The safety and efficacy of endoscopic submucosal dissection for treating early oesophageal carcinoma: a meta-analysis

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ABSTRACT

INTRODUCTION Oesophageal carcinoma is the sixth most lethal cancer in the world. At present, the choice of specific surgical methods is controversial. This study compares the safety and efficacy of endoscopic submucosal dissection and endoscopic mucosal resection in treating early oesophageal carcinoma.

METHODS We carried out a search of online databases including the Web of Science, PubMed, Embase and the Cochrane Library with no language restrictions. The inclusion criteria were patients with early oesophageal carcinoma who accepted the treatment of endoscopic submucosal dissection compared with endoscopic mucosal resection.

FINDINGS A total of 1,462 patients with 1,650 lesions from nine studies were included in the meta-analysis. When compared with the endoscopic mucosal resection group, the en bloc resection (endoscopic submucosal dissection 67.94% vs endoscopic mucosal resection 52.78%; odds ratio 19.79, $p = 0.000$) and complete resection (endoscopic submucosal dissection 75.57% vs endoscopic mucosal resection 59.47%; odds ratio 16.10, $p = 0.000$) rates were significantly higher in the endoscopic submucosal dissection group, while the local recurrence rate was significantly lower in the endoscopic submucosal dissection group (endoscopic submucosal dissection 0.08% vs endoscopic mucosal resection 2.66%; odds ratio 0.08, $p = 0.000$). The incidence of complications and procedural time were also tested.

KEYWORDS

Early oesophageal carcinoma – Endoscopic submucosal dissection – Endoscopic mucosal resection – Meta-analysis

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Introduction

Oesophageal carcinoma is a common digestive cancer and is the sixth most lethal cancer in the world.¹ Despite progress in therapy, the five-year survival rate from oesophageal cancer is still less than 20%.² Early oesophageal cancer, confined to the mucosa or superficial submucosa, accounts for about 20% of all oesophageal cancers.³

Surgical resection has long been the standard treatment for early oesophageal carcinoma, but because of its high complication rate, oesophagectomy severely affects the quality of life of patients after surgery.⁴ The development of the gastroscope has greatly improved the treatment of early oesophageal cancer. In the latest guidelines for the diagnosis, treatment and follow-up of oesophageal carcinoma by the European Society for Medical Oncology,

both endoscopic mucosal resection (EMR) and endoscopic submucosal dissection (ESD) are included as effective.⁵ EMR has been used as a mucosal biopsy technique for clinical diagnosis. Noguchi *et al* first applied EMR for the treatment of oesophageal carcinoma in the 1990s.⁶ Since then, EMR has been widely accepted in the treatment of early gastrointestinal cancer, owing to its safety and minimal invasiveness.^{7,8} ESD is a new surgical method developed in Japan for the treatment of early gastric cancer.⁹ In clinical practice, the choice of two surgical methods in different hospitals depended largely on technical competence. Is ESD superior to EMR in the treatment of early oesophageal carcinoma?

Although many studies have focused on this issue, the results remain controversial. In a 2014 meta-analysis, five

retrospective studies were included to compare the efficacy of ESD and EMR in the treatment of early oesophageal carcinoma.¹⁰ However, the study did not assess the quality of the included articles and did not report publication bias or sensitivity.

In recent years, endoscopy has made great progress. In the present study, a cumulative meta-analysis was performed to assess the stability of the main results and a single-arm meta-analysis was performed to detect the positive results of related indicators for ESD and EMR. In addition, the publication bias and sensitivity analysis confirmed that the present study was robust and reliable.

Methods

The present study was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis guidelines.¹¹

Search strategy and study selection

The literature from January 2000 to March 2019 was systematically searched using online databases including Web of Science, PubMed, Embase and Cochrane Library, with no language restrictions. The main retrieval statements were as follows: Search (((("Esophageal Squamous Cell Carcinoma"[Mesh]) OR (((("Esophageal Squamous Cell Carcinoma"[Title/Abstract]) OR "Esophageal Carcinoma"[Title/Abstract]) OR "Esophagus Cancer"[Title/Abstract])))) AND ((("Endoscopic Submucosal Dissection"[Title/Abstract]) OR ESD[Title/Abstract])) AND ((("Endoscopic Mucosal Resection"[Mesh]) OR ((("Endoscopic Mucosal Resection"[Title/Abstract]) OR EMR[Title/Abstract])). Related references of included articles were also read and selected to supplement the meta-analysis.

The inclusion criteria were patients with early oesophageal carcinoma who accepted the treatment of ESD compared with EMR. Reviews or editorials, case reports and conference abstracts or letters were excluded. In addition, the content of articles with no relation to the inclusion criteria was also excluded.

Data extraction and quality assessment

The data extraction and quality assessment were independently performed by two investigators. Valid information was recorded in Microsoft Excel, including the baseline data of the included articles, primary (en bloc resection rate, complete resection rate and local recurrence rate) and secondary (complications including major bleeding, perforation and stenosis, and procedural time) outcomes.

As the included articles were all retrospective studies, the modified Newcastle–Ottawa Scale was used to evaluate the quality of these studies.

Statistical analysis

Stata software (Stata 15.1, MP-Parallel Edition) was used for the statistical analysis. The odds ratio (OR, 95% confidence

interval, CI]) was used to analyse the data of binary variables, while the weighted mean difference (WMD, 95% CI) was used to estimate the data of continuous variables. Cumulative meta-analysis was performed to assess the stability of the main results. Single-arm meta-analysis was used to detect the positive results of related indicators for ESD and EMR. The chi-square and I-square (I^2) tests were used to evaluate the heterogeneity of the studies. When I^2 was 50% or less, a fixed-effect model was used to analyse the data, and when I^2 was greater than 50%, a random-effect model was used. Funnel plots (binary variables and continuous variables), Harbord (binary variables), Peters (binary variables) and Egger's (continuous variable) tests were used to evaluate publication bias. In addition, a sensitivity analysis of the main results was also conducted. All results were two-sided, and a p -value less than 0.05 indicated statistical significance.

Findings

Study selection and quality assessment

A total of 278 citations were obtained from the online database (January 2000 to March 2019). In addition, citations were also obtained through other sources. A total of 211 records remained after the removal of duplicates. Of these, 56 reviews or editorials, 6 case reports and 41 conference abstracts or letters were excluded after reviewing the title and abstract of the articles. Some 84 articles that had no correlation to the endoscopic treatment of patients with oesophageal carcinoma were also excluded. After reading the full texts, 9 citations were included in the meta-analysis and 15 citations were removed for different reasons (Fig 1).^{12–20} The baseline data and quality assessment of the included studies are presented in Table 1. The demographics of the included studies are presented in Table 2.

En bloc resection rate

En bloc resection was defined as the overall resection of tumour tissues, which was characterised by the positive results of the margin and basal histology after surgery, requiring additional surgery or follow-up. The meta-analysis revealed that the en bloc resection rate was significantly higher in the ESD group when compared with the EMR group for patients with early oesophageal cancer (OR 19.79, 95% CI 8.64–45.32, $p = 0.000$; Fig 2A). The result has heterogeneity, and a random-effect model was applied ($I^2 = 63.6\%$, $p = 0.005$; Fig 2A). In the single-arm synthesis, the en bloc resection rate in the ESD group was 67.94% (95% CI 45.48–90.40), while the