

Endoscopic diagnosis and treatment of gastric dysplasia and early cancer: Current evidence and what the future may hold

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Abstract

Gastric cancer accounts for a significant proportion of worldwide cancer-related morbidity and mortality. The well documented precancerous cascade provides an opportunity for clinicians to detect and treat gastric cancers at an endoscopically curable stage. In high prevalence regions such as Japan and Korea, this has led to the implementation of population screening programs. However, guidelines remain ambiguous in lower prevalence regions. In recent years, there have been many advances in the endoscopic diagnosis and treatment of early gastric cancer and precancerous lesions. More advanced endoscopic imaging has led to improved detection and characterization of gastric lesions as well as superior accuracy for delineation of margins prior to resection. In addition, promising early data on artificial intelligence in gastroscopy suggests a future role for this technology in maximizing the yield of advanced endoscopic imaging. Data on endoscopic resection (ER) are particularly robust in Japan and Korea, with high rates of curative ER and markedly reduced procedural morbidity. However, there is a shortage of data in other regions to support the applicability of protocols from these high prevalence countries. Future advances in endoscopic therapeutics will likely lead to further expansion of the current indications for ER, as both technology and proceduralist expertise continue to grow.

Key Words: Gastric cancer; Endoscopy; Endoscopic imaging; Endoscopic mucosal resection; Endoscopic submucosal dissection

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Core Tip: There have been numerous recent advances in the endoscopic detection, characterization and treatment of precancerous gastric lesions and early gastric cancers. Accumulating evidence suggests that endoscopic submucosal dissection results in at least equivalent disease-related outcomes with a marked reduction in morbidity compared to gastrectomy. Supportive data are robust in regions with high gastric cancer prevalence, however a paucity of western data results in inconsistencies in clinical practice in these regions. This article serves to review existing evidence regarding endoscopic imaging and therapeutics in gastric cancer, as well as identify future areas for research and development.

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INTRODUCTION

Gastric cancer remains a leading cause of cancer-related morbidity and mortality, accounting for 780000 deaths and more than 1 million new diagnoses worldwide in 2020 alone[1,2]. Conventional surgical management with gastrectomy is associated with significant morbidity and mortality[3]. Countries with a high prevalence of gastric cancer have implemented systematic screening programs and demonstrated the benefit of early detection and endoscopic resection (ER) of precancerous gastric lesions and early gastric cancers (EGCs), offering curative treatment with considerably less morbidity[4,5]. Future challenges and opportunities remain, including the judicious surveillance of gastric metaplasia in lower prevalence communities, utilising improvements in endoscopic imaging and further refining existing ER techniques, while at all times accumulating high-quality collaborative data sets to inform and shape future management algorithms.

ENDOSCOPIC DIAGNOSIS OF GASTRIC NEOPLASIA

Endoscopic gastric cancer screening

Rates of gastric cancer in Eastern Asia (particularly Japan and Korea) are markedly higher than Western regions, which has resulted in implementation of population screening programs as an evidence based, cost effective measure for preventing gastric cancer-related mortality and morbidity[4-6]. Screening programs facilitate the detection of precancerous lesions and EGCs at an endoscopically resectable stage. Japanese guidelines suggest biennial or triennial endoscopic screening for those over the age of 50. This approach could prevent up to 63% of gastric cancer related mortality, resulting in 27.2 quality-adjusted life years gained *per* 1000 individuals[4]. In Korea, guidelines similarly suggest biennial screening but commencing at age 40. This is supported by data showing a 38% reduction in age-standardised mortality rate in the screening group at large, at a cost of less than the average gross expenditure product *per* capita[5].

In Western regions including North America and Australasia, the age-standardised incidence of gastric cancer is 6.5-8.8 *per* 100000 population, four-times lower than East Asia[6]. The lower incidence may be attributable to a combination of reduced *Helicobacter pylori* prevalence as well as environmental, lifestyle (diet, smoking) and genetic factors[6]. Given this comparatively low gastric cancer incidence, Western countries are yet to adopt population screening. Instead, guidelines in these regions are varied. The American Gastroenterology Association does not recommend population screening, only surveillance for patients with gastric intestinal metaplasia (GIM), while the British Society of Gastroenterology (BSG) recommends endoscopic screening in patients with multiple risk factors for gastric cancer (male, smoker, pernicious anaemia, family history in first degree relative), citing low-grade evidence[7,8]. Unsurprisingly, low disease prevalence combined with variable guidelines leads to

inconsistencies in clinical practice, as demonstrated in a 2016 survey of American endoscopists[9]. An additional challenge in these low prevalence regions is the management of individuals who have migrated from areas where gastric cancer incidence is high, as data show persistently elevated gastric cancer risk for at least two generations, yet the infrastructure and guidelines in terms of screening are not established[10,11]. These factors would undoubtedly contribute to the discrepancy in gastric cancer survival between Western and East Asian regions, highlighting the need for additional research in these populations[12].

Progression of precancerous gastric lesions

Gastric cancer develops through a well-established precancerous cascade: From atrophic gastritis (AG) to GIM, low-grade dysplasia (LGD), high-grade dysplasia (HGD) and eventually carcinoma, with the likelihood of progression increasing as this cascade advances[13]. Although eradication of *Helicobacter Pylori* has been clearly demonstrated to reduce rates of development of this precancerous cascade, data have been more variable regarding prevention of progression from GIM, implying a 'point of no return' in the gastric cancer cascade[14-16]. These observations underpin the utility of screening and surveillance endoscopy, providing the opportunity to identify and treat curable lesions. In order to maximise yield, guidelines also suggest routine 'mapping' biopsies according to the updated Sydney protocol (including two biopsies taken from the antrum and one from each of the incisura, lesser curve and greater curve) in addition to biopsies of any suspicious areas during surveillance endoscopy, which results in improved AG and GIM detection compared to non-systematic biopsies[8,17].

Japanese data suggests an overall 5-year cumulative gastric cancer incidence of 1.9%-10% in AG and 5.3%-9.8% in GIM[18]. The Operative Link on Gastritis/Intestinal Metaplasia Assessment (OLGIM) scoring system further assists in differentiating between degrees of AG and GIM with regard to gastric cancer risk[19]. Those with high-risk lesions meeting OLGIM stage III/IV have an odds ratio for gastric cancer of 2.41 and 3.99 respectively[20]. Accordingly, guidelines suggest that patients with OLGIM stage III/IV AG or with GIM have 3-yearly surveillance endoscopy or 1- to 2-yearly endoscopy in the presence of a family history of gastric cancer[21]. Although these scoring systems are consistently reported in high-prevalence regions, the limited experience in lower prevalence regions again results in inconsistencies, as pathologists rarely report according to OLGIM staging and thus endoscopist adherence to GIM surveillance guidelines is variable[9].

In the context of biopsy-detected LGD and HGD, the risks of progression to gastric cancer are reportedly between 2.8%-11.5% and 10%-68.8% respectively; therefore guidelines suggest endoscopic removal of any defined lesion with dysplasia[22-26]. Importantly, lesions are also frequently upgraded histologically once endoscopically resected. In a 2015 study, 25% of lesions initially diagnosed as LGD were upgraded after ER; 16.7% to HGD and 6.9% to carcinoma[27]. Accordingly, gastric lesions with any degree of biopsy proven dysplasia should be regarded as potentially housing adenocarcinoma.

Endoscopic imaging techniques

The endoscopic detection and characterisation of EGCs and precancerous lesions is therefore critical in establishing cancer risk and directing appropriate treatment and surveillance. Consensus guidelines from the BSG and the Japanese Gastroenterological Endoscopy Society (JGES) define endoscopic standards to maximise detection of gastric mucosal lesions, including a minimum 7 min gastric examination time, as well as adequate mucosal visualisation using sufficient air insufflation, mucosal cleaning techniques (mucolytic and defoaming agents) and consideration of peristalsis inhibiting medications if views are obstructed by movement[28,29]. While a consensus has not yet been reached regarding the role of advanced endoscopic imaging techniques, a number of recent advances in endoscopic imaging have demonstrated higher detection rates and more accurate characterisation of mucosal lesions.

