-related morbidity and mortality in Europe. Second, the technological innovation on which the R&D strategy is based (i. e., Narrow Band Imaging, Blue Light Imaging, I-scan) is widely available in European endoscopy centers, so any delay would be hard to justify. Third, the scientific community appropriately updated the standard of care by creating and validating dedicated classifications for optical diagnosis. The NBI International Colorectal Endoscopic (NICE) represents a successful compromise between Western and Japanese perspectives, resulting in a clear differentiation between hyperplastic and adenomatous polyps, as well as accurate prediction of deeply invasive cancer [1,2]. In addition, the

recent Workgroup serrated polyps and Polyposis (WASP) classification showed promising accuracy for optical diagnosis of sessile serrated polyps [3]. Fourth, a large amount of data mainly coming from tertiary centers successfully validated the clinical efficacy of the R&D strategy, based on both the intrinsic high accuracy of optical diagnosis and fulfillment of the PIVI set by the American Society for Gastrointestinal Endoscopy [4,5].

Decision-making by any *scientific* society should be driven by exploitation of a widely accepted and objective methodology. ESGE recently embraced GRADE as the most suitable methodology for clinical decisions [6]. According to GRADE, the choice between “to recommend” or “to recommend against” a clinical intervention should be based on an objective comparison between benefit on one side and risks and burden – both economic and financial – on the other [6].

*What are the main benefits and risks (burden) of the R&D strategy?* Saving the histological costs associated with  $\leq 5$  mm polyps is by far the most relevant benefit. While already accounting for over 80% of diagnosed lesions [7], detection of polyps  $\leq 5$  mm is likely to further increase due to current recommendations to boost the adenoma detection rate of individual endoscopists [8,9]. A second benefit is the possibility of immediately assigning appropriate post-polypectomy surveillance after colonoscopy in most cases, marginalizing the burden of a second visit after histology to those relatively few patients with polyps  $\geq 5$  mm.

On the other hand, the main drawback of R&D strategy is clearly represented by the fear of inappropriately delaying surveillance due to misinterpretation of an adenoma as a hyperplastic polyp (i. e., a false-negative optical diagnosis). However, such risk strictly depends on stratification adopted within the reference guidelines for post-polypectomy surveillance. In detail, ESGE recommends return to screening or 10-year colonoscopy in those without advanced neoplasia, irrespective of

whether a lesion < 10 mm is a non-advanced adenoma or hyperplastic [10]. Thus, such a recommendation marginalizes any risk associated with potential false-negative optical diagnosis. That differs from American guidelines, which recommends offering patients with non-advanced adenomas 5- to 10-year surveillance versus the somewhat delayed 10-year interval in those with hyperplastic polyps [11]. It could be argued that an additional risk is represented by those very few patients who harbor an advanced histology within a lesion  $\leq 5$  mm, as optical diagnosis is likely to be ineffective in discriminating between advanced and non-advanced adenomas  $\leq 5$  mm. Three-year surveillance would, indeed, be warranted in those patients according to both ESGE and American guidelines rather than the 10-year interval that would be assigned based on an apparently correct optical diagnosis strategy [10, 11]. However, the actual rate of advanced neoplasia (i. e., high-grade dysplasia, villosity) is very low in diminutive adenomas, where the risk of invasive cancer is, if any, exceptionally rare [12, 13]. In addition, there is some evidence that risk of metachronous advanced neoplasia in patients stratified as high risk due to diminutive polyps is actually very low.

In a cost-effective simulation model published in this issue of this journal, Vleugels J et al. were able to compare the potential benefit of the R&D strategy – mainly its economic saving – with all the potential sources of risks, including the loss of life-years due to inappropriately delayed surveillance in patients at high risk due to advanced adenomatous or serrated neoplasia within a polyp  $\leq 5$  mm [14]. The Authors succeeded in showing the cost-saving profile of the R&D strategy, while excluding any loss in life expectancy coupled with it [14]. These findings are critically relevant for implementation of a R&D strategy. First, the cost-saving profile was shown in a simulated program with an immunochemical fecal test that represents the predominant scenario in Europe. This excludes any detrimental effect of implementation of optical diagnosis in ongoing programs. Second, it is the first model that takes into account the possibility of sessile serrate polyp within polyps  $\leq 5$  mm. Third, unlike previous models [15, 16], Vleugels J et al. actually based their simulation on accuracy data computed in non-tertiary centers, ensuring the generalizability and reproducibility of the study outcomes [14]. Fourth, the results of the model were confirmed when adopting ESGE versus Dutch guidelines, showing a relative independence from the selected setting [7].

When considering the favorable data from Vleugels J et al., *should ESGE call for an immediate and indiscriminate application of the R&D strategy based on optical diagnosis?* Despite the unequivocal validity of this model, there are still major barriers that must be addressed before widespread implementation of the R&D strategy is allowed. First, when discarding a polyp, no post-polypectomy specimen is actually collected. Thus, photo-documentation must replace pathology storage both for clinical and legal reasons. Additional evolution of endoscopic databases may be required to ensure long-term maintenance of this relevant documentation. Second, the unexpectedly suboptimal performance shown when implementing optical diagnosis by community-based endoscopists underscores the need for both training and auditing [17]. Of note, most training in optical di-

agnosis can be conveniently performed with interactive tools that are shown to be extremely effective in non-expert settings [18]. Education and training represent the core ESGE mission. Thus, ESGE can be expected to perform an active role in implementing such training, and to play a persuasive role in convincing national societies to activate a formal process for monitoring, certification, and auditing.

In 2014, ESGE was the first scientific society to officially give a (weak) recommendation for implementation of R&D strategy in clinical practice [19], pending fulfillment of unequivocal criteria, namely: *'the optical diagnosis has to be reported using validated scales, must be adequately photo-documented, and can be performed only by experienced endoscopists who are adequately trained and audited.'* [19]

ESGE's position on R&D very recently was adopted by the National Institute for Health and Care Excellence, which also supported its clinical implementation pending conditions very similar to those required by ESGE [20]. These societies did their best to indicate what the new standard of care is to be. It is time now for the endoscopy community to show their commitment to being trained in and audited on optical diagnosis, in order to implement R&D strategy in clinical practice. What may appear to be a relatively small step for endoscopy may become a huge savings for society!

## Competing interests

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None

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