Definition of competence standards for optical diagnosis of diminutive colorectal polyps: European Society of Gastrointestinal Endoscopy (ESGE) Position Statement

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ABSTRACT

Background The European Society of Gastrointestinal Endoscopy (ESGE) has developed a core curriculum for high quality optical diagnosis training for practice across Europe. The development of easy-to-measure competence standards for optical diagnosis can optimize clinical decision-making in endoscopy. This manuscript represents an official Position Statement of the ESGE aiming to define simple, safe, and easy-to-measure competence standards for endoscopists and artificial intelligence systems performing optical diagnosis of diminutive colorectal polyps (1 – 5 mm).

Methods A panel of European experts in optical diagnosis participated in a modified Delphi process to reach consensus on Simple Optical Diagnosis Accuracy (SODA) competence standards for implementation of the optical diagnosis strategy for diminutive colorectal polyps. In order to assess the clinical benefits and harms of implementing optical diagnosis with different competence standards, a systematic literature search was performed. This was complemented with the results from a recently performed simulation study that provides guidance for setting alternative competence standards for optical diagnosis. Proposed competence standards were based on literature search and simulation study results. Competence standards were accepted if at least 80 % agreement was reached after a maximum of three voting rounds.

Recommendation 1 In order to implement the leave-in-situ strategy for diminutive colorectal lesions (1–5 mm), it is clinically acceptable if, during real-time colonoscopy, at least 90 % sensitivity and 80 % specificity is achieved for high confidence endoscopic characterization of colorectal neoplasia of 1–5 mm in the rectosigmoid. Histopathology is used as the gold standard.
Level of agreement 95 %.

Recommendation 2 In order to implement the resect-and-discard strategy for diminutive colorectal lesions (1–5 mm), it is clinically acceptable if, during real-time colonoscopy, at least 80 % sensitivity and 80 % specificity is achieved for high confidence endoscopic characterization of colorectal neoplasia of 1–5 mm. Histopathology is used as the gold standard.
Level of agreement 100 %.

Conclusion The developed SODA competence standards define diagnostic performance thresholds in relation to clinical consequences, for training and for use when auditing the optical diagnosis of diminutive colorectal polyps.

ABBREVIATIONS

CRC	colorectal cancer
ESGE	European Society for Gastrointestinal Endoscopy
FICE	flexible spectral imaging color enhancement
FIT	fecal immunochemical test
HPP	hyperplastic polyp
NBI	narrow-band imaging
NICE	National Institute for Health and Care Excellence
SODA	Simple Optical Diagnosis Accuracy
SSL	sessile serrated lesion

SOURCE AND SCOPE

This Position Statement is an official statement of the European Society of Gastrointestinal Endoscopy (ESGE). This position statement is the first in a series that will give details of new optical diagnosis standards. The recommendations presented here are based on a consensus procedure among endoscopists considered to be experts in optical diagnosis who are involved in optical diagnosis training and training courses in Europe.

Introduction

The European Society of Gastrointestinal Endoscopy (ESGE) has a vision to create a thriving community of endoscopy services and endoscopists in Europe, to provide a high quality of endoscopy care. ESGE has developed a core curriculum for optical diagnosis practice across Europe for high quality optical diagnosis training [1, 2]. The development of easy-to-measure competence standards for optical diagnosis that are focused on clinical consequences could help to optimize clinical management in gastrointestinal endoscopy.

Recently, a spin-off task force of the Curricula Working Group for optical diagnosis training has developed a methodological framework, which can provide guidance when developing new competence standards for optical diagnosis in gastrointestinal endoscopy. The development of such standards could be a first step in optimizing clinical treatment and surveillance decisions within gastrointestinal endoscopy. As a first step, in 2021, this task force started the initiative to develop competence standards for the optical diagnosis of diminutive colorectal polyps (1 – 5 mm).

Rationale for developing competence standards for optical diagnosis of diminutive colorectal polyps

Diminutive colorectal polyps, with a negligible risk of harboring cancer, constitute up to 60 % of all colorectal polyps [3, 4]. The current management of polyps, including diminutive polyps, is to resect and submit them all for histological assessment. While the detection and removal of polyps contributes toward the reduction in colorectal cancer (CRC), histological assessment of these diminutive polyps results in substantial burdens and costs for colonoscopy units. These costs and burdens could be reduced by implementing an "optical diagnosis strategy" for diminutive colorectal polyps [5]. In this optical diagnosis strategy, endoscopists or artificial intelligence systems diagnose diminutive polyps during colonoscopy with high or low confidence. When these diminutive polyps are diagnosed with high confidence, they can be resected and discarded without histological evaluation (i. e. the "resect-and-discard strategy"). In addition, non-neoplastic lesions located in the rectum and sigmoid can be left in situ without resection, as they have no malignant potential (i. e. the "leave-in-situ strategy") [6, 7].

Though not yet achieved, the implementation of optical diagnosis for diminutive colorectal polyps into routine clinical practice remains an important goal as it would greatly reduce colonoscopy-associated costs [8, 9]. The implementation of this strategy is therefore also endorsed by several international societies [10–12].

