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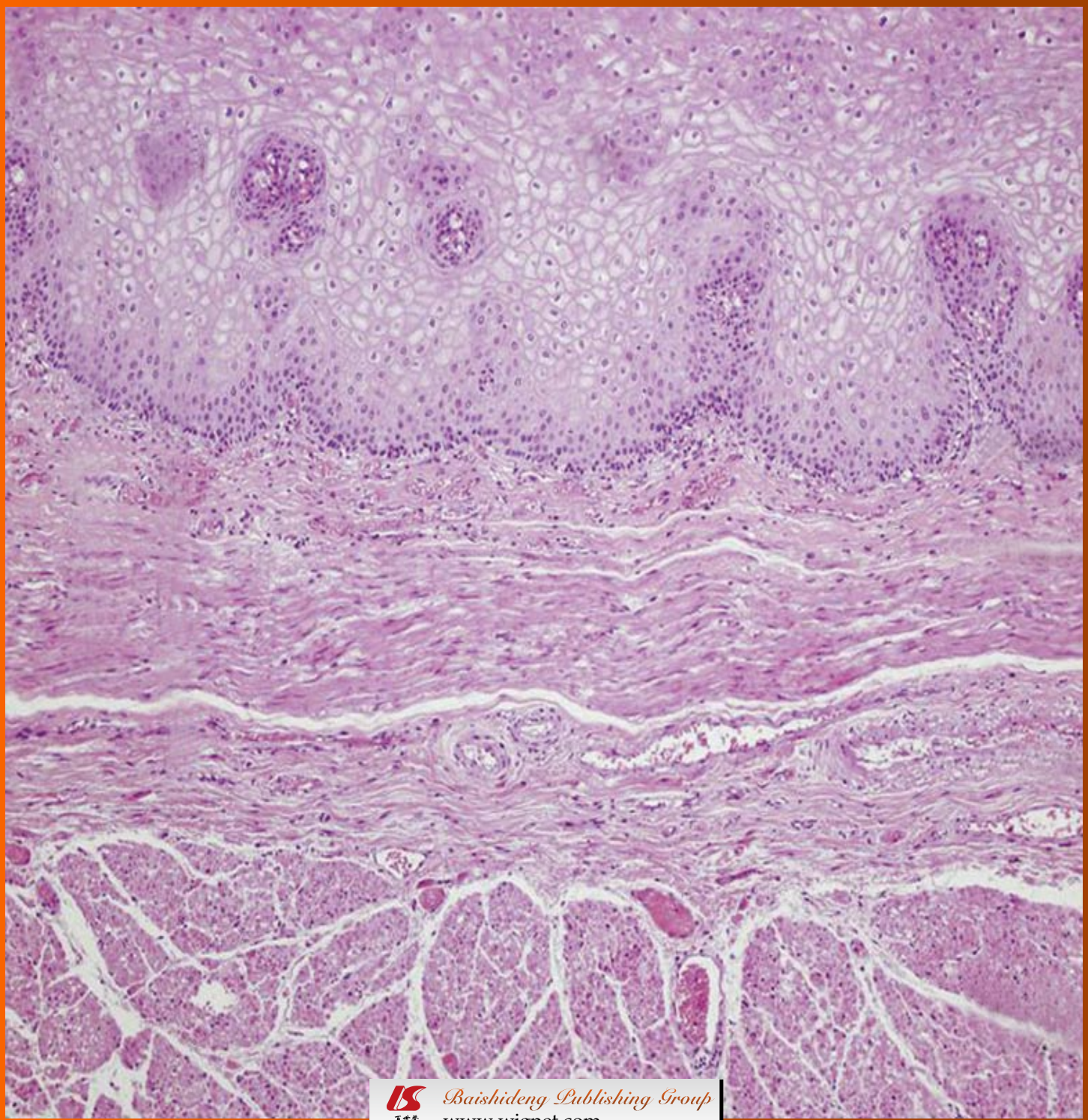

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REVIEW

Endoscopic resection techniques and ablative therapies for Barrett's neoplasia

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Abstract

Esophageal adenocarcinoma is the most rapidly increasing cancer in western countries. High-grade dysplasia (HGD) arising from Barrett's esophagus (BE) is the most important risk factor for its development, and when it is present the reported incidence is up to 10% per patient-year. Adenocarcinoma in the setting of BE develops through a well known histological sequence, from non-dysplastic Barrett's to low grade dysplasia and then HGD and cancer. Endoscopic surveillance programs have been established to detect the presence of neoplasia at a potentially curative stage. Newly developed endoscopic treatments have dramatically changed the therapeutic approach of BE. When neoplasia is confined to the mucosal layer the risk for developing lymph node metastasis is negligible and can be successfully eradicated by an endoscopic approach, offering a curative intention treatment with minimal invasiveness. Endoscopic therapies include resection techniques, also known as tissue-acquiring modalities, and ablation therapies or non-tissue acquiring modalities. The aim of endoscopic treatment is to eradicate the whole Barrett's segment, since the risk of developing synchronous and metachronous lesions due to the persistence of molecular aberrations in the residual epithelium is well established.

Key words: Barrett's oesophagus; Esophageal adenocarcinoma; Endoscopic mucosal resection; Endoscopic submucosal dissection; Radiofrequency ablation

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INTRODUCTION

Esophageal adenocarcinoma (EAC) is the most rapidly increasing cancer in western countries. Its incidence has increased up to six-fold in the past decade in the United States[1] and it is estimated that about 10 000 new cases were diagnosed last year[2]. Barrett's esophagus (BE) increases the risk for developing EAC up to 30-40 times and the presence of high-grade dysplasia (HGD) is the most important risk factor[2,3].