White light endoscopy: White light endoscopy (WLE) is the conventional endoscopic imaging modality. It is sufficient for detecting some features of carcinomatous transformation of gastric lesions, including red discolouration of the mucosal surface, depressed-type lesions and mucosal ulceration[30,31]. However, the sensitivity for WLE in detecting GIM, LGD/HGD and EGC has been reported to be as low as 29%-59.1%, 51%-74% and 48%-72% respectively[32-36]. As a result, more advanced endoscopic imaging techniques are now used for lesion detection and characterisation.

Chromoendoscopy: Traditional chromoendoscopy requires the topical application of stains or dyes (usually methylene blue, indigo carmine and/or acetic acid) in an effort to enhance tissue characterisation[37,38]. Studies have demonstrated the superiority of chromoendoscopy in the detection of EGCs and precancerous gastric lesions, with a 2016 meta-analysis demonstrating pooled sensitivity of 90% and specificity of 82% [38]. However, the requirement for local dye application has limited its use in the context of the wide field required for gastric lesion detection, particularly following the development of virtual chromoendoscopy.

Narrow-band imaging: Narrow-band imaging (NBI) is the most commonly used form of virtual chromoendoscopy; utilising a rotating optical interference filter to restrict incident light into two narrow bands of different wavelengths (Figure 1). This enhances the definition of the surface mucosa, while emphasising the contrast of the vascular network[39]. NBI is superior to WLE in detection of early precancerous gastric lesions, with pooled sensitivity of 69% and specificity of 91% for GIM[40]. Prospective trials have demonstrated a 40% increase in detection of all focal gastric lesions and more than twice the detection rates for GIM using NBI compared to WLE [32,41].

High-magnification NBI: High-magnification endoscopy (Figure 2) uses a movable lens in the tip of the endoscope to allow up to 150 times optical zoom without any degradation of image quality[42]. This is usually combined with the use of a translucent cap to stabilize the focal length between the lens and the target tissue, as well as near-focus imaging that allows the endoscope to be positioned closer to the mucosal surface[42]. High-magnification endoscopy has been combined with NBI (ME-NBI) to facilitate detailed assessment of the mucosa and enhance lesion detection and characterisation.

Uedo *et al*[42] first described the 'light blue crest' seen on ME-NBI (Figure 2) which has been demonstrated to detect GIM with a sensitivity of 80%-89% and a specificity of 93%-96% [36,43,44]. In regard to characterisation of dysplasia, a prospective multicentre study in 2016 showed an improvement in sensitivity from 74% to 92% with the use of ME-NBI over WLE[36]. Detailed assessment of surface microvascular patterns on polypoid lesions using ME-NBI results in sensitivity of up to 86.2% and specificity of up to 97% for the presence of dysplasia[45].

In the assessment of EGCs, there have been a number of classification systems using ME-NBI. Yao *et al*[45] first described the 'VS' system in 2008, which has a sensitivity of 86%-97% for EGCs[46-49]. This system requires detailed assessment of the microvascular and surface mucosal pattern to ascertain features of irregularity, which in the presence of a demarcation line is suggestive of carcinoma[46]. The VS classification was further simplified by Yamada *et al*[49] in 2014, who demonstrated that the presence of a demarcation line with an irregular microvascular pattern was 95% sensitive and 96% specific for EGC[49].

The accuracy of ME-NBE was confirmed in a 2015 meta-analysis of a combined 2171 patients, demonstrating 86% sensitivity and 96% specificity for the diagnosis of EGC [50,51]. Direct comparator studies of ME-NBI *vs* WLE have also shown up to twice the rate of EGC detection with ME-NBI[52-54].

In addition, ME-NBI is valuable in determining tumour margins at the time of ER, resulting in 97.4%-98.1% accuracy of endoscopic markings[55-57]. Comparator studies have demonstrated the superior precision of ME-NBI *vs* chromoendoscopy in this context, with 17%-20% higher rates of accurate endoscopic markings[55,57]. The use of ME-NBI is also beneficial when lesion margins are unclear on chromoendoscopy, as demonstrated by Nagahama *et al*[57] who found that 72.6% of lesions with an unclear margin on chromoendoscopy were able to be clearly delineated using ME-NBI[57].

Blue laser imaging: Blue laser imaging (BLI) uses laser to create a highly narrowed blue band, enhancing vascular structures without using a filter as is required for NBI, thereby resulting in a higher light intensity[58,59]. There is a paucity of evidence regarding BLI in comparison to other endoscopic imaging, however recent studies have demonstrated superior sensitivity (93%-94%) in detection of EGCs compared to WLE (46%-50%)[60,61]. While direct comparator studies are limited, Kaneko *et al*[61] compared BLI and NBI in 39 patients with gastrointestinal neoplasia and found that BLI maintained sufficient brightness and contrast up to 40 mm while NBI deteriorated beyond 20 mm. This could be of relevance in detection of EGCs where endoscopists may benefit from increased field of view, however further studies in this area are required.

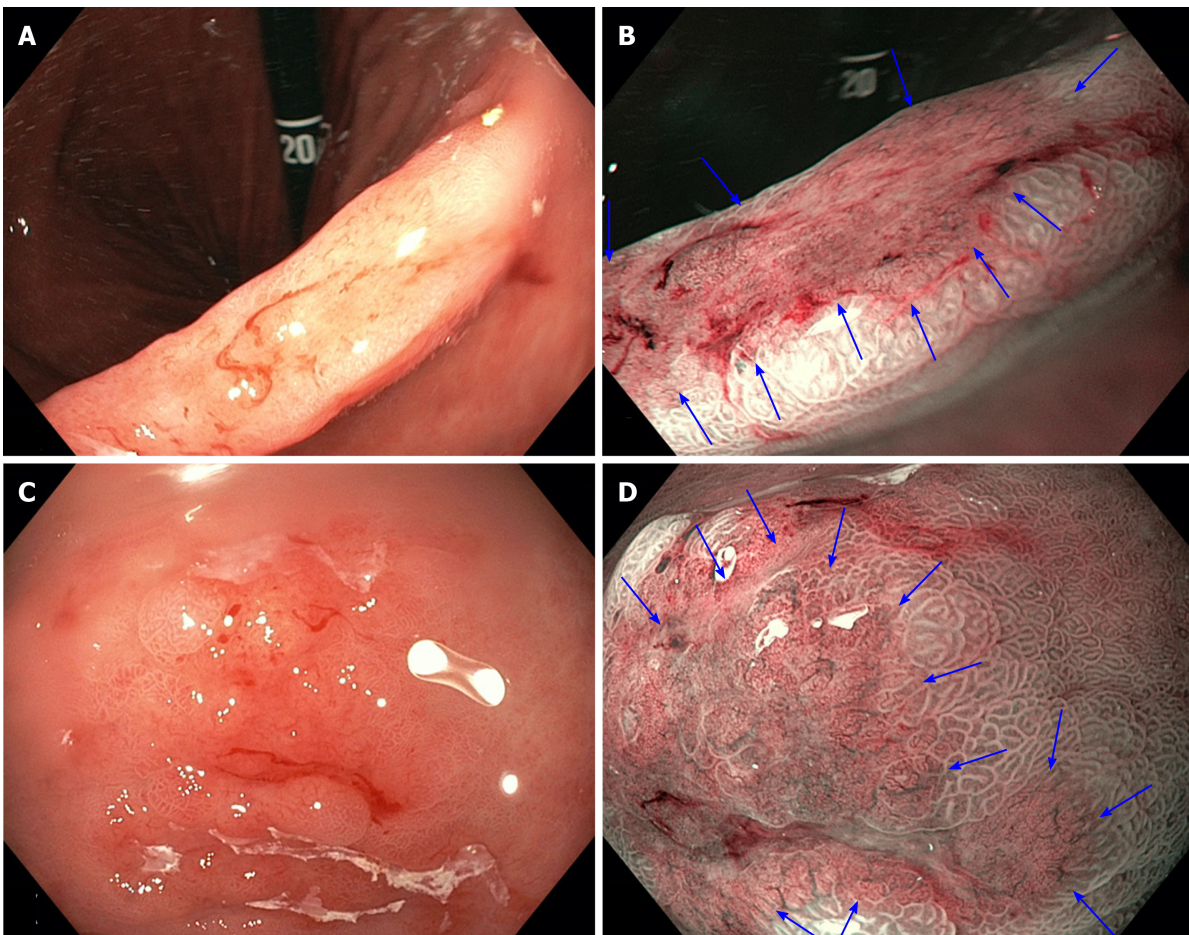


Figure 1 White light endoscopy compared to narrow-band imaging in gastric lesions, demonstrating clear demarcation lines and irregular microvascular/microsurface patterns on narrow-band imaging. A: Early gastric cancer at the incisura seen on white light endoscopy (WLE); B: The same lesion seen on narrow-band imaging (NBI) (blue arrows); C: Early gastric cancer in the antrum seen on WLE; D: The same lesion seen on NBI (blue arrows).