However, because misdiagnosis of diminutive lesions can result in inappropriate surveillance intervals and neoplastic lesions being left in situ, proficiency in optical diagnosis must be guaranteed before implementation. To address this, the ESGE Curricula Working Group for optical diagnosis training has comprehensively described the major training steps to achieve and maintain proficiency in optical diagnosis of diminutive colorectal polyps [1, 2]. ESGE suggests that an endoscopist is competent after attending a validated training course, including an in vivo phase, and after reaching the endorsed competence standards during real-time colonoscopy. The currently endorsed PIVI competence criteria are however impractical and difficult to implement in daily practice. Developing alternative, easy-to-measure competence criteria might facilitate the implementation of the optical diagnosis strategy in clinical practice.

Aims

With this modified Delphi procedure, the European Society of Gastrointestinal Endoscopy (ESGE) aimed to reach consensus on evidence-based competence standards for the optical diagnosis of diminutive colorectal polyps that are clinical acceptable, achievable, relevant, and easy to measure in daily practice. These standards are defined as the Simple Optical Diagnosis Accuracy (SODA) standards.

Methodology

A panel of European experts in optical diagnosis was asked to participate in a modified Delphi process to reach consensus on competence standards for the optical diagnosis of diminutive colorectal lesions (the SODA competence standards) [13–15]. This panel consisted of experts from the 2019 ESGE guideline group on advanced imaging for the detection and differentiation of colorectal neoplasia [11] and the ESGE Curriculum Working Group on optical diagnosis training [2]. During an online meeting, experts were introduced to the methodology of the Delphi procedure [13–15]. In addition, the methodology and results of a recent simulation study that provides guidance

for setting alternative competence standards for the optical diagnosis of diminutive polyps were shown [16].

During the Delphi procedure, several competence standards for the optical diagnosis of diminutive polyps were proposed to the panel. For each proposed competence standard, the potential clinical benefits and harms of implementing the optical diagnosis strategy with this standard were shown. These potential benefits and harms were based on a systematic literature review, complemented by the results of a recent simulation study [16]. Because the clinical consequences of implementing the resect-and-discard strategy and the leave-in-situ strategy for diminutive colorectal polyps are different, the results and potential competence standards were presented separately. An extensive description of the methodology and Delphi procedure can be found in the methodological framework paper [17].

SODA competence standards for implementation of the optical diagnosis strategy for diminutive colorectal polyps

Leave-in-situ strategy

RECOMMENDATION

1 In order to implement the leave-in-situ strategy for diminutive colorectal lesions (1–5 mm), it is clinically acceptable if, during real-time colonoscopy, at least 90 % sensitivity and 80 % specificity is achieved for high confidence endoscopic characterization of colorectal neoplasia of 1–5 mm in the rectosigmoid. Histopathology is used as the gold standard.

Level of agreement 95 % (14 Strongly agree; 7 Agree; 0 Neither agree nor disagree; 1 Disagree; 0 Strongly disagree).

The panel took into account a number of considerations in the development of this SODA competence standard for implementation of the leave-in-situ strategy, which are detailed in the following sections.

Potential impact on short-term consequences

To establish safe and easy-to-measure competence standards for the leave-in-situ strategy for diminutive colorectal lesions, decisions should be made on clinically acceptable short-term consequences of implementing this strategy. When applying the leave-in-situ part of the optical diagnosis strategy, not recognizing neoplastic diminutive lesions could result in neoplastic lesions being left in the rectosigmoid, whereas not recognizing non-neoplastic diminutive lesions could result in unnecessary polypectomies of non-neoplastic lesions in the rectosigmoid.

In addition, it could be argued that the correct diagnosis of each polyp subtype is not of equal clinical importance. The clinical implications of incorrectly diagnosing neoplastic lesions in the rectosigmoid (i. e. leaving in situ a neoplastic lesion) and incorrectly diagnosing non-neoplastic lesions in the rectosigmoid (i. e. performing unnecessary polypectomy of a non-neoplastic lesion) are completely different. Therefore, from a patient safety point of view, correctly diagnosing non-neoplastic lesions may not be as clinically important as correctly diagnosing neoplastic lesions. However, from a time and cost-effectiveness point of view, correctly diagnosing non-neoplastic lesions is also important. Therefore, competence standards should take both scenarios into account.

To provide guidance for setting alternative competence standards for the optical diagnosis of diminutive colorectal polyps, a recent simulation study determined the relationship between the proportion of correctly optically diagnosed diminutive polyps and the above-mentioned short-term clinical consequences (i. e. [non]neoplastic lesions that would remain in situ in the rectosigmoid and surveillance interval agreement).

SHORT DESCRIPTION OF THE SIMULATION APPROACH USED [16].

In this simulation approach, a virtual endoscopist/an artificial intelligence system performed optical diagnosis of diminutive polyps with a fixed diagnostic performance level (“strategy”) on two existing cohorts of patients who underwent colonoscopy in either a primary colonoscopy screening or fecal immunochemical test setting [18, 19]. A total of 756 strategies were defined by systematically varying the proportion of correct optical diagnoses for each polyp subtype (i. e. adenomas, sessile serrated lesions, hyperplastic polyps). For each strategy the short-term clinical consequences (i. e. surveillance interval agreements, number of [non]neoplastic lesions left in situ in the rectosigmoid) were determined using Monte Carlo Sampling with 1000 repetitions.

This simulation study showed that the proportion of correctly diagnosed diminutive polyps (i. e. adenomas, sessile serrated lesions [SSLs], hyperplastic polyps [HPPs]) could be used as easy-to-implement competence standards for the performance of optical diagnosis of diminutive polyps. However, the question remained as to what an endoscopy society would consider clinically acceptable competence standards. Different proportions of correctly diagnosed diminutive polyps lead to different clinical consequences depending on the clinical setting and the surveillance guidelines used.