The global incidence of EAC arising from BE is 0.5% per year[2,3] and increases to 10% per patient-year when HGD is present[4]. A recently published meta-analysis reports an estimated incidence of 6.3 cases/1000 patient-years of follow-up and a mortality by cancer of 3/1000 patient-years of follow-up[5]. Adenocarcinoma in the setting of BE develops through a well known histological sequence, from non-dysplastic Barrett's to low grade dysplasia (LGD) and then HGD and cancer[6]. Despite the lack of randomized controlled trials and cost-effective analysis, endoscopic surveillance programs, with targeted biopsies from any visible lesion and random four-quadrant biopsies according to the Seattle protocol[7], have been shown to detect the presence of neoplasia at a potentially curative stage. The widely accepted approach in high-risk selected patients; is further endoscopic surveillance at follow-up intervals which are determined according to the presence and grade of dysplasia[8,9].

A careful examination with high-resolution endoscopy (HRE) is the first step for an appropriate selection of patients who are potential candidates for endoscopic therapy. Newly developed imaging techniques such as narrow band imaging, autofluorescence imaging or confocal endomicroscopy can be helpful for detection of early neoplastic lesions. Surgery has been advocated as the appropriate treatment for HGD due to the high reported rates of occult adenocarcinoma in esophagectomy specimens, up to 40% in some series[10,11]. The current consensus definition of invasive cancer includes lesions involving the submucosal layer (T1sm/T1b). A recent review demonstrated that the true prevalence of cancer invading the submucosal layer in patients with prior diagnosis of HGD was 12.7%[12] although subsequent studies have shown rates of 7%, and even lower (3%) in the absence of visible lesions[13]. These large differences are explained by the use in several studies of an inaccurate definition of invasive cancer that included T1a lesions, and by the low proportion (30%) of patients included in these studies who had been enrolled in an endoscopic surveillance program with an appropriate biopsy protocol[12].

It is also important to keep in mind that esophagectomy is associated with significant morbidity and mortality rates, even in high volume centers[14,15] and has been performed in patients with HGD or intramucosal carcinoma (IMC). These patients have a risk of lymph node (LN) metastasis lower than 1%[16-19] and could be successfully treated by endoscopic therapies. Newly developed endoscopic treatments have dramatically changed the therapeutic approach of BE. The rationale for endoscopic therapy is that lesions confined to the mucosal layer have negligible risk for developing LN metastasis and can be successfully eradicated by an endoscopic approach, offering a curative intention treatment with minimal invasiveness[20]. Risk of LN metastasis[16,21] and tumor differentiation grade[22,23] (G1 well differentiated, G2 moderately differentiated and G3 poorly differentiated) in early Barrett's adenocarcinoma are clearly related to the depth of tumor infiltration in the esophageal wall. The incidence of LN metastasis is between 0% and 3% for lesions limited to the mucosa (T1m), rising to 30% when the lesion involves the submucosal layer[17-19].

A recently published study, that includes a review of 805 endoscopic resections from 472 patients, showed that the depth of invasion correlates with differentiation grade (G3 0.9% in T1m1 *vs* 41.4% in T1sm3), lymphatic vessel involvement (0.6% in T1m1 *vs* 44.8% in T1sm3) and venous involvement (0% in T1m1 *vs* 13.8% in T1sm3), all well established risk factors for LN metastasis[22]. According to these findings, the endoscopic approach is clearly indicated for IMC and might be extended to lesions with limited invasion into the submucosa (< 200 μm, T1sm1) because of the low risk for LN metastasis reported in some studies[24-27]. Further investigations should be conducted to establish if patients with type I-II lesions, superficial submucosal invasion (T1sm1) and low risk of LN involvement, such as good differentiation grade (G1/G2) and no lymphovascular invasion, could be considered candidates for endoscopic therapy in high volume centers[27]. Figure 1 displays the esophageal layers and shows the subclassification of T1 lesions according to the depth of invasion. The aim of endoscopic therapy is to eradicate the whole Barrett's segment, since the risk of developing synchronous and metachronous lesions, due to the persistence of molecular aberrations in the residual epithelium, is well established[28]. Endoscopic eradication can be achieved through resection techniques (tissue-acquiring modalities), or through ablation therapies (non-tissue acquiring modalities)[29,30].

ENDOSCOPIC RESECTION TECHNIQUES

Endoscopic resection is the basis of endoscopic therapy for BE and has been advocated not only as a therapeutic approach but also as a staging tool in Barrett's neoplasia. The major advantage of the tissue-acquiring modalities is their ability to provide resection samples of appropriate size and depth for an accurate histopathological diagnosis. *En-bloc* resection techniques allow lateral resection margins to be assessed for the need of further treatments[29]. In 1984 Tada *et al*[31] introduced the use of "strip-off biopsy" for treatment of early gastric cancer. Endoscopic mucosal resection (EMR) of early esophageal neoplasia was first described in 1991 in two different manuscripts by Makuuchi *et al*[32] and Inoue *et al*[33], who published their results in four patients, three with squamous cell cancer and one

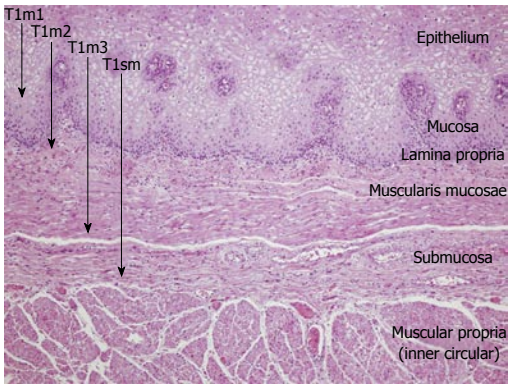

Figure 1 Esophageal Layers and T1 staging (HE × 100). T1m1: Lesion limited to the epithelial layer; T1m2: Invasion of *lamina propria*; T1m3: Invasion of *muscularis mucosae*; T1sm1-3: Invasion of submucosa (T1sm1 invasion into the superficial one third, < 200 μm).

with adenocarcinoma. In all cases complete resection was achieved and no recurrence neither metachronous lesions were observed during follow-up[33].