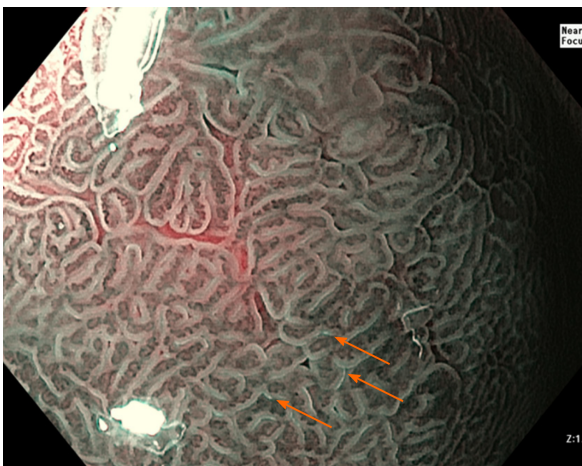


Figure 2 Narrow-band imaging demonstrating the 'light blue crest' (orange arrows) consistent with intestinal metaplasia.

Confocal laser endomicroscopy: Confocal laser endomicroscopy (CLE) uses a low-power laser to illuminate tissue, detecting reflected fluorescent light and allowing high-resolution endoscopic histological assessment[62,63]. CLE was first assessed in precancerous gastric lesions by Guo *et al*[63] who reported sensitivity and specificity of 98% and 95% for the detection of GIM[63]. A more recent meta-analysis demonstrated the accuracy of CLE for the diagnosis of all stages of precancerous gastric lesions and

EGCs, with pooled sensitivity of 92% for GIM, 81% for LGD/HGD and 91% for EGC [64,65]. However, its use is limited by the equipment required (either a dedicated endoscopic system or a probe-based system inserted *via* the therapeutic channel), the time required for image acquisition, as well as the learning curve of image interpretation[63].

Future prospects

Artificial intelligence (AI) has demonstrated efficacy in detection and classification of multiple gastrointestinal lesions[66]. Real-time AI gastric lesion detection has not yet been studied, however convolutional neural networks have been generated from endoscopic images with a sensitivity of 92% using WLE and 97% using ME-NBI[67-69]. This could be of particular benefit for improving lesion detection and characterisation for endoscopists without expertise in advanced imaging interpretation.

Texture and colour enhancement imaging (TXI) is a recently developed technology aiming to improve lesion detection by enhancing texture, brightness and colour tone (Figure 3) using stacked images, while maintaining a similar colour spectrum to WLE [70]. By improving lesion detection within WLE, TXI may facilitate superior detection rates during endoscopic screening, although studies are required to investigate this.

Whilst WLE remains the mainstay for the majority of endoscopists, accumulating evidence as presented above points to a significant additive benefit in repeat interrogation of suspicious areas with chromoendoscopy. The trade-off between time, cost, availability and feasibility means that most proceduralists employ virtual chromoendoscopy with ME-NBI.

Assessment of invasion depth and nodal metastases

Endoscopic ultrasound: While computed tomography (CT) and positron emission tomography/CT are endorsed by guidelines for the assessment of distant metastases and locally advanced gastric cancers, endoscopic ultrasound (EUS) has been recommended for EGCs, in particular for distinction of T1 and T2 lesions[71]. However, data on the utility of EUS in assessment of EGC depth of invasion have been varied. Han *et al*[72] reported under-staging in 16.7% of T2 gastric cancers with EUS, and Choi *et al*[71] reported no advantage of EUS over conventional endoscopic assessment using surface nodularity and fold convergence[71]. In comparison, Mouri *et al*[73] reported that lesions classified by EUS as being intramucosal or submucosal border lesions were histologically either intramucosal or invading < 500 µm into the submucosal space (SM1) in 99% and 87% of cases[73]. A 2015 Cochrane review also demonstrated 87% sensitivity for submucosal invasion[74,75]. Regarding specific EUS characteristics, Kim *et al*[76] reported that an arch-shaped submucosal deformity on EUS was associated with a negative predictive value for SM2 (> 500 µm submucosal invasion) or greater of 94.4%, with a sensitivity and specificity of 84% and 83%[76]. More recently, EUS miniature probes have been demonstrated to have higher resolution but less penetration compared to conventional EUS[77]. Miniature probes have demonstrated superiority for assessment of submucosal invasion, with an overall accuracy of 84.5% *vs* 61.6% using conventional EUS when assessing lesions less than 2 cm in diameter without endoscopic features of submucosal invasion[78]. While the role of conventional EUS in the confirmation of suitability for ER remains unclear, miniature probe EUS may have a role in < 2 cm lesions which are indeterminate endoscopically.

Concurrent to these improvements in EUS, the addition of technologies such as CT with multiplanar reformations and virtual gastroscopy has led to overall accuracy as high as 94% for the diagnosis of EGC[79]. In addition, high-speed magnetic resonance imaging (MRI) and diffusion-weighted imaging have also addressed many of the limitations of MRI for the assessment of T-stage, though this remains infrequently used in the assessment of EGCs[80,81]. While a detailed comparison of radiological methods for staging gastric cancers is beyond the scope of this review, improvements in these technologies may facilitate accurate non-invasive assessment of EGCs in the future.

With respect to exclusion of nodal disease prior to ER for EGC, the use of EUS has again been associated with variable accuracy. In a 2008 meta-analysis, the pooled sensitivity of EUS for N1 disease was as low as 58.2%[82]. More recent data have shown an improved sensitivity and specificity of 74%-83% and 67%-70% in detecting nodal positivity[75,83,84]. However, this improved accuracy still remains inadequate to guide consideration of endoscopic management of disease with metastatic potential. Despite technological advances, CT also remains inaccurate for the detection of nodal metastases, with sensitivity between 62.5%-91.9%[85]. Accordingly, gastric cancers