► **Table 1** shows the short-term clinical consequences of implementing the leave-in-situ strategy using a range of settings for the proportion of correctly optically diagnosed adenomas and HPPs in a primary colonoscopy and fecal immunochemical test (FIT)-positive screening cohort. Results in this table are presented per 1000 individuals with at least one diminutive polyp. The impact on the number of diminutive neoplastic lesions that would remain in situ in the rectosigmoid and the number of unnecessary polypectomies that would be avoided (i. e. the number of diminutive non-neoplastic lesions that would be left in situ) is shown. For example, when, in a colonoscopy screening cohort, 90 % of all diminutive adenomas and

▶ **Table 1** Impact of implementing the leave-in-situ strategy with different proportions of correctly optically diagnosed ≤5-mm adenomas and hyperplastic polyps (HPPs) in a primary colonoscopy screening and fecal immunochemical test (FIT)-positive screening cohort on the overall proportion of correctly diagnosed ≤5-mm polyps and the number of (non-)neoplastic lesions left in situ in the rectosigmoid, with histopathology as the gold standard. Results are presented per 1000 individuals with at least one ≤5-mm polyp.

Strategy[1]		Colonoscopy screening individuals			FIT-positive screening individuals		
Correctly diagnosed ≤5-mm adenomas, %	Correctly diagnosed ≤5-mm HPPs, %	Correctly diagnosed ≤5-mm polyps, %	Neoplastic lesions of ≤5 mm left in situ, n (%)[2]	Non-neoplastic lesion of ≤5 mm left in situ, n (%)[3]	Correctly diagnosed ≤5-mm polyps, %	Neoplastic lesions of ≤5 mm left in situ, n (%)[2]	Non-neoplastic lesion of ≤5 mm left in situ, n (%)[3]
60	60	59	80 (26 %)	243 (39 %)	60	143 (26 %)	137 (39 %)
60	80	68	80 (26 %)	324 (52 %)	64	143 (26 %)	182 (52 %)
60	100	78	80 (26 %)	404 (65 %)	69	143 (26 %)	227 (65 %)
70	60	63	62 (20 %)	243 (39 %)	67	107 (20 %)	137 (39 %)
70	80	73	62 (20 %)	324 (52 %)	72	107 (20 %)	182 (52 %)
70	100	83	62 (20 %)	404 (65 %)	77	107 (20 %)	227 (65 %)
80	60	68	44 (14 %)	243 (39 %)	74	72 (14 %)	137 (39 %)
80	80	78	44 (14 %)	324 (52 %)	79	72 (14 %)	182 (52 %)
80	100	87	44 (14 %)	404 (65 %)	84	72 (14 %)	227 (65 %)
90	60	73	26 (8 %)	243 (39 %)	82	37 (8 %)	137 (39 %)
90	**80**	**82**	**26 (8 %)**	**324 (52 %)**	**87**	**37 (8 %)**	**182 (52 %)**
90	100	92	26 (8 %)	404 (65 %)	91	37 (8 %)	227 (65 %)
100	60	77	8 (2 %)	243 (39 %)	89	2 (2 %)	137 (39 %)
100	80	87	8 (2 %)	324 (52 %)	94	2 (2 %)	182 (52 %)
100	100	96	8 (2 %)	404 (65 %)	99	2 (2 %)	227 (65 %)

[1] At each given proportion of correctly diagnosed diminutive adenomas and HPPs, we assumed that 40 % of all diminutive sessile serrated lesions would be diagnosed correctly with high confidence to ensure that the clinical consequences are a reflection of daily practice.
[2] The number and proportion of all diminutive neoplastic lesions that would be left in situ in the rectosigmoid in a cohort of 1000 individuals.
[3] The proportion and number of unnecessary polypectomies that would be avoided per 1000 individuals (i. e. diminutive non-neoplastic lesions that would remain in situ).

80% of all diminutive HPPs were diagnosed correctly by optical diagnosis, 26 diminutive neoplastic lesions would remain in situ in the rectosigmoid per 1000 patients (i. e. one diminutive neoplastic lesion in every 38 patients with a diminutive lesion), representing 8 % of all diminutive neoplastic rectosigmoid lesions. In addition, 324 unnecessary polypectomies would be avoided per 1000 patients, representing a 52 % reduction in unnecessary polypectomies (i. e. diminutive non-neoplastic lesions that would be left in situ).

Table 1 s (see online-only Supplementary material) shows the impact on the number of diminutive neoplastic lesions that would remain in situ in the rectosigmoid and the number of unnecessary polypectomies that would be avoided if patients without a polyp were also included.

In addition, this simulation study showed that increasing and decreasing the proportion of high confidence diagnoses of all types of diminutive polyps by 10 % barely affected the clinical outcome (i. e. there was hardly any impact on the short-term clinical consequences). As the malignant potential of SSLs is increasingly being emphasized, in this simulation approach, the impact of correctly optically diagnosing diminutive SSLs was also assessed [21, 22]. The simulation showed that the proportion of correctly diagnosed diminutive SSLs barely affects surveillance interval agreement and the number of (non)neoplastic lesions that would remain in situ. The fact that diminutive SSLs have little relevance is likely to be because of their low prevalence. In addition, individuals often have synchronous adenomas and/or large lesions found at colonoscopy that predominantly determine the surveillance intervals. However, the influence of SSLs on surveillance and the number of SSLs that would remain in situ might expand in the future as the detection rates of SSLs are currently increasing owing to increasing awareness of these subtle lesions among endoscopists [23].