Endoscopic mucosal resection

Several EMR techniques have been developed for excision of mucosal based lesions; the most commonly used are the cap-assisted technique (ER-Cap) and the multiband ligation assisted technique (MBM). No significant differences in the safety and efficacy profiles have been reported between these two approaches. The only observed difference was the maximum diameter of the resected specimens, where the ER-cap method was favoured[34-36]. In both modalities, after marking 2 mm away from the lesion margins and lifting with saline solution injection, the targeted area is suctioned into the cap and grasped by the snare or by releasing the rubber band to create a pseudopolyp. The lesion is then cut using a snare with blended-current electrocautery. If the MBM technique is performed, the procedure can be carried out safely with no prior submucosal injection and lifting[37-40].

There is extensive experience of performing focal EMR for treatment of macroscopically visible lesions arising in BE. The available data show complete regression of neoplasia in 97%-100% of cases and 5-year survival rates of 98%-100%[41-54] (Table 1). EMR is the only endoscopic technique that has proved increasing the 5-year survival rate in Barrett's patients in uncontrolled trials[41]. In addition, endoscopic resection has been demonstrated to be a highly safe technique. Alvarez-Herrero *et al*[38] reporting the outcome of more than 1000 EMR procedures performed in 243 patients, observed an acute bleeding rate was 2.9% and delayed bleeding rate of 2.1%, with no perforations and successfully management of all adverse events by an endoscopic approach.

The radical differences between treatments for T1m and T1sm tumors make a definitive histopathological staging essential, in order to identify the patients amenable for curative endoscopic therapy. There are several concerns about the ability of conventional biopsy specimens to provide an accurate histological diagnosis. The

Table 1 Focal endoscopic mucosal resection in early Barrett's neoplasia

Author	*n*	Complete regression of dysplasia/esophageal cancer (%)	Histology	Follow-up (mo)
Ell *et al*[43], 2000	64	86	HGD/EC	12 ± 8
May *et al*[44], 2002	28	79 (100[1])	HGD/EC	34 ± 10
May *et al*[45], 2002	70	70 (98[1])	HGD/EC	34 ± 10
Behrens *et al*[48], 2005	14	93 (100[1])	HGD	38
Peters *et al*[49], 2005	33	79 (100[1])	Barrett's esophagus	19
Conio *et al*[50], 2005	39	97.5	HGD/EC	35
Ell *et al*[53], 2007	100	88 (99[1])	Adenoca.	36
Pech *et al*[41], 2008	231	95.7	EC	61
Moss *et al*[54], 2010	35	77 (85[1])	HGD/EC	31

[1]Results after second treatment. EC: Esophageal cancer; HGD: High grade dysplasia.

Table 2 Changes in final histopathological diagnosis after endoscopic mucosal resection

Author	*n*	Discrepant diagnosis (%)	Upstaging (%)	Downstaging (%)
Hull *et al*[59], 2006[1]	41	39	34	5
Chennat *et al*[60], 2009	49	44.8	14	31
Moss *et al*[54], 2010	75	48	20	28

[1]Includes esophageal and gastric neoplasms.

sampling error associated with the random biopsy protocol is well known and there are also important doubts about the adequacy of the depth of specimen obtained with conventional biopsy forceps. Published studies have reported a limited reproducibility, particularly for dysplasia, as well as low inter-observer agreement rates. Rates are between 61% and 75% when three categories are evaluated (no dysplasia, indefinite for dysplasia/LGD and HGD/carcinoma), but go down to κ value of 0.49 when HGD is diagnosed separately from carcinoma[55].

A recent study performed in two tertiary referral centers, has demonstrated a higher inter-observer agreement for diagnosis of dysplasia from the analysis of EMR specimens than from conventional biopsies (κ 0.33 *vs* 0.22, $P < 0.001$ for LGD; 0.43 *vs* 0.35, $P = 0.018$ for HGD). Submucosa was present in up to 88% of EMR specimens but only in 1% of biopsy samples and the presence of muscularis mucosae was observed only in 58% of biopsy specimens[56]. EMR samples permit an accurate evaluation of depth and lateral resection margins and also provide information about the presence of submucosal involvement. The histological examination of EMR pieces can also asses the degree of lymph and blood vessel invasion, important risk factors for the presence of LN metastasis[57-59]. Different studies have shown that final staging by EMR modifies the previous diagnosis in up to 48% of cases[54,59,60] and dramatically changes the clinical management of these patients (Table 2). Similar discrepancy rates have been reported for gastrointestinal neoplasia from other locations[61]. Finally, EMR staging has shown to be consistent

Table 3 Complete Barrett's eradication-endoscopic mucosal resection results

Author	*n*	Complete regression of intestinal metaplasia (%)	Complete regression of dysplasia/esophageal cancer (%)	Sessions (%)	Recurrence (%)	Progression (%)	Follow-up (mo)
Seewald *et al*[65], 2003	12	100	100	2.5	0	0	9
Giovannini *et al*[66], 2004	21	75	86	2	14	0	18
Peters *et al*[67], 2006	39	89	95	3	0	0	11
Larghi *et al*[68], 2007	24	87	100	1.8	4	0	28
Lopes *et al*[69], 2007	41	76	90	1.5	12	0	31.6
Chennat *et al*[60], 2009	49	97	100	2.1	0	0	17
Moss *et al*[54], 2010	35	97	97	2	0	0	31
Pouw *et al*[63], 2010	169	97.6	85.2	2	1.8	0.6	27

Table 4 Complete Barrett's eradication-endoscopic mucosal resection complications

Author	*n*	Perforation (%)	Bleeding[1] (%)	Stricture (%)
Seewald *et al*[65], 2003	12	0	0	16.6
Giovannini *et al*[66], 2004	21	0	0	0
Peters *et al*[67], 2006	39	2.56	2.56	26
Larghi *et al*[68], 2007	24	0	0	12.5
Lopes *et al*[69], 2007	41	9.5	0	4.76
Chennat *et al*[60], 2009	49	0	0	36.7
Moss *et al*[54], 2010	35	0	0	14.3
Pouw *et al*[63], 2010	169	2.4	2.4	50

[1]Only bleeding cases in which endoscopic treatment was needed.

with surgical pathology staging. The presence of free of disease margins in EMR samples, directly correlates with the absence of residual tumor at esophagectomy[62].