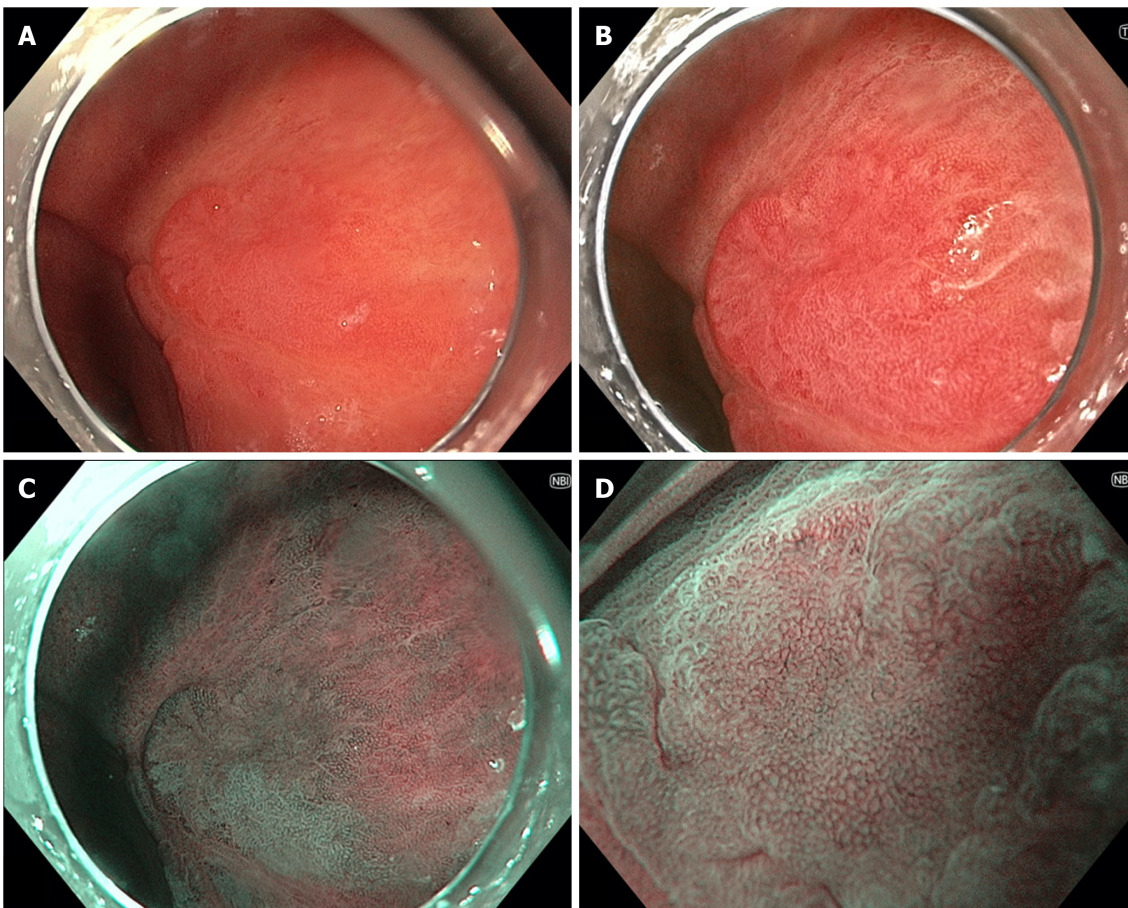


Figure 3 Gastric body lesion with low-grade dysplasia seen on multiple forms of endoscopic imaging. A: White light endoscopy; B: Texture and colour enhancement imaging; C: Narrow-band imaging (NBI); D: high-magnification NBI.

with a significant potential for lymph node metastasis based on lesion characteristics are generally managed surgically with lymphadenectomy to evaluate for lymphatic involvement, as reliable non-invasive exclusion of lymph node metastases (LNM) remains elusive.

ENDOSCOPIC TREATMENT OF GASTRIC NEOPLASIA

ER is indicated for all discrete gastric lesions with histological evidence of dysplasia given the risk of concurrent or future EGC. In addition, data supports ER for lesions histologically indefinite for dysplasia, as the rate of true dysplasia or EGC in resected specimens is as high as 90.8%, particularly in males; lesions > 5 mm in diameter; or lesions with erosions[86]. For gastric mucosal lesions < 1 cm in diameter with LGD, either endoscopic mucosal resection (EMR) or endoscopic submucosal dissection (ESD) can be performed, however ESD is preferred in larger lesions and those demonstrating HGD/EGC[87].

Indications for ESD

In the context of histologically confirmed carcinoma, ESD was initially indicated only for the resection of macroscopically intramucosal (T1a) differentiated gastric carcinomas < 2 cm in diameter without ulcer or scar[87]. These have subsequently been labelled 'absolute criteria', as data now support the efficacy of ESD for the resection of a broader range of EGCs termed 'expanded criteria'. In the 2015 JGES guidelines, expanded criteria lesions include all differentiated T1a EGCs > 2 cm without ulcer/scar, differentiated T1a lesions < 3 cm with ulcer/scar, and undifferentiated EGCs < 2 cm in diameter, while the 2015 European Society of Gastrointestinal Endoscopy (ESGE) guidelines also include differentiated lesions < 3 cm with superficial submucosal invasion (SM1 ≤ 500 μm)[87,88].

Another evolving potential indication for ESD is for the resection of submucosal gastric tumours. He *et al*[88] first demonstrated the efficacy and safety of ESD for gastrointestinal stromal tumours (GIST) in 2013, when they reported successful ESD in 25 large gastric GISTs with a mean diameter of 2.7 cm[88]. More recently, An *et al*[89] published data on 168 cases of ESD for gastric GISTs, with complete and en bloc resection in 100% of lesions[89]. Delayed bleeding occurred in only 1.2% and there were no other significant complications. While additional data are required before recommending ESD as a standard of care option for GIST management, early data support this as a potential future indication.

Efficacy of ESD

Data on the efficacy of ESD (Table 1) are particularly robust in East Asian countries where the incidence of gastric cancer is significantly higher than it is in Western countries. Studies in Japan and South Korea have demonstrated en bloc resection in 95.3%-99.2%, complete resection in 87.7%-95.5% and curative resection in 81.7%-84.1% [90-94]. In Western countries however, data are more limited and results are variable. En bloc resection rates are between 92%-97.8%, with complete resection in 75.6%-89% and curative resection in 72.2%-79.2% [95-100].

One contributing factor to this discrepancy is the differing incidence of gastric cancer, resulting in comparatively limited experience in Western centres. This was supported by a 2020 Italian survey where only 41% of included interventionalists had performed more than 80 ESDs and 31% had performed < 40[98]. This study also demonstrated that rates of en bloc resection were higher and rates of perforation lower in more experienced proceduralists. However, there are multiple other contributing factors. Firstly, there are differences in lesion classification, as the Japanese classification of gastric carcinoma includes EGCs which would by European guidelines be classified as HGD[101]. The non-aggressive and non-invasive nature of HGD would result in bias in favour of Japanese outcomes. Further to this, there appear to be differences in disease behaviour in East Asian compared to Western populations. Studies in Korea reviewing rates of LNM in surgical specimens at gastrectomy have reported LNM in 0.3% of absolute criteria lesions and 0.4% in expanded criteria, while marginally higher at 3.2% in undifferentiated carcinomas[102-104]. In contrast, American studies report LNM in 7.5%-13.6% of expanded criteria lesions at gastrectomy[105,106]. Guidelines developed based on data from East Asian populations should therefore be used with caution in Western populations until further evidence is able to clarify this.

EMR vs ESD: ESD is associated with longer procedure times and an almost three times higher perforation rate compared to EMR, however multiple meta-analyses have established the superiority of ESD over EMR in regard to en bloc resection rates (OR 9-10 for ESD), complete resection rates (OR 5.7-8.4) and curative resection rates (OR 2.9 [38,107,108]). Tao *et al*[107] also reported a reduction in local recurrence (OR 0.18), likely resulting from the aforementioned superior rates of en bloc, complete and curative resection[107].

ESD vs surgery: Increasing evidence suggests that ESD is associated with equivalent overall survival compared to gastrectomy, while reducing procedural complications. A 2015 retrospective Chinese study used propensity score matching to compare outcomes for surgery and ESD in 176 patients with a median follow up of 77 mo[109]. There was no significant difference in overall survival, and while local recurrence occurred in 1.7% of ESD, all but one of the recurrent lesions were treated endoscopically. There was no difference in early complication rates, but late complications were significantly more common in the surgical group (6.8% vs 0%). A similar 2017 Korean study found no difference in 5-year survival between groups, with a complication rate of 15% in gastrectomy vs 5.1% in ESD[110]. In regard to expanded criteria lesions, data have also reported equivalent survival with a reduction in complications using ESD, with a 2017 study actually demonstrating improved 5-year survival after propensity score matching in the ESD group (97.1% vs 85.8%)[109,111,112]. Unsurprisingly, a recent meta-analysis reported higher rates of local recurrence and metachronous cancer in the ESD group, resulting in lower disease-free survival (HR 4.58)[113]. However, the majority of recurrence is able to be treated with repeat ESD and thus lower disease-free survival is not reflected in any difference in disease-specific survival [109,113]. Further to this, the same meta-analysis reported a mean 128 min shorter operation time, 7 d shorter hospital stay, lower procedure-related death and fewer complications[113].

Table 1 Studies reporting *en bloc*, complete and curative resection rates using endoscopic submucosal dissection

Ref.	Location	Total lesions	<i>En bloc</i> resection	Complete resection	Curative resection
Suzuki <i>et al</i> [90], 2019	Japan	10821	99.2%	91.6%	81.7%
Ryu <i>et al</i> [91], 2018	Korea	1541	97.3%	95.5%	N/A
Chung <i>et al</i> [92], 2009	Korea	1000	95.3%	87.7%	N/A
Watanabe <i>et al</i> [93], 2017	Japan	511	97.4%	92.9%	84.1%
Ngamruengphong <i>et al</i> [94], 2020	North America	347	92%	82%	N/A
Manta <i>et al</i> [95], 2020	Italy	299	97.6%	89%	72.5%
Abdelrahim <i>et al</i> [96], 2019	Europe	175	92.5%	83.4%	N/A
Tate <i>et al</i> [99], 2019	Australia	135	94.8%	86.7%	79.2%
Pagano <i>et al</i> [98], 2019	Italy	41	97.8%	75.6%	72.2%

N/A: No application.