Potential impact on long-term consequences

The impact of implementing the leave-in-situ strategy on the long-term consequences, such as increase in CRC incidence, CRC mortality, and cost-effectiveness, should be considered. Two studies have evaluated the implementation of the full optical diagnosis strategy (i. e. leave-in-situ and resect-and-discard) [9, 10] (▶ **Table 2**).

Using the Adenoma and Serrated pathway to Colorectal CAncer (ASCCA) model, Vleugels et al. simulated a biennial FIT screening program, in which they compared an optical diagnosis strategy with the current strategy, submitting all diminutive polyps for histopathology assessment [9]. Implementation of an optical diagnosis strategy in a FIT-based screening program led to one CRC case, one additional CRC death in a cohort of 10 000 individuals, and a cost-saving of €6 per individual.

The National Institute for Health and Care Excellence (NICE) diagnostic guidance on "Virtual chromoendoscopy to assess colorectal polyps during colonoscopy" published in 2017 [10, 24] modelled CRC risk and economic consequences of adopting the complete optical diagnosis strategy using a range of narrowed spectrum technologies (narrow-band imaging [NBI], flexible spectral imaging color enhancement [FICE], iSCAN). Very similar lifetime risks of CRC were reported using histopathology (3.025 %) versus narrowed spectrum-based optical diagnosis (3.020 %–3.045 %) to determine surveillance intervals. NBI and iSCAN were shown to be economically dominant to histopathology in all scenario analyses. Therefore, both modelling studies demonstrate that implementing the optical diagnosis strategy (which includes the leave-in-situ strategy) only marginally influenced long-term outcomes, such as CRC incidence and mortality, whilst saving costs.

Risk of leaving in situ a diminutive lesion with advanced neoplasia

The risk of cancer in diminutive polyps is very low and estimated to be roughly 1 in 3000 [26]. However, this estimate is not evenly distributed across all populations undergoing colonoscopy. In a pooled review consisting of five FIT cohorts and seven colonoscopy cohorts, a greater prevalence of advanced histology was seen in the FIT cohorts compared with the colonoscopy cohorts across all histological subtypes, although for CRC and villous histology the differences were not statistically significant [4]. In the FIT and colonoscopy cohorts, the pooled prevalence of advanced histology within diminutive polyps was 7.1 % and 1.5 % (P = 0.04). The pooled prevalence of CRC was 0.08 % in the FIT cohorts and 0.01 % in the colonoscopy cohorts (P = 0.37). This suggests that there may be a difference in the rates of advanced histology in diminutive polyps depending on the indication for colonoscopy.

Both the progression of untreated diminutive adenomas and the incidence of newly developed lesions should be considered when evaluating the incidence of advanced neoplasia (i. e. the risk of leaving in situ a diminutive lesion with advanced neoplasia). Longitudinal follow-up data on individuals with untreated diminutive adenomas are scarce. However, in the Japanese series of Sekiguchi et al. [27], the 5-year cumulative incidence of advanced neoplasia in individuals with untreated diminutive adenomas diagnosed by magnification was 1.4 % (95 %CI 0.5 %–3.4 %). Of the 508 untreated diminutive adenomas, none of the lesions progressed to advanced neoplasia during the follow-up period, all of the detected advanced neoplastic lesions (n = 21) were newly diagnosed in a different location from that in which the untreated diminutive adenoma was originally found.

A systematic review in 2017, including three studies with 327 patients, also showed that untreated diminutive adenomas have an indolent and benign course [7]. Only 0.6 % of all adenomas (2/340) developed into advanced adenomas in 2 to 3 years. Another Japanese study, that of Ninomiya, confirmed these low numbers when using magnification [28]. In their study with 706 patients with diminutive polyps on initial colonoscopy (excluding depressed lesions and Kudo V pit pattern), only two T1 cancers were detected on surveillance colonoscopy, and both were treated radically by endoscopic resection.

Data show that polyps are not equal in terms of their cancer risk. In particular, if there is a depressed area in the polyp, this

▶ **Table 2** Overview of optical diagnosis modelling studies: base-case assumptions, increase colorectal cancer (CRC) burden, and lifetime cost-savings when implementing the optical diagnosis strategy calculated per individual.