The major drawback of using focal EMR as the only treatment for Barrett's neoplasia is the possible development of synchronous, metachronous and recurrent lesions, arising in the residual Barrett's epithelium. After a mean follow-up period of 3 years, the reported incidence rates range between 11% and 47% and are even higher with longer follow-up. Because of this, complete Barrett's resection has been proposed as an alternative treatment[41-54].

Complete Barrett eradication endoscopic mucosal resection

The rationale for radical endoscopic resection of BE is the proven coexistence of multifocal HGD in Barrett's mucosa, the aforementioned high rate of synchronous and metachronous lesions when focal EMR is performed as single treatment and the lack of histological correlation of the non-tissue acquiring ablative techniques[29,30,63]. With this approach, the whole Barrett's segment is eradicated by endoscopic resection in a single or multiple sessions, achieving the treatment of any occult neoplasia and preventing the development of any new lesion during follow-up[60]. It was firstly described by Satodate *et al*[64], and since then, several studies have been conducted involving a total of 390 patients with HGD or IMC[54,60,63,65-69] and achieving complete eradication of IM in 86% to 100% of cases and eradication of any neoplasia from 75% to 100% of patients (Table 3). The global recurrence rate of neoplasia after a follow-up period of up to 32 mo was 3% (12/390), much lower than the previously reported with focal EMR[54,60,63,65-69].

Only one case of disease progression was observed (0.25%) with this approach. In the largest published series, Pouw *et al*[63] reported one case of progression to T1sm1 tumor after complete removal of a T1m2 cancer, the subsequent surgery showed neither residual tumor nor LN involvement. In the same study, all cases with recurrence of neoplasia [3 patients (1.8%), two HGD and one of T1sm1 tumor] were found distally to the neo-esophagogastric junction. This finding highlights the recommendation of a careful inspection of this area[63]. The complete Barrett's eradication EMR (CBE-EMR) is a safe procedure when performed by expert endoscopists and complications are successfully treated by an endoscopic approach with no need of additional surgery in most of cases (Table 4).

The major limitation for CBE-EMR is the high incidence of symptomatic stenosis, with rates reaching 50% in some reports. The rate of esophageal stricture was related to the length of Barrett's resected segment[63] and significant statistical differences were found with regard to the number of EMR procedures between patients who did and did not develop strictures[60]. New strategies to prevent the development of strictures should be evaluated[63]. A recent study reports a decrease in the incidence and severity of stricture after EMR/endoscopic submucosal dissection (ESD) involving more than 75% of circumference when preventive dilation is performed. Endoscopic balloon dilation was carried out 1 wk after treatment and once a week thereafter, until the mucosal defect was healed. No complications related to endoscopic dilation were observed[70]. Despite the relative low number of patients enrolled in these studies and the short follow-up period, CBE-EMR has shown excellent endoscopic and histological short-term results and could be considered as an alternative to esophagectomy in high volume centers for selected patients with short Barrett's segment ($\leqslant$ 5 cm)[60,63].

Endoscopic submucosal dissection

ESD is regarded in Japan as the treatment of choice for intramucosal gastric neoplasias, and when performed by experts the results for esophageal and colonic lesions are

Table 5 Endoscopic submucosal dissection in esophageal cancer

Author	*n*	*En bloc* resection rate (%)	Curative resection rate (resection margins free of neoplasia) (%)	Recurrence (%)	Histology	Follow-up (mo)
Oyama *et al*[75], 2005	102	95	95	-	Squamous	-
Fujishiro *et al*[76], 2006	43	100	-	2.3	Squamous	17
Kakushima *et al*[77], 2006	30	97	70	0[1]	Adenoca.[2]	15
Motohashi *et al*[78], 2009	9	100	100	0	N/D	12
Ono *et al*[79], 2009	84	100	88	3.6	N/D	21
Ishii *et al*[80], 2010	35	100	95	0[1]	Adenoca./Squamous	19
Neuhaus *et al*[81], 2010	18	83	22	5.5	BE (HGIN/IMC)	1.5
Yoshinaga *et al*[82], 2008	24	100	72	0[1]	Adenoca.[2]	30

[1]R0 margin lesions (free of disease margins); [2]Esophagogastric junction lesions; N/D: No data; BE: Barrett's esophagus; HGIN: High-grade intraepithelial neoplasia; IMC: Intramucosal carcinoma.

Table 6 Endoscopic mucosal resection *vs* endoscopic submucosal dissection in esophageal cancer

Author	*n*		*En bloc* resection rate (%)		Curative resection rate (resection margins free of disease) (%)		Complications[1] (%)	
	EMR	ESD	EMR	ESD	EMR	ESD	EMR	ESD
Ishihara *et al*[84], 2008	148	29	78.5	100	57.8	97	0.03	0.03
Jung *et al*[85], 2008	69	37	25	97.3	53.1	86.5	12.5	16
Teoh *et al*[86], 2008	26	11	71.4	94.4	-	-	0.06	0.36
Deprez *et al*[87], 2010	25	25	0	96	24	64	52	24

[1]Perforations + bleeding + stricture demanding dilatation. All of them were successfully treated by endoscopic approach. EMR: Endoscopic mucosal resection; ESD: Endoscopic submucosal dissection.

encouraging and superior to conventional EMR in terms of curative resection rate and recurrence[71-73]. With this approach, *en bloc* resection can be achieved regardless of the size of the lesions but it is a challenging technique, time consuming and is associated with a higher rate of adverse events[72,74,75].

The first step is marking the targeted lesion 5 mm away from its limits and perform submucosal injection using any of the available solutions (saline solution, hyaluronic acid, glycerine). The addition of epinephrine (1:100 000-1:300 000) is used for vasoconstriction of small submucosal vessels and indigo-carmine for a better visualization of the stained submucosal layer. Incision at the proximal and distal margins and then circumferential cutting of the surrounding mucosa is performed. Finally, dissection of the tissue beneath the isolated mucosa is carried out to achieve the removal of the lesion in one piece. Many different knives have been designed and developed.