In regard to complications of surgical management, gastrectomy is associated with significant post-operative complication rates of 9.6%-18.1% for laparoscopic and 17.4%-29.3% for open gastrectomy, as well as a 30-d mortality rate of 2%-4.1% [3,114-116]. In addition, Yu *et al* [116] assessed quality of life scores after gastrectomy and found that fatigue, diarrhoea, reflux, dysphagia and eating restriction scores all remained persistently worse at 5-year follow-up after surgery [116].

A 2015 study demonstrated the lower overall medical costs of ESD compared to surgery for EGC, with ESD costing a median \$2374 USD compared to \$4954 USD for surgery ($P < 0.001$) [117,118]. This was confirmed by Shin *et al* [109] who reported approximate total hospital stay costs averaging \$1871 USD for ESD vs \$5925 USD for subtotal gastrectomy and \$6476 for total gastrectomy [109].

Long-term outcomes: Long-term data on ESD for EGCs has been extensively reported in Japan and South Korea, where studies including up to 5-9 years of follow-up have documented local recurrence rates of 0%-1.8% in absolute criteria lesions and 0.6%-7.0% in expanded criteria lesions [119-123]. In these same cohorts there were no cases of LNM in absolute criteria lesions, and LNM rates were between 0%-0.48% in expanded criteria lesions. Min *et al* [123] reported long-term outcomes (48 mo follow-up) for only lesions meeting criteria for curative resection, in whom 0.3% of absolute and no expanded criteria lesions had local recurrence [123]. In a study by Suzuki *et al* [124] in 2015 (again reporting only on curative resections), despite overall 5-year overall survival being as low as 92.2% due to other comorbidities, the 5-year disease-specific survival was 99.9% in both absolute and expanded criteria lesions [124]. In Western populations, long-term data are limited, but studies have reported local recurrence rates of 4.8%-7% for expanded criteria lesions [125-127].

ESD in 'outside of criteria' lesions: ESD is often also employed for the treatment of lesions outside of even the expanded criteria when patients are unsuitable for major surgery. Abe *et al* [127] followed 14 patients who had ESD for undifferentiated non-curatively resected lesions who were not suitable for or had declined further surgery [127]. Over a median of 76.4 mo follow-up, there was only one case of local recurrence which was managed with repeat ESD. A 2013 Japanese study reviewed 104 patients who undergone ESD despite being outside of criteria in regard to lesion characteristics, who had declined or been deemed unsuitable for surgical management [128,129]. Patients were followed-up for a median of 47 mo after resection, with 5-year overall survival of 70% but disease-specific survival of 91.5%. In patients with comorbidities precluding them from major surgery, ESD may therefore be beneficial even in lesions outside of the expanded criteria.

Approach to incomplete and non-curative resection

Incomplete resection: The limited available evidence supports repeat ESD where possible for lesions with positive horizontal margins after initial resection. Jung *et al* [129] reported 28 patients with a positive horizontal margin after initial ESD, in whom the curative resection rate of repeat ESD was 89.3% [129]. In a 2018 study, Jeon *et al* [130] also reported improved disease-free survival following repeat ESD for non-

curative resections due to positive lateral margins (89.2% *vs* 69.1%)[130].

Non-curative resection: The management of lesions determined to be beyond the expanded criteria histologically after ER (non-curative resection) remains controversial. A large 2019 meta-analysis demonstrated improved 5-year overall and disease-specific survival (OR 3.5 and 3.99 respectively) following additional surgery after non-curative resection[131,132]. However, these data are retrospective and are therefore susceptible to bias associated with the selection of less systemically unwell and comorbid patients in the additional surgery group. Other studies have reported rates of LNM or residual tumour as low as 5.1%, with differences in overall survival but no difference in disease-specific survival between those treated with additional gastrectomy and those managed with surveillance[133,134]. These studies have hypothesised that further data may delineate a group in whom surveillance after non-curative resection is associated with equivalent long-term outcomes.

Multiple studies have addressed factors to stratify the risk of LNM or residual tumour in patients who have had non-curative ESD. In regard to LNM, lymphovascular invasion (LVI) and depth of submucosal invasion histologically are reported to be the most consistent predictors[135,136]. Goto *et al*[134] reported that the presence of depth of invasion > SM1 or LVI was 100% sensitive and 86% specific for the presence of LNM[135]. For predicting the presence of residual tumour, a 2020 meta-analysis reported significant risk factors to be tumour size > 30 mm and the presence of positive horizontal margins[137]. Although additional data are required to guide decision making, patients who have non-curative resections may not warrant additional surgery provided the invasion depth is ≤ SM1 without evidence of LVI, while patients with tumour size > 30 mm or positive horizontal margin may be appropriate for repeat ESD.

This concept led to a 2017 study by Hatta *et al*[137], who developed the eCura scoring system for predicting the risk of LNM using data from 1101 patients who underwent radical surgery after non-curative ESD[137]. The presence of a positive vertical margin, submucosal invasion > SM1, tumour size > 30 mm and vascular invasion were each assigned 1 point, while lymphatic invasion was assigned 3 points. Patients scoring 0-1 points were classified as low-risk (2.5% risk of LNM), 2-4 points intermediate-risk (6.7% risk of LNM) and 5-7 points high-risk (22.7% risk of LNM). The scoring system was then validated on 905 patients with non-curative ESD who declined surgery. 5-year cancer-specific survival was 99.6% in the low-risk group (60.4% of patients), 96% in the intermediate risk group (27.6% of patients) and 90% in the high-risk group (11.9% of patients), suggesting that ESD without additional surgical management may be sufficient in low-risk patients according to the eCura system[138].

These risk stratification tools are of particular importance when considering patients with radiologically enlarged lymph nodes that may or may not signify the presence of LNM. Lee *et al*[138] reported 47 cases of ESD for expanded criteria lesions, where patients had at least one enlarged lymph node on CT[138]. 12 of 47 patients had surgical resection, with no evidence of metastatic disease, while the remaining 35 patients had serial CT monitoring over a median 56 mo. Of these 35 patients, 21 patients had reduction in size or complete resolution of lymphadenopathy, while 13 patients had no change. Only one case had progressive lymph node enlargement but declined biopsy due to age. Assessment of the risk of LNM may therefore help direct decision making regarding the need for additional surgery in the context of radiologically enlarged lymph nodes.

In patients at risk of LNM, future studies may explore the role of ER with additional laparoscopic lymph node resection. A 2011 study by Cho *et al*[139] described 9 patients who had endoscopic full thickness resection (FTR) with laparoscopic regional lymph node resection[139]. Despite 4 lesions having histological LVI, there were no cases of LNM. There may also be a future role for targeted lymph node resection using sentinel node detection strategies. While data have been inconsistent regarding the accuracy of gastric sentinel node detection, these strategies have been most successful in T1 EGCs and thus may be of use following higher-risk ESD[140,141]. Studies using dye have reported a sensitivity of only 75%, however in the context of dual tracer with radiolabelled tin colloid and blue dye, the sensitivity for LNM is up to 93%, with an overall accuracy of 99%[142]. Further studies are therefore required to assess the adequacy of sentinel node guided laparoscopic lymph node resection as a treatment strategy after non-curative ESD.

Complications of ESD

While ESD offers the promise of reduced morbidity, both acute (bleeding, perforation)

and chronic (stenosis, recurrence, metachronous lesions) complications can occur[107,108,113].

Bleeding: The risk of delayed bleeding with ESD is equivalent to that in EMR, with most studies reporting rates between 4% and 6%[143-146]. Nam *et al*[145] retrospectively reviewed 1,864 cases of ESD, in which post-procedural bleeding occurred in 4.1% of patients, with the majority occurring within 24 h of ESD[145]. In their multivariate analysis, predictors of delayed bleeding were patient age \leq 65 years, resection size $>$ 30 mm, procedure time $>$ 20 min, lesions located in the lower third of the stomach and the presence of erosions. In regard to treatment, delayed bleeding after ESD is generally amenable to routine endoscopic management[146].