Study	Screening program	Base-case assumptions for optical diagnosis of diminutive colorectal polyps			Cost-savings per individual	Increased lifetime risk of CRC	Increased lifetime mortality risk from CRC
		Sensitivity for neoplastic lesions	Sensitivity for non-neoplastic lesions	High confidence predictions			
Vleugels et al. [9]	FIT screening	92 % adenomas; 91 % SSLs	88 %	76 %	€6	0.00466 %	0.00141 %
NICE (2017) Picot et al. [10, 24]	FIT screening	NBI 91 %; FICE 81.4 %; iSCAN 96.2 %	NBI 81.9 %; FICE 85.0 %; iSCAN 90.6 %	78.6 %	NBI £6.11; FICE £887.70; iSCAN £8.49	NBI 0.005 %; FICE 0.02 %; iSCAN 0.004 %	NR
Kessler et al.[1] [25]	Primary colonoscopy	90 %	90 %	100 %	$174	0.0076 %[2]	
Hassan et al.[1] [8]	Primary colonoscopy	94 %	89 %	83 %	$25	NR	NR

SSL, sessile serrated lesion; NICE, National Institute for Health and Care Excellence; FICE, flexible spectral imaging color enhancement; NBI, narrow-band imaging; NR, not reported.
[1] Modelling studies that only incorporated the resect-and-discard part of the optical diagnosis strategy.
[2] Missed CRCs.

substantially increases the risk that there might be a malignant component. Given the negligible risk that diminutive polyps harbor cancer, few data are available on this matter. Recently Oka et al. [29] presented a large study, in which the risk of submucosal invasion of diminutive adenomas was 0.19% (15/7801). Of these 15 lesions, 11 had a depressed area and only 0.01% of non-depressed diminutive adenomas (1/7687) had deep submucosal invasion. Therefore, if depressed adenomas were excluded from the leave-in-situ strategy, the risk of leaving in situ a cancerous lesion would be greatly reduced. Because of the higher prevalence of advanced histology that has been described, the panel encourages increased detection of non-polypoid and depressed lesions. These lesions should be resected and referred to the pathologist.

Pathological accuracy and reproducibility

Despite histology being the reference standard for differentiating between polyp subtypes, it is also hampered by some degree of misdiagnosis owing to error in sampling or retrieval, or pathology diagnosis [30–32]. Therefore, a 10% error rate in the pathological discrimination between polyp subtypes may be assumed unless an enhanced reference standard is used, such as specialist review from multiple pathologists combined with cutting all available tissue. When replacing a pathological with an endoscopic diagnosis, it is preferable that this error rate should not be increased; most studies however have not used an enhanced reference standard.

Furthermore, as a starting point, most studies assume that every polyp is retrieved and available for histological analysis. However, even at expert centers, up to 10% of polyps may be lost or destroyed after resection. The standard approach to lost or destroyed polyps is to assume that these are adenomas; however, reanalysis from the original DISCARD study suggests that, when taking this issue into account, the lower accuracy of optical diagnosis (versus a non-enhanced pathological reference standard) is balanced by the loss of polyps available for pathological diagnosis that have to be (over)called as adenomas. Therefore, in clinical practice, optical diagnosis and pathology may have similar accuracy on a "per polyp detected" basis [33].

Attitudes of endoscopists and patients with regards to a leave-in-situ strategy

Willems et al. performed an international survey among 808 endoscopists from nine endoscopy societies to evaluate their attitudes and practices with regards to a leave-in-situ strategy [34] In total, 63% of the participants partly or completely agreed that diminutive polyps could be left unresected until the next screening colonoscopy because of the low associated cancer risk. Endoscopists were evenly split on the effects of leaving such polyps unresected, with about 50% thinking that leaving diminutive polyps in place would increase the cancer risk of patients. Moreover, 52% of endoscopists were already leaving diminutive polyps that appeared non-neoplastic in situ in their daily practice. These results are somewhat different from a survey by Gellad et al. in 2013, which reported that the majority of endoscopists would be somewhat agreeable to leaving diminutive polyps in place if guidelines were to support this practice [35].

Little is known regarding whether patients would accept a leave-in-situ strategy. The only evidence comes from von Renteln et al. who performed a study among 557 patients to investigate the valuable question of whether patients would find a leave-in-situ practice acceptable [36]. They found that approximately 50% of individuals undergoing a routine colonoscopy would be agreeable to deferring resection of diminutive polyps until the next surveillance colonoscopy and participating in a trial to evaluate this approach.

Resect-and-discard strategy

RECOMMENDATION

2 In order to implement the resect-and-discard strategy for colorectal lesions of 1–5 mm, it is clinically acceptable if, during real-time colonoscopy, at least 80% sensitivity and 80% specificity is achieved for high confidence endoscopic characterization of colorectal neoplasia of 1–5 mm. Histopathology is used as the gold standard.
Level of agreement 100% (17 Strongly agree; 5 Agree; 0 Neither agree nor disagree; 0 Disagree; 0 Strongly disagree).

The panel took into account a number of considerations in the development of this SODA competence standard for implementation of the resect-and-discard strategy, which are detailed in the following sections.

Potential impact on short-term consequences

When applying the resect-and-discard part of the optical diagnosis strategy, not recognizing neoplastic diminutive lesions could result in longer than appropriate surveillance intervals, whereas not recognizing non-neoplastic diminutive lesions could result in shorter than appropriate surveillance intervals. Again, it could be argued that the correct diagnosis of each polyp subtype is not of equal clinical importance. The clinical implications of incorrectly diagnosing neoplastic lesions (i.e. a longer surveillance interval) and incorrectly diagnosing non-neoplastic lesions (i.e. a shorter surveillance interval) are completely different. Therefore, competence standards should take both scenarios into account.