Because of the low incidence of BE and adenocarcinoma in Japan and other eastern countries, the reported experience with early esophageal neoplasia is mainly limited to squamous cancer[75-81] (Table 5). Yoshinaga *et al*[82] reported a 100% of *en bloc* resection and a curative resection rate of up to 72% in adenocarcinoma located at the esophagogastric junction. When compared to EMR, ESD shows a better *en bloc* resection rate and a better curative resection rate (free of disease resection margins) for treatment of superficial tumors in the gastrointestinal tract, leading to a dramatically reduced local recurrence rate[75,83,84]. Perforation and bleeding were significant higher in the ESD group, although most of them were successfully managed by endoscopic intervention. There were no studies from western countries and no randomized controlled trials included in this analysis[83-87] (Table 6).

It is important to keep in mind that ESD is a time-consuming and technically demanding procedure. Learning methods should be standardized, with animal models playing a significant role[88-90] and the technique should be performed in an appropriate stepwise fashion. The minimum training requirements recommended by a panel of experts were recently published: enough previous experience with conventional EMR; knowledge of indications, instruments and complications management; visits to expert centers and observation of at least 15 live procedures performed by the experts; hands-on experience in isolated animal models and live pigs; starting with treatments on less challenging locations such as rectum and then moving to distal stomach, colon, proximal stomach and esophagus[73]. There is no consensus regarding of the minimum case load, but Japanese experts recommend at least 50 ESD procedures in distal stomach before performing the technique in the more challenging locations[91,92]. The role of ESD in the therapeutic algorithm of BE in the western countries is still not established[87,93]. Long-term results with EMR techniques are excellent, as previously shown, and ESD is a challenging technique with an increased risk of perforation compared to EMR and it does not provide a high R0 rate (lateral resection margins free of tumor) in Barrett's lesions. In these patients, the entire Barrett's segment must be eradicated af-

Table 7 Radiofrequency ablation non-randomized prospective trials

Author	*n*	Complete regression of intestinal metaplasia (%)	Complete regression of dysplasia/early cancer (%)	Patients	Study	Follow-up (mo)
Roorda *et al*[97], 2007	13	46	71	BE	Single-center	12
Sharma *et al*[98], 2007	70	70	-	Non D-BE	Multic.	12
Fleischer *et al*[99], 2008[1]	70	70-98	-	Non D-BE	Multic.	12-30
Ganz *et al*[100], 2008	142	54.3	80.4-90.2	HGD	Multic.	12
Pouw *et al*[101], 2008	44	98	-	BE	Single-center	21
Gondrie *et al*[102], 2008	11	100	100	BE	Single-center	14
Gondrie *et al*[103], 2008	12	100	100	BE	Single-center	14
Sharma *et al*[104], 2008	10	90	100	LGD	Single-center	24
Hernandez *et al*[105], 2008	10	70	-	BE	Single-center	12
Sharma *et al*[106], 2009	63	79	89	LGD/HGD	Single-center	24
Velanovich[107], 2009	66	93	-	BE	Single-center	12
Vassiliou *et al*[108], 2010	25	78.5	-	LGD/HGD/IMC	Single-center	20
Lyday *et al*[109], 2010	429	72	89	LGD/HGD	Multic.	9
Eldaif *et al*[110], 2010	27	100	-	Non D-BE/LGD	Single-center	2
Fleischer *et al*[111], 2010[2]	50	92	-	Non D-BE	Multic.	60

[1]Outcomes at 2.5 years f/u; [2]Outcomes at 5 years f/u. Non D-BE: Non dysplastic Barrett's esophagus; BE: Dysplastic and non dysplastic Barrett's esophagus; LGD: Low grade dysplasia; HGD: High grade dysplasia; IMC: Intramucosal carcinoma.

ter resection of any visible lesion regardless of the negative resection margins. Thus, the potential advantages of ESD compared to conventional EMR could be less relevant in treatment of early Barrett's neoplasia[93].

ABLATIVE THERAPIES

The rationale for developing new ablative methods for BE is the well established presence of molecular abnormalities in the remaining Barrett's epithelium after focal resection of neoplastic lesions[28], making the eradication of the entire Barrett's segment essential. The current consensus for use of non-tissue-acquiring modalities is in the eradication of all BE after endoscopic resection of all visible lesions for an accurate staging. When no visible lesion is macroscopically detected after a carefully examination with HRE, ablative methods may be the first of choice therapy for HGD[29].

Radiofrequency ablation

Radiofrequency ablation (RFA) using the HALO® system (BÂRRX Medical Inc., Sunnyvale, California, United States) uniformly delivers thermal energy with a prefixed density (12-15 J/cm^2) and power (40 W/cm^2). With these settings, the tissue penetration depth of the RF energy is limited to 500-1000 μm, which has been demonstrated as sufficient for the successful ablation of esophageal epithelium with no submucosal injury in animal models and humans[94]. The HALO360® device is a balloon catheter with spindle-shaped electrodes on its surface that allows the ablation of 3 cm long segments in a circumferential fashion. In order to choose the appropriate balloon size (available diameters 18 mm, 22 mm, 25 mm, 28 mm, 31 mm and 34 mm) an inflatable sizing balloon is used to measure the esophageal inner diameter. The catheter is introduced into the esophagus over a guide-wire and the RFA is performed under endoscopic direct view. The HALO90® is a square-shaped catheter with the same electrodes on its external surface, which is attached to the tip of the endoscope. It allows the focal ablation of small areas of residual Barrett's epithelium[29,95,96].

The available data from prospective trials are summarized in Table 7; they show a complete eradication of dysplasia in 70%-100% of cases and the eradication of IM in 50% to 100%[97-111]. Several trials assessing the efficacy and safety of RFA in BE have been conducted. After the publication of several studies in non dysplastic BE[97-99] Ganz et colleagues in 2008 conducted the first study in patients with HGD. A complete regression of IM, any dysplasia and HGD was achieved respectively in 54%, 80% and 90% of the 142 enrolled patients[100]. In the only multicenter, randomized and sham-controlled trial conducted to date, 127 patients with prior diagnosis of dysplastic BE (63 HGD and 64 LGD) were randomized in a 2:1 ratio to receive either RFA or sham endoscopic procedure (control group). After 1-year follow-up, all measured primary and secondary outcomes showed significant differences favoring the treatment group: progression rate, progression rate to cancer, complete regression of IM, complete regression of LGD and complete regression of HGD[112] (Table 8). Only three relevant adverse events occurred in the treatment group and five patients (6%) developed esophageal stricture (with or without dysphagia), a rate markedly lower than reported with resection therapies[112].