Studies have addressed prevention strategies for post-ESD bleeding, with data supporting post-operative proton-pump inhibitor (PPI) use after ESD with an OR of 0.4-0.49 for delayed bleeding[147,148]. A 2016 meta-analysis on the use of PPI prior to ESD found a reduction in gastric pH at the time of procedure, but no pooled difference in delayed bleeding[149]. Previously, routine re-look endoscopies were performed in many centres after ESD in an attempt to prevent rebleeding; a method extrapolated from data supporting second endoscopy after treatment of bleeding peptic ulcers [150]. However, Goto *et al*[144] reported no difference in rates of bleeding before or after routine follow-up endoscopy within one week of initial ESD, suggesting limited benefit from this strategy[144].

Perforation: Perforation occurs more frequently in ESD than in EMR[107,108]. Rates of perforation are generally reported between 1.5% and 9.6%, with a large meta-analysis by Arezzo *et al*[150] demonstrating a pooled perforation rate of 4.9%[95,100,151-156]. Risk factors for perforation include lesions located in the upper third of the stomach, the presence of submucosal invasion or fibrosis and longer procedure times[152,153,157]. Longer procedure times may reflect either more complicated resections or less proceduralist experience, while perforations in upper third gastric lesions likely reflect thinner proximal gastric wall in comparison to the antrum[158].

When macroscopic perforations occur during ESD, more than 97% of cases are able to be treated endoscopically with clip closure[155,156]. Micro-perforations, or suspected perforations that are not endoscopically visible, are usually able to be conservatively managed with fasting and intravenous antibiotics[155].

Delayed perforation, when no intraprocedural perforation occurs but symptoms of peritonism and radiological evidence of perforation develop post-procedure, is a phenomenon that appears to be specific to ESD. It is most common in the thin upper third of the stomach and the majority of cases occur within 24 h[159,160]. Yamamoto *et al*[158] reported 5 cases of delayed perforation in a 2017 case series, of which 4 out of 5 were able to be managed endoscopically[158].

Stenosis: Post-ESD stenosis occurs most commonly following resection of gastric antral (occurring in up to 7% of cases) or cardiac lesions, presenting with either oesophageal or gastric outlet obstruction[161,162]. Sumiyoshi *et al*[160] analysed predisposing factors, with the only risk factor after multivariate analysis being a $>$ 75% circumferential post-resection defect[160]. In regard to treatment, while data is limited, most patients have improvement in their symptoms following either balloon dilation if severe, or conservative management if mild-moderate symptoms[162,163].

Local recurrence and metachronous gastric lesions: Guidelines recommend close ongoing surveillance after ESD for EGC, with ESGE and JGES guidelines suggesting 3- to 6-monthly and 6- to 12-monthly surveillance endoscopy respectively[87,88]. The aim of surveillance after ESD is for early detection of not only local recurrence but also metachronous precancerous gastric lesions. These lesions occur in up to 6.9%-13% of patients after ESD, with a 2019 study reporting a cumulative incidence of metachronous gastric cancer of 33.2 cases *per* 1000 patient-years[95,164,165]. In regard to treatment of metachronous lesions, Kim *et al*[165] reported 117 cases of metachronous gastric neoplasms, of which 77% were able to be retreated with curative ESD[165].

FUTURE DIRECTIONS FOR THE ENDOSCOPIC TREATMENT OF GASTRIC NEOPLASIA

Methods for generating counter-traction

Generating counter-traction during ESD is of benefit in reducing procedural time and

complications[166,167]. Depending on the position of the lesion being resected, gravity may not provide sufficient access to submucosal tissue planes. There have been a number of recent developments with regard to endoscopic equipment and techniques to generate counter-traction.

Magnetic anchor guided ESD: Magnetic anchor guided ESD uses a large external electromagnet combined with an internal magnet attached to the lesion *via* a clip (Figure 4). No comparative studies have assessed the advantages of this technique over conventional ESD, however studies have shown feasibility as well as subjective benefit from the point of view of endoscopists[168,169]. The main limitations of this technique are the equipment required and the coupling strength of the magnets relative to the abdominal wall thickness[170].

Dual channel endoscope: This technique requires a dedicated dual working channel endoscope, often employed for the ‘grasp-and-snare’ technique in EMR[171]. Hua *et al* [171] compared conventional ESD (24 patients) with dual channel ESD (22 patients), using one channel for dissection while grasping the lesion *via* the second channel[171]. Mean procedure times were significantly shorter with dual channel ESD (20.5 min *vs* 49.1 min) with no other differences in outcomes or complications. There are two main limitations of dual channel endoscopy: The requirement for a dedicated endoscope and the limited distance between working channels inhibiting angulation of traction.

Additional working channel: The use of an attachable additional working channel (Figure 5) aims to overcome some of these limitations of dual channel endoscopy by providing greater distance between working channels as well as allowing the use of a conventional therapeutic endoscope. The additional working channel consists of a flexible attachment, a long shaft and an adaptor for fixation at the endoscope handle [172,173]. This technique has been compared with conventional ESD in porcine stomachs, where it resulted in a reduction in procedure time (24.5 min *vs* 32.5 min) and lower rates of muscularis damage (3.13% *vs* 18.75%)[173]. However, minimal data exist in humans apart from feasibility studies reporting successful resection of 8 lesions by ESD and 6 lesions by EMR[174,175]. The main limitation of this method is the inability to generate significant angulation on the grasping forceps, preventing the most effective direction of counter-traction.

Double endoscopes: Using two separate endoscopes allows maximal angulation for the grasping forceps, optimising counter-traction. Generally, the first endoscope is inserted and a circumferential incision is made. Following this, a second smaller calibre endoscope is inserted to grasp and lift the edge of the lesion while the proceduralist proceeds with dissection. In 2017, Ogata *et al*[175] demonstrated the efficacy of this method in 122 patients, with a 97.5% en bloc resection rate and 86.9% curative resection rate, with perforation and delayed bleeding in 3.3% and 2.5% respectively [175]. While there are no direct comparator trials with conventional ESD, Çolak *et al* [176] employed this method in 6 patients where positioning made conventional ESD difficult[176]. They reported no difference in resection times compared to more straightforward ESDs. There are a number of obvious limitations to this method, including the requirement for two endoscopists, endoscopes and light sources, as well as space limitations in both the oral cavity and within the lumen where one endoscope can obstruct the view of the other[176]. Other groups have reported various methods to overcome some of these limitations. Higuchi *et al*[177] reported double endoscope ESD using a single light source, where the light source from the first endoscope is removed and attached to the second endoscope for insertion until the lesion is grasped [177]. Following this, the light source is reattached to the initial main endoscope. This technique resulted in improved accuracy of dissection compared to historical controls, without any serious intraprocedural complications. Alternatively, Ahn *et al*[178] employed a trans-nasal endoscope for applying traction, maximising space within the oral cavity and within the gastrointestinal tract due to the smaller calibre endoscope [178].

Endo-lifter: The ‘endo-lifter’ (Figure 6) consists of a transparent hood with grasping forceps, mounted on the tip of an endoscope, with the forceps running externally to the endoscope to allow dissection *via* the working channel[179]. The attachment of the forceps to the hood produces an arc that aims to provide superior angulation for countertraction. Minimal data exist using the endo-lifter in animal models, with variable results. Schölvinck *et al*[180] reported shortened procedure times when used by ESD-experienced but not inexperienced endoscopists[180]. Teo *et al*[179] reported increased visualisation of the submucosa and a reduction in subjective procedural