The aforementioned simulation study also determined the relationship between the proportion of correctly optically diagnosed diminutive polyps (adenomas and HPPs) and the surveillance interval agreement when implementing the resect-and-discard strategy in a primary colonoscopy and FIT-positive screening cohort (▶ **Table 3**; **Tables 2s** and **3s**). Results in the tables are presented per 1000 individuals with at least one diminutive polyp. The impact on surveillance interval agreement is indicated by showing the proportion in agreement with the US Multi-Society Task Force on Colorectal Cancer surveillance guideline [37] and the proportion in agreement with the ESGE surveillance guideline [38]. For example, if 80% of all diminu-

tive adenomas and 80 % of all diminutive HPPs were to be diagnosed correctly with optical diagnosis in the primary colonoscopy screening program (i. e. 78 % of all diminutive polyps correctly diagnosed), the proposed surveillance intervals would agree with those determined by histological analysis for 80 % of the cases when using the US guideline and for 95 % of the cases when using the ESGE guideline.

▶ **Fig. 1** shows the impact of implementing the resect-and-discard strategy for colorectal lesions of 1–5 mm with 80 % sensitivity and 80 % specificity for high confidence endoscopic characterization of 1–5 mm colorectal neoplasia on surveillance interval agreements. Different thresholds for the proportion of correctly diagnosed diminutive polyps again lead to different proportions in agreement with the surveillance guidelines depending on the guidelines and the clinical setting.

Potential impact on long-term consequences

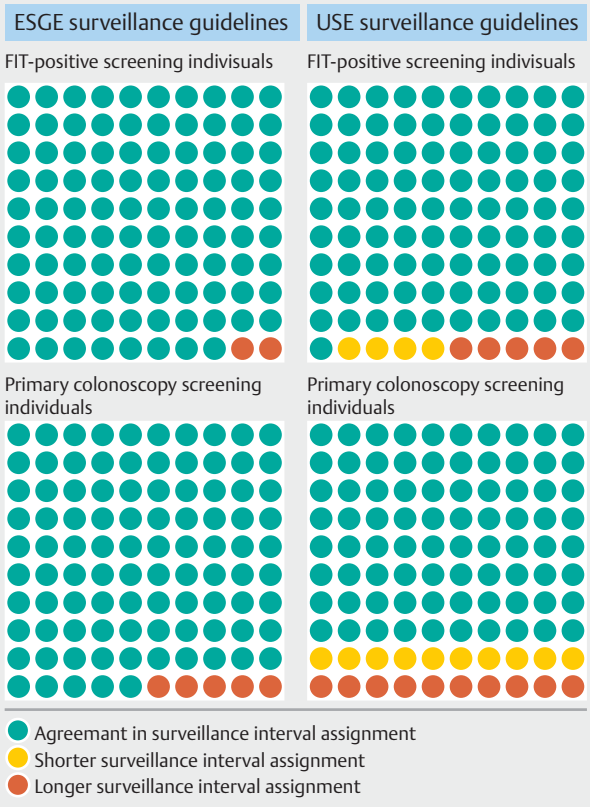
Data on the long-term clinical consequences and cost-effectiveness of implementing the resect-and-discard strategy are limited to four modelling studies (▶ **Table 2**). Two of these evaluated the implementation of the complete optical diagnosis strategy and demonstrated that implementation only marginally influenced long-term outcomes, such as CRC incidence and mortality, whilst saving costs [1, 9, 33]. Two studies exclusively evaluated the implementation of the resect-and-discard strategy [8, 25]. In the modelling study by Kessler et al. [25], the estimated cost-savings of implementing the resect-and-discard strategy in a primary colonoscopy setting was $174 per individual, with a number needed to harm because of missed interval cancer of 7979. In the modelling study by Hassan et al., adoption of the resect-and-discard strategy in a primary colonoscopy screening program resulted in a saving of $25 per individual, without any meaningful effect on screening efficacy [8]. In summary, the modelling studies described above have provided evidence that implementation of the optical diagnosis strategy is associated with substantial cost-savings with negligible impact on patients' cancer risk.

Data on the impact of varying the rate of high confidence diagnosis on long-term clinical consequences are limited to two modelling studies. These studies showed that varying the proportion of high confidence diagnoses did not increase the CRC burden [8, 9]. They demonstrate that the cost-effective-

▶ **Table 3** Impact of implementing the resect and-discard strategy with different proportions of correctly optically diagnosed ≤5-mm adenomas and hyperplastic polyps (HPPs) in a primary colonoscopy screening and fecal immunochemical test (FIT)-positive cohort on the overall proportion of correctly diagnosed ≤5-mm polyps and surveillance interval agreement with histopathology as the gold standard.
Results are presented per 1000 individuals with at least one ≤5-mm polyp.

Strategy*		Colonoscopy screening individuals			FIT-positive screening individuals		
Correctly diagnosed ≤5-mm adenomas, %	Correctly diagnosed ≤5-mm HPPs, %	Correctly diagnosed ≤5-mm polyps, %	Surveillance interval agreement, %		Correctly diagnosed ≤5-mm polyps, %	Surveillance interval agreement, %	
			ESGE	US		ESGE	US
60	60	60	95	66	60	97	84
60	80	68	95	73	64	97	86
60	100	78	95	80	69	97	88
70	60	63	95	69	67	98	87
70	80	73	95	76	72	98	89
70	100	83	95	84	77	98	91
80	60	68	95	73	74	98	90
80	**80**	**78**	**95**	**80**	**79**	**98**	**91**
80	100	87	95	88	84	98	93
90	60	73	95	76	82	99	92
90	80	82	96	83	87	99	94
90	100	92	96	92	91	99	96
100	60	77	96	79	89	99	94
100	80	87	96	87	94	100	97
100	100	96	96	96	99	100	99

ESGE, European Society of Gastrointestinal Endoscopy (ESGE) post-polypectomy surveillance guidelines; US, US Multi-Society Task Force on Colorectal Cancer guidelines.
* At each given proportion of correctly diagnosed diminutive adenomas and HPPs, we assumed that 40 % of all diminutive sessile serrated lesions would be diagnosed correctly with high confidence to ensure that the clinical consequences are a reflection of daily practice.