A systematic review of nine observational studies, involving 429 patients, and at least 12 mo of follow-up was recently published[113]. After analysis, complete eradication of IM was achieved in 46%-100% of patients and complete regression of neoplasia in 46%-100%. There were only 6 cases of stenosis after treatment (1.4%) and no major complications were observed. RFA has proved to be a safe procedure. Of all 657 patients involved in the aforementioned trials, only one case of perforation

Table 8 Radiofrequency ablation randomized, prospective and sham-control trial[113]

Study characteristics	Radiofrequency ablation group	Sham group	*P* value
n = 127 Dysplastic Barrett's esophagus patients	84	43	-
Complete regression of intestinal metaplasia	77.4%	2.3%	< 0.001
Complete regression of low grade dysplasia	90.5%	22.7%	< 0.001
Complete regression of high grade dysplasia	81.0%	19.0%	< 0.001
Global progression rate	3.6%	16.3%	< 0.05
Progression to cancer rate	1.2%	9.3%	< 0.05

Table 9 Stepwise treatment (endoscopic mucosal resection + radiofrequency ablation)

Results	End of treatment	Follow-up (22 mo)
Pouw *et al*[115], 2010		
Complete regression of neoplasia	20/21 (95%)[1]	24/24 (100%)
Complete regression of intestinal metaplasia	21/24 (88%)[2]	20/24 (83%)
Progression	0%	0%
Buried glands (1201 biopsies)	0%	0%
Pouw *et al*[116], 2010		
Complete regression of neoplasia	55/55 (100%)	N/A
Complete regression of intestinal metaplasia	53/55 (96%)	N/A
Progression	0%	N/A
Buried glands	N/D	N/A

[1]100% after escape endoscopic mucosal resection (EMR); [2]96% after escape EMR; N/D: No data.

has been reported (0.15%) and only 3 patients required hospitalization for any complication related to ablation. The global rate of stenosis is 2.3%, with all instances successfully treated by endoscopic dilation, and the most frequent adverse event is chest pain, usually controlled with conventional analgesics[97-111].

The Amsterdam group has reported excellent outcomes from the stepwise treatment in patients with HGD and any visible lesion in the index endoscopy exam. This approach consists of the resection of all macroscopic lesions and the subsequent ablation by RFA of the remaining Barrett's epithelium. Initially, circumferential ablation with HALO360® is performed with a maximum of three sessions; thereafter focal ablation with a HALO90® device is performed in order to eradicate any residual IM, with the same three session limit[102,103,114-116]. Complete eradication of neoplasia is achieved in up to 100% of cases and complete regression of IM in 96%. Escape EMR is performed if any abnormality is seen during follow-up. No recurrence of neoplasia has been observed 22 mo after treatment[114-116] (Table 9).

One of the most relevant concerns about RFA and other ablative therapies is the incidence of buried IM after treatment. The aforementioned review revealed only one case of buried Barrett's epithelium, after the assessment of more than 8500 biopsy samples obtained during follow up from the 429 patients enrolled in the 9 analyzed trials[113]. No randomized controlled trials comparing RFA *vs* CBE-EMR have been conducted to date. According to the published data, stepwise treatment should be the treatment of choice for patients with visible lesions arising on HGD[117] and CBE-EMR could be recommended, in high volume centers, for patients with short segment BE (SSBE).

Photodynamic therapy

In this technique, ablation is achieved by light activation of a photosensitizer drug, which leads to oxygen radicals formation and thereafter cell death. The photosensitizing agent, usually porfimer sodium, is administered before the procedure and it is selectively accumulated in the malignant esophageal mucosa. Cylindrical or balloon-based diffuser fibers are then placed over the targeted lesion under endoscopic view[20,29]. The published trials have proved the efficacy of photodynamic therapy (PDT) in eradicating Barrett's dysplasia[118-123] (Table 10). The only randomized and controlled trial reported complete regression of IM in 52% of cases and complete regression of any dysplasia in 59% out of 138 patients with dysplastic BE[122].

The major drawback of PDT is the relatively high rate of reported adverse events, mainly photosensitivity and symptomatic strictures, which have been reported in up to 36% of patients. Number of PDT treatments per session, prior EMR and a previous history of esophageal stenosis are associated with development of strictures[124]. Buried glands under the neo-squamous epithelium after PDT have been described in up to 51% of patients[125] and cases of adenocarcinoma arising from buried Barrett's glands have also been reported[120]. For all these reasons, PDT has been abandoned in recent years in favour of other ablation techniques. Further investigations aimed to identify biomarkers, which may stratify the patients more likely to respond to this treatment, and the development new photosensitizing agents could improve its safety profile[29].

Cryotherapy ablation

This is the latest added option to the therapeutical armamentarium of BE and has shown promising results in the available reports. For ablation, a liquid cryogen is focally sprayed onto the targeted lesion and results in freezing of the epithelium, causing intracellular disruption and ischemia. Liquid nitrogen and carbon dioxide have been used as cryogenic agents. The depth of ablation is limited to 2 mm and treatment sessions are performed every 4-6 wk until complete remission of the IM is achieved[126]. Several trials have shown cryotherapy as a safe and effective

Table 10 Photodinamic therapy in Barrett's esophagus

Autor	*n*	Study	Sessions	Complete regression of intestinal metaplasia (%)	Complete regression of dysplasia/early cancer (%)	Recurrence (%)	Follow-up (mo)
Wolfsen *et al*[118], 2002	48	Case series	1	56	98	N/D	18.5
Ackroyd *et al*[119], 2003	40	Case series	1	0	100	2.5	53
Overholt *et al*[120], 2003	94	Case series	1-2	56	80	N/D	50
Wolfsen *et al*[121], 2004	102	Case series	1	56	N/D	N/D	19
Overhalt *et al* [122], 2005	138	Randomized controlled trial	2	52	59	1.4	24
Pech *et al*[123], 2005	66	Case series	1.2	N/D	98	17	37