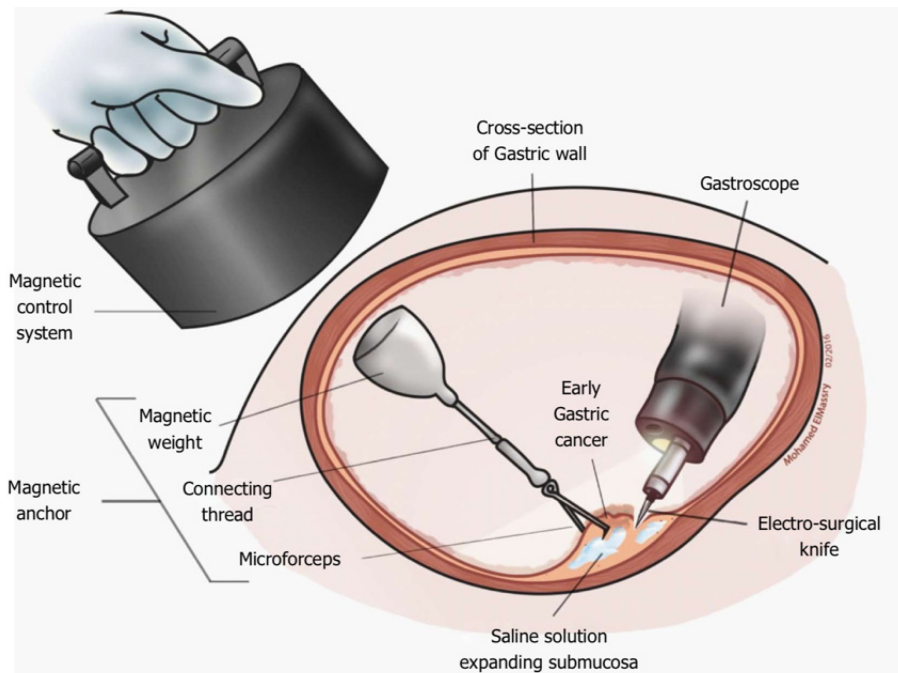


Figure 4 Magnetic anchor-guided endoscopic submucosal dissection[169]. Citation: Mortagy M, Mehta N, Parsi MA, Abe S, Stevens T, Vargo JJ, Saito Y, Bhatt A. Magnetic anchor guidance for endoscopic submucosal dissection and other endoscopic procedures. *World J Gastroenterol* 2017; 23: 2883-2890. ©The Author(s) 2017. Published by Baishideng Publishing Group Inc.

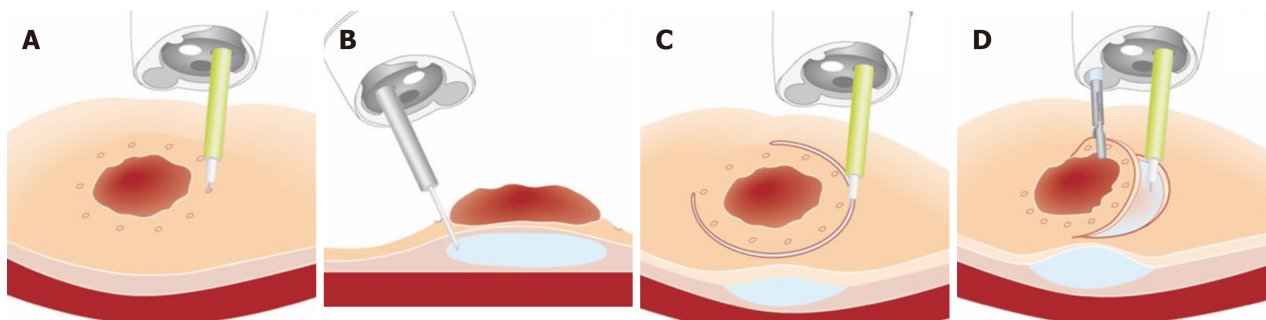


Figure 5 Endoscopic submucosal dissection using an additional working channel[172]. A: Lesion marked *via* usual working channel; B: Submucosal injection; C: Near-circumferential incision made; D: Lesion grasped for countertraction *via* additional working channel while dissection underway. Citation: Knoop RF, Wedi E, Petzold G, Bremer SCB, Amanzada A, Ellenrieder V, Neesse A, Kunsch S. Endoscopic submucosal dissection with an additional working channel (ESD+): a novel technique to improve procedure time and safety of ESD. *Surg Endosc* 2021; 35: 3506-3512. ©The Author(s) 2021. Published by Springer Open Access Article.

difficulty rating from endoscopists[179].

Spring and loop clip traction (using an S-O clip): This method uses the S-O clip (Figure 7) which is attached to a spring and then a loop of nylon[181,182]. One clip is attached to the edge of the lesion, while the other clip is attached to an area of opposing gastric wall to provide traction. Nagata[181] reported data from 140 patients of which 51 had spring and loop clip traction, with shorter procedure times and no difference in complication rates compared to conventional ESD[181]. The main limitations of this technique are the requirement for specific equipment (*i.e.*, the S-O clip) as well as only allowing one direction of traction once the clips are deployed.

Other clip methods: Various methods have been described employing readily available endoscopic equipment with clips to minimise cost. Yoshida *et al*[182] reported the efficacy of the ‘dental floss clip’ (DFC) traction device using dental floss tied to the proximal end of a clip before attaching the clip to the edge of the lesion, with the dental floss running externally to the endoscope[182]. There was no difference in procedure time overall, however in upper and middle greater curvature lesions DFC traction reduced procedure time by approximately 50%. In addition, the



Figure 6 'Endo-lifter' (Olympus-Tokyo, Japan)[192]. Citation: Harlow C, Sivananthan A, Ayaru L, Patel K, Darzi A, Patel N. Endoscopic submucosal dissection: an update on tools and accessories. *Ther Adv Gastrointest Endosc* 2020; 13: 2631774520957220. ©The Author(s) 2020. Published by Open Access Article.

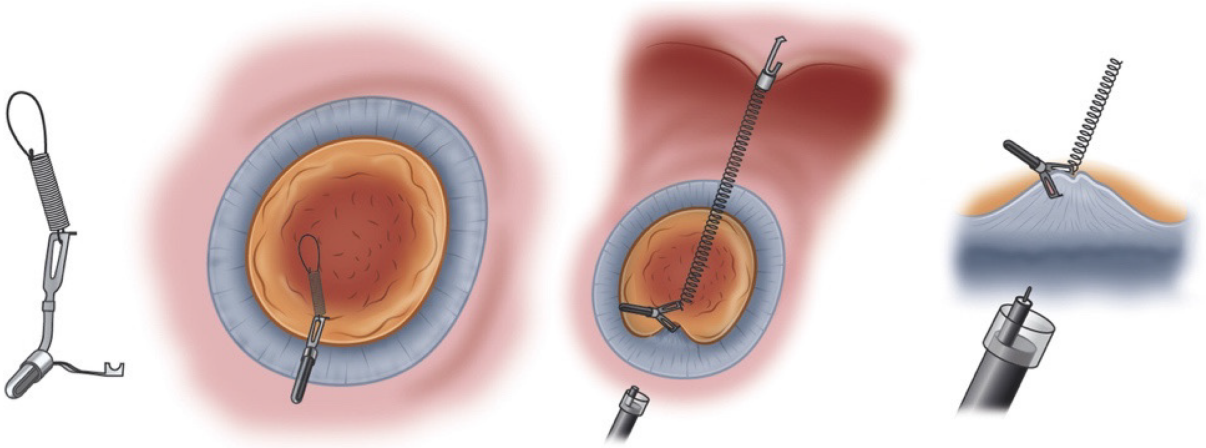


Figure 7 Spring and loop clip traction[193]. Citation: Nagata M, Fujikawa T, Munakata H. Comparing a conventional and a spring-and-loop with clip traction method of endoscopic submucosal dissection for superficial gastric neoplasms: a randomized controlled trial (with videos). *Gastrointest Endosc* 2021; 93: 1097-1109. ©The Author(s) 2021. Published by Open Access Article.

use of DFC traction reduced perforation rates compared to conventional ESD (0.3% *vs* 2.2%)[183]. Noda *et al*[183] added a polypectomy snare sheath external to the endoscope through which the thread (dental floss) was passed, which was then inserted along with the endoscope. The use of the sheath allows the thread to be moved without interference from the endoscope, as well as allowing both 'pull' and 'push' motions by advancing the entire sheath. In an 88 patient study comparing polypectomy snare sheath ESD with conventional ESD, this technique resulted in a reduction in procedure time and lower rates of significant bleeding[183]. Yoshida *et al* [184] also reported a reduction in procedure time by simplifying this technique to their 'clip and snare' technique: A snare with its sheath external to the endoscope is attached to the proximal end of a clip, then inserted and attached to the lesion[184]. Zhang *et al*[185] then modified the clip and snare technique (Figure 8), by using additional clips to attach the snare to the circumference of the lesion, allowing multifocal lifting of the lesion, as well as placing clips attached to the snare on opposing gastric wall mucosa to alter the direction of traction[185].