▶ **Fig. 1** Impact of implementing the resect-and-discard strategy for colorectal lesions of 1–5 mm with 80 % sensitivity and 80 % specificity for high confidence endoscopic characterization of 1–5 mm colorectal neoplasia on surveillance interval agreement using the ESGE surveillance guideline [38] and US Multi-Society Task Force on Colorectal Cancer surveillance guideline [37].
Histopathology is used as the gold standard. Results are presented per 100 individuals.

ness of the optical diagnosis strategy appears to be dependent on the proportion of high confidence diagnoses [39]. Hassan et al. showed a linear relationship between the rate of high confidence prediction and the undiscounted savings projected in the US population, when implementing the optical diagnosis strategy in a colonoscopy screening program [8]. Assuming a 100 % (best-case scenario) and 50 % (worst-case scenario) proportion of high confidence diagnoses, the undiscounted benefit for the US population would be $40 million and $20 million, respectively. In another simulation study, varying the proportion of high confidence diagnoses from 50 % to 100 % led to cost-savings of €5 and €7, respectively, per individual in a biennial FIT screening program [9].

Risk of metastatic disease after resecting and discarding a diminutive lesion with cancer

The risk of metastatic disease after resecting and discarding a diminutive polyp in situ that contained cancer is very limited. In the study of Oka et al. [29], for seven diminutive invasive polyp cancers that were treated surgically, no lymph node metastases were seen.

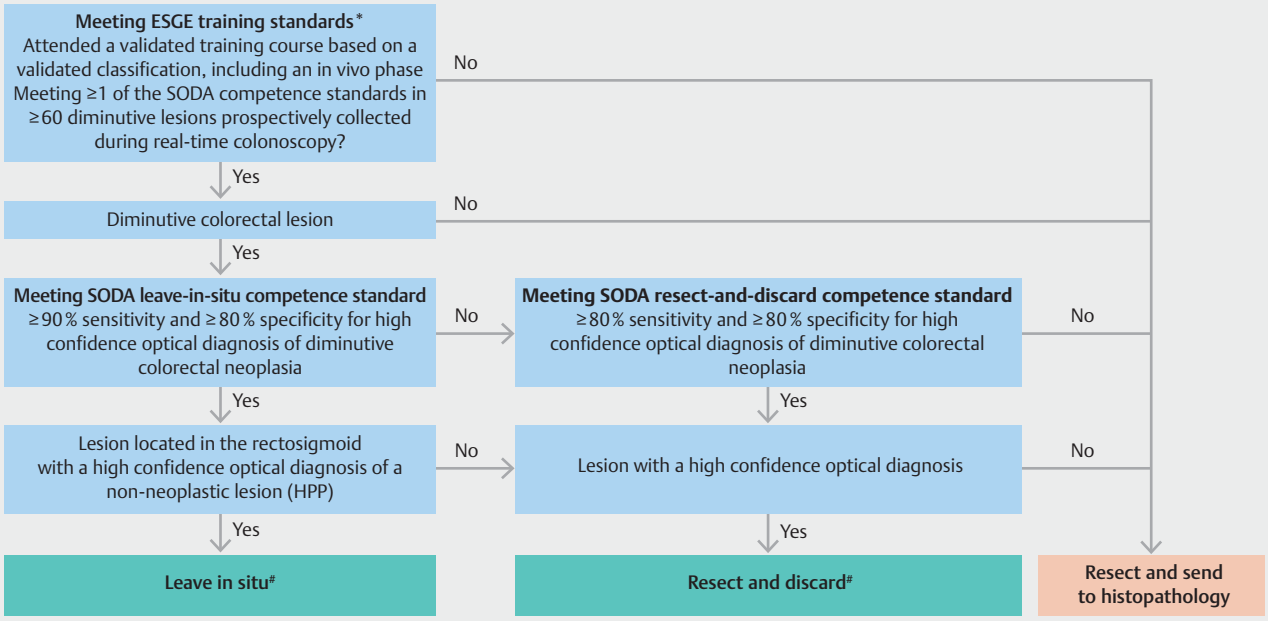
Attitudes of endoscopists and patients with regards to a resect-and-discard strategy

When Willems et al. asked endoscopists in their worldwide survey about barriers to implementation of a resect-and-discard strategy, it appears the clinical uptake of resect-and-discard is low [34]. They found that only 15.8 % of the endoscopists used the resect-and-discard strategy in their current practice and 59.9 % thought that implementation of the resect-and-discard strategy was not feasible in its current form. Of all endoscopists, 44.6 % were afraid of making a wrong diagnosis, 53.8 % were concerned about potential medicolegal issues, and 58.3 % were afraid of assigning incorrect surveillance intervals to patients. These findings are similar to those of Soudagar et al. in 2016, where medicolegal concerns were the main barrier to implementation of the resect-and-discard strategy for the 105 gastroenterologists surveyed during a national conference in the USA [40]. While the consensus for most regions was that resect-and-discard was not feasible, 54 % of the European endoscopists showed an increased adoption of the strategy.