Table 11 Cryotherapy in Barrett's esophagus

Author	*n*	Complete regression of intestinal metaplasia (%)	Complete regression of dysplasia (%)	Complete regression of high grade dysplasia (%)	Patients	Follow-up (mo)
Johnston *et al*[127], 2005	9	78	-	-	Non D-BE/LGD/HGD	6
Canto *et al*[128], 2009	44	50	84	86	HGD/IMC	12
Greenwald *et al*[129], 2010	21	46	79	83	HGD/IMC	12
Shaheen *et al*[130], 2010	60	57	87	97	HGD	10.5

Non D-BE: Non dysplastic Barrett's esophagus; LGD: Low grade dysplasia; HGD: High grade dysplasia; IMC: Intramucosal carcinoma.

tool[127-130]. Short-term results are promising with eradication rates of IM in 46%-78% and of dysplasia between 79% and 87% of cases (Table 11). No major complications have been reported except for a gastric perforation in one patient with Marfan syndrome. This therapy is now contraindicated in patients with limited distensibility of the stomach. Multi-center randomized trials are required to confirm these results and determine the long-term response. It is still necessary to establish the optimal treatment protocol, duration and number of cycles per session, and frequency of treatment sessions. Finally, it remains to be determined if there is any clinical relevant difference in safety or efficacy profiles between CO_2 and N_2[126].

Other ablation modalities

Argon plasma coagulation has reported eradication rates of IM in non dysplastic Barrett's patients of up to 100%[131-134] and about 75% in cases of HGD, although with significant long term recurrence rates[29,135]. Techniques such as multipolar electrocoagulation and laser therapies have been replaced by the ablation modalities discussed in this manuscript[20,29].

CONCLUSION

According to the results achieved by endoscopic therapies, the reported rates of LN metastasis in lesions limited to the mucosal layer, and true prevalence of occult invasive adenocarcinoma in HGD, esophagectomy should not be routinely considered as a part of therapeutical algorithm for HGD in BE.

Barrett's patients with any visible superficial lesion should be treated by endoscopic resection for an accurate histopathological staging. In cases with favorable histology, all residual Barrett's epithelium should be ablated in order to avoid the risk of developing synchronous or metachronous lesions. Of all available ablation modalities, RFA has shown the best efficacy and safety profile. Patients with Barrett segment $\leqslant$ 5 cm could be considered for complete eradication by EMR in selected high volume centers[60,63]. The role of endoscopic ablation therapies is well established for HGD. Further investigations should be conducted to establish its role in LGD and non-dysplastic BE.

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Events Calendar 2011

January 14-15, 2011
AGA Clinical Congress of Gastroenterology and Hepatology: Best Practices in 2011
Miami, FL 33101, United States

January 20-22, 2011
Gastrointestinal Cancers Symposium 2011
San Francisco, CA 94143, United States

January 28-29, 2011
9. Gastro Forum München
Munich, Germany

February 04-05, 2011
13th Duesseldorf International Endoscopy Symposium
Duesseldorf, Germany

February 13-27, 2011
Gastroenterology: New Zealand CME Cruise Conference
Sydney, NSW, Australia

February 24-26, 2011
Inflammatory Bowel Diseases 2011-6th Congress of the European Crohn's and Colitis Organisation
Dublin, Ireland

February 24-26, 2011
2nd International Congress on Abdominal Obesity
Buenos Aires, Brazil

February 26-March 1, 2011
Canadian Digestive Diseases Week
Westin Bayshore, Vancouver
British Columbia, Canada

March 03-05, 2011
42nd Annual Topics in Internal Medicine
Gainesville, FL 32614, United States

March 14-17, 2011
British Society of Gastroenterology Annual Meeting 2011
Birmingham, England, United Kingdom

March 17-19, 2011
41. Kongress der Deutschen Gesellschaft für Endoskopie und Bildgebende Verfahren e.V.
Munich, Germany

March 17-20, 2011
Mayo Clinic Gastroenterology & Hepatology 2011
Jacksonville, FL 34234, United States

March 25-27, 2011
MedicReS IC 2011 Good Medical Research
Istanbul, Turkey

April 07-09, 2011
International and Interdisciplinary Conference Excellence in Female Surgery
Florence, Italy

April 15-16, 2011
Falk Symposium 177, Endoscopy Live Berlin 2011 Intestinal Disease Meeting, Stauffenbergstr. 26
Berlin 10785, Germany

April 18-22, 2011
Pediatric Emergency Medicine: Detection, Diagnosis and Developing Treatment Plans
Sarasota, FL 34234, United States

April 20-23, 2011
9th International Gastric Cancer Congress, COEX, World Trade Center, Samseong-dong
Seoul 135-731, South Korea

April 25-27, 2011
The Second International Conference of the Saudi Society of Pediatric Gastroenterology, Hepatology & Nutrition
Riyadh, Saudi Arabia

April 28-30, 2011
4th Central European Congress of Surgery
Budapest, Hungary

May 07-10, 2011
Digestive Disease Week
Chicago, IL 60446, United States

May 12-13, 2011
2nd National Conference Clinical Advances in Cystic Fibrosis
London, England, United Kingdom

May 21-24, 2011
22nd European Society of Gastrointestinal and Abdominal Radiology Annual Meeting and Postgraduate Course
Venise, Italy

May 25-28, 2011
4th Congress of the Gastroenterology Association of Bosnia and Herzegovina with international participation, Hotel Holiday Inn
Sarajevo, Bosnia and Herzegovina

June 11-12, 2011
The International Digestive Disease Forum 2011
Hong Kong, China

June 13-16, 2011
Surgery and Disillusion XXIV Spigc II ESYS, Napoli, Italy

June 22-25, 2011
ESMO Conference: 13th World Congress on Gastrointestinal Cancer
Barcelona, Spain