Endoscopic full-thickness resection

FTR can either be performed free-hand, attempting to maintain the serosa although often resulting in macroscopic perforation, or device assisted (Figure 9) using an 'over-the-scope' clip[186,187]. While some data exist regarding the use of FTR for gastric GIST where successful resection rates are as high as 96.8%, there is no evidence

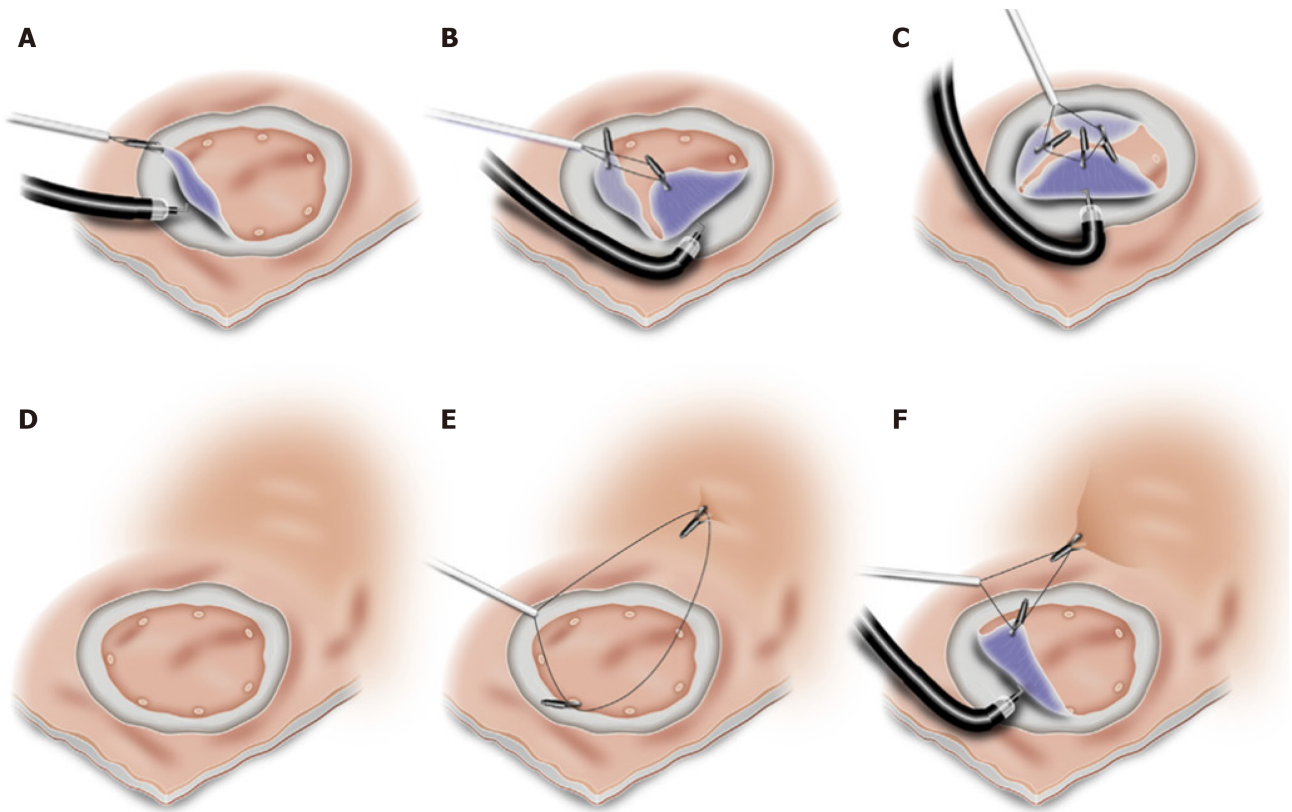


Figure 8 Modified endo-clip and snare[185]. A-C: Multiple clips used to provide multifocal traction; D-F: Clip applied to opposing gastric wall for countertraction. Citation: Zhang Q, Yao X, Wang Z. A modified method of endoclip-and-snare to assist in endoscopic submucosal dissection with mucosal traction in the upper GI tract. *VideoGIE* 2018; 3: 137-141. ©The Author(s) 2018. Published by Open Access Article.

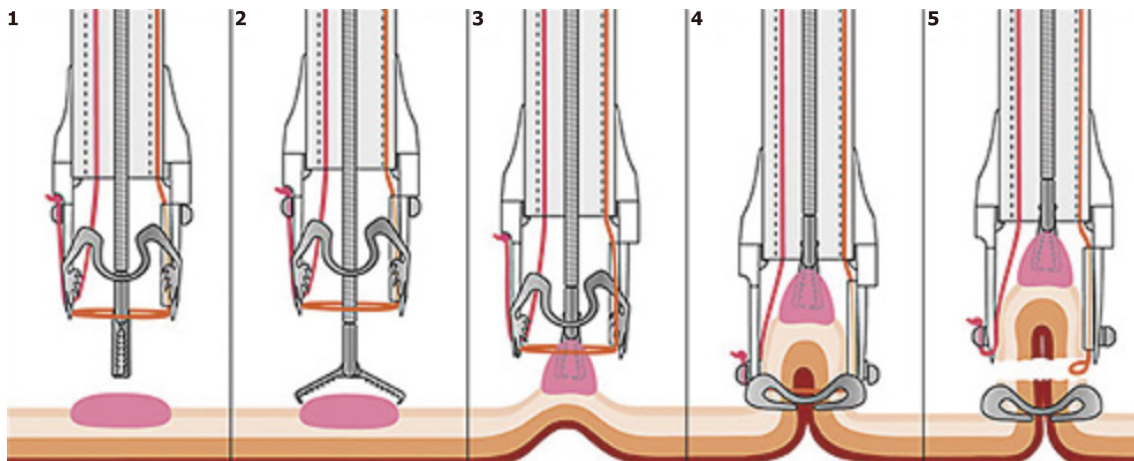


Figure 9 ‘Over-the-scope clip’ (Ovesco, Germany) full-thickness resection[194]. Citation: Mão de-Ferro S, Castela J, Pereira D, Chaves P, Dias Pereira A. Endoscopic Full-Thickness Resection of Colorectal Lesions with the New FTRD System: Single-Center Experience. *GE Port J Gastroenterol* 2019; 26: 235-241. ©The Author(s) 2019. Published by Open Access Article.

regarding the use of FTR in EGCs[188]. Theoretical roles for gastric FTR could include treatment of recurrent lesions within EMR/ESD scar limiting repeat resection, or using FTR in combination with laparoscopic nodal resection in non-candidates for gastrectomy with lesions outside of expanded criteria for ESD. Chae *et al*[188] reported a successful case of FTR for an EGC with a positive horizontal margin after initial ESD which had resulted in severe fibrosis[188]. Cho *et al*[138] reported a series of 9 patients treated with FTR and laparoscopic lymph node resection who had lesions outside of expanded criteria, in whom lymph nodes were positive in only 1 case[138].

Robot-assisted ESD

The 'Master And Slave Transluminal Endoscopic Robot' (MASTER) was developed in an attempt to mitigate the technical difficulties commonly encountered in interventional endoscopy[189-191]. Initial feasibility studies were performed in 2010 in ex-vivo and in-vivo porcine stomachs, where 20 gastric lesions were successfully resected using MASTER assisted ESD with no difference in procedure time compared to conventional ESD[190]. Subsequently, a small case series was reported in 2012, using MASTER assisted ESD in 5 patients, demonstrating clear resection margins in all cases with no major complications[192]. More studies are required to further explore the role of robot-assisted ESD, however this technique will clearly be limited by the cost and availability of equipment, while proceduralists already successfully perform more conventional ESD techniques at a fraction of the cost.

CONCLUSION

Advances in endoscopic imaging and therapeutics have enhanced the detection, characterisation and treatment of precancerous gastric lesions and EGC, allowing for pre-emptive minimally invasive intervention at an early stage. Endoscopic treatment of precancerous lesions and EGCs not only reduces rates of advanced carcinoma, but also avoids the requirement for high-risk surgical interventions with associated short- and long-term complications. The significant disparity in gastric cancer outcomes between East Asian and Western regions reflects extensive endoscopist experience, exhaustive research and clear guidelines in East Asia. Accordingly, there is a requirement for high-quality collaborative data from Western populations to aid in the development of clear management algorithms. Globally there are a multitude of opportunities for further research in both endoscopic imaging and resection techniques to optimise lesion detection and outcomes of ER, as well as potentially establish new indications for ER into the future.

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