Rex et al. surveyed American colonoscopy patients and found that 66 % of them would accept a resect-and-discard strategy [26]. Of those unwilling to accept resect-and-discard, 50 % wanted an absolute zero chance of cancer in diminutive polyps and were willing to pay out of their own pocket for histological assessment of these diminutive polyps. Vu et al. further assessed this by approaching patients with the hypothetical question of whether they would be willing to pay approximately $150 for pathology rather than use the resect-and-discard strategy if the risk of a cancer in their polyp was 1 : 3000 [41]. Over two-thirds of patients would be willing to pay to have their diminutive polyp sent for pathological evaluation.

Conclusion and future prospects

This ESGE Position Statement provides new competence standards for the optical diagnosis of diminutive colorectal polyps that are clinically acceptable, achievable, and easy to measure in daily practice (SODA standards). ▶ **Fig. 2** provides a flowchart of the application of the optical diagnosis strategy using the SODA competency standards for diminutive colorectal polyps. The development of these standards is based on the currently available evidence and a Delphi-based consensus process undertaken by a designated ESGE task force. These new standards facilitate implementation of the optical diagnosis strategy in daily practice. However, an accreditation and monitoring scheme should be set up to assess competence and audit performance. In addition, these new clinically based standards clearly define diagnostic performance thresholds for optical diagnosis of diminutive polyps by artificial intelligence systems in relation to the clinical actions and consequences.



▶ **Fig. 2** Flowchart of the application of the optical diagnosis strategy using the Simple Optical Diagnosis Accuracy (SODA) competence standards for diminutive colorectal polyps (derived from Wang and East [33]). HPP, hyperplastic polyp. * Derived from Dekker et al. [2]. # The resect-and-discard and leave-in-situ strategies should only be applied in "average risk patients." The term "average risk patients" refers to patients undergoing screening colonoscopy who do not have colitis or a hereditary syndrome. This is derived from the 2019 ESGE Advanced Imaging Guideline [11].

Disclaimer

ESGE Guidelines and Position Statements represent a consensus of best practice based on the available evidence at the time of preparation. They might not apply in all situations and should be interpreted in the light of specific clinical situations and resource availability. Further controlled clinical studies may be needed to clarify aspects of these statements, and revision may be necessary as new data appear. Clinical considerations may justify a course of action at variance with these recommendations. ESGE Guidelines and Position Statements are intended to be an educational device providing information that may assist endoscopists in providing care to patients. They are not rules and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment.

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Competing interests

R. Bisschops has received research support from Cook and Medtronic, and financial support for symposium organization from Cook, Boston Scientific, Olympus, and Erbe (2009–2109), and speakers' fees from Boston Scientific and Medtronic (2009–2019). E. Coron has received speaker's fees from Fujifilm (2018–2020). E. Dekker has received speaker's fees from Roche (2018), Norgine (2019), Olympus and GI Supply (both 2019 to 2020), and Fujifilm (2020), and has provided consultancy to Fujifilm (2018), CPP-FAP (2019), GI Supply (2019 to 2020), Olympus (2020 to present), PAION and Ambu (both 2021); she received a research grant from Fujifilm (2017 to 2020) and her department has equipment on loan from Fujifilm (2017 to present) and Olympus (2021). M. Dinis-Ribeiro receives an educational grant from Olympus (2020 to present) and a research grant from Fujifilm (2020 to present); he is co-editor in-chief of *Endoscopy*. J.E. East has provided consultancy to, and holds share options in, Satisfai Health (2020 to present). C. Hassan has received research support from Fujifilm (2017 to present); his department has received support from Sonoscape. M. Iacucci receives research support from Pentax (2011 to present), Olympus (2017 to present) and Fujifilm (2018 to present). Y. Mori receives consultancy and speaker's fees from Olympus (2018 to present) and has an ownership interest in Cybernet System Corp. (2020 to present). H. Neumann has provided consultancy to Fujifilm, Sonoscope, and Boston Scientific (all 2019 to 2020). M. Pellisé has received consultancy and speaker's fees from Norgine Iberia (2015 to 2020), a consultancy fee from GI Supply (2019), speaker's fees from Casen Recordati (2016 to 2019), Olympus (2018), and Jansen (2018), and research funding from Fujifilm Spain (2019), Fujifilm Europe (2020), and Casen Recordati (2020); her department has received loan material from Fujifilm Spain (2017 to present), a research grant from Olympus Europe (2005 to 2019), and loan material and a research grant from Fujifilm Europe (2020 to 2021); she is a Board member of ESGE and SEED, and is a co-editor of *Endoscopy* (2015 to 2021). I. Puig has provided advisory services to Fujifilm (2020 to present) and has equipment on loan from Olympus and Fujifilm (both 2019 to present). B. Saunders receives research funding from Olympus (2019 to present). D.J. Tate received an educational grant from Olympus (2018 to 2019). G. Antonelli, M. Bustamante-Balén, G. Cortas, V.M.H. Coupé, D.E. Dobru, M.J.E. Greuter, Y. Hazewinkel, B.B.S.L. Houwen, R. Jover, R. Kuvaev, G. Longcroft-Wheaton, M.D. Rutter, and J.L.A. Vleugels declare that they have no conflict of interest.

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