September 10-11, 2011
New Advances in Inflammatory Bowel Disease
La Jolla, CA 92093, United States

September 10-14, 2011
ICE 2011-International Congress of Endoscopy, Los Angeles Convention Center, 1201 South Figueroa Street
Los Angeles, CA 90015, United States

September 30-October 1, 2011
Falk Symposium 179, Revisiting IBD Management: Dogmas to be Challenged, Sheraton Brussels Hotel
Brussels 1210, Belgium

October 19-29, 2011
Cardiology & Gastroenterology Tahiti 10 night CME Cruise
Papeete, French Polynesia

October 22-26, 2011
19th United European Gastroenterology Week
Stockholm, Sweden

October 28-November 02, 2011
ACG Annual Scientific Meeting & Postgraduate Course
Washington, DC 20001, United States

November 11-12, 2011
Falk Symposium 180, IBD 2011: Progress and Future for Lifelong Management, ANA Interconti Hotel, 1-12-33 Akasaka, Minato-ku
Tokyo 107-0052, Japan

December 01-04, 2011
2011 Advances in Inflammatory Bowel Diseases/Crohn's & Colitis Foundation's Clinical & Research Conference
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INSTRUCTIONS TO AUTHORS

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The columns in the issues of *WJGE* will include: (1) Editorial: To introduce and comment on major advances and developments in the field; (2) Frontier: To review representative achievements, comment on the state of current research, and propose directions for future research; (3) Topic Highlight: This column consists of three formats, including (A) 10 invited review articles on a hot topic, (B) a commentary on common issues of this hot topic, and (C) a commentary on the 10 individual articles; (4) Observation: To update the development of old and new questions, highlight unsolved problems, and provide strategies on how to solve the questions; (5) Guidelines for Basic Research: To provide guidelines for basic research; (6) Guidelines for Clinical Practice: To provide guidelines for clinical diagnosis and treatment; (7) Review: To review systemically progress and unresolved problems in the field, comment on the state of current research, and make suggestions for future work; (8) Original Article: To report innovative and original findings in gastrointestinal endoscopy; (9) Brief Article: To briefly report the novel and innovative findings in gastrointestinal endoscopy; (10) Case Report: To report a rare or typical case; (11) Letters to the Editor: To discuss and make reply to the contributions published in *WJGE*, or to introduce and comment on a controversial issue of general interest; (12) Book Reviews: To introduce and comment on quality monographs of gastrointestinal endoscopy; and (13) Guidelines: To introduce consensuses and guidelines reached by international and national academic authorities worldwide on basic research and clinical practice in gastrointestinal endoscopy.

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Acknowledgments

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3 **Tian D**, Araki H, Stahl E, Bergelson J, Kreitman M. Signature of balancing selection in Arabidopsis. *Proc Natl Acad Sci USA* 2006; In press

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4 **Diabetes Prevention Program Research Group**. Hyperten sion, insulin, and proinsulin in participants with impaired glucose tolerance. *Hypertension* 2002; **40**: 679-686 [PMID: 12411462 PMCID:2516377 DOI:10.1161/01.HYP.0000035706.28494.09]

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5 **Vallancien G**, Emberton M, Harving N, van Moorselaar RJ; Alf-One Study Group. Sexual dysfunction in 1, 274 European men suffering from lower urinary tract symptoms. *J Urol* 2003; **169**: 2257-2261 [PMID: 12771764 DOI:10.1097/01.ju.0000067940.76090.73]

No author given

6 21st century heart solution may have a sting in the tail. *BMJ* 2002; **325**: 184 [PMID: 12142303 DOI:10.1136/bmj.325.7357.184]

Volume with supplement

7 **Geraud G**, Spierings EL, Keywood C. Tolerability and safety of frovatriptan with short- and long-term use for treatment of migraine and in comparison with sumatriptan. *Headache* 2002; **42** Suppl 2: S93-99 [PMID: 12028325 DOI:10.1046/j.1526-4610.42.s2.7.x]

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Books

Personal author(s)

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11 **Lam SK**. Academic investigator's perspectives of medical treatment for peptic ulcer. In: Swabb EA, Azabo S. Ulcer disease: investigation and basis for therapy. New York: Marcel Dekker, 1991: 431-450

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15 Morse SS. Factors in the emergence of infectious diseases. Emerg Infect Dis serial online, 1995-01-03, cited 1996-06-05; 1(1): 24 screens. Available from: URL: http://www.cdc.gov/ncidod/eid/index.htm

Patent (list all authors)

16 **Pagedas AC**, inventor; Ancel Surgical R&D Inc., assignee. Flexible endoscopic grasping and cutting device and positioning tool assembly. United States patent US 20020103498. 2002 Aug 1

Statistical data

Write as mean ± SD or mean ± SE.

Statistical expression

Express *t* test as *t* (in italics), *F* test as *F* (in italics), chi square test as χ^2 (in Greek), related coefficient as *r* (in italics), degree of freedom as υ (in Greek), sample number as *n* (in italics), and probability as *P* (in italics).

Units

Use SI units. For example: body mass, m (B) = 78 kg; blood pressure, p (B) = 16.2/12.3 kPa; incubation time, t (incubation) = 96 h, blood glucose concentration, c (glucose) 6.4 ± 2.1 mmol/L; blood CEA mass concentration, p (CEA) = 8.6 24.5 μg/L; CO_2 volume fraction, 50 mL/L CO_2, not 5% CO_2; likewise for 40 g/L formaldehyde, not 10% formalin; and mass fraction, 8 ng/g, *etc.* Arabic numerals such as 23, 243, 641 should be read 23 243 641.

The format for how to accurately write common units and quantums can be found at: http://www.wjgnet.com/wjg/help/15.doc.

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Italics

Quantities: *t* time or temperature, *c* concentration, *A* area, *l* length, *m* mass, *V* volume.
Genotypes: *gyrA*, *arg* 1, *c myc*, *c fos*, *etc.*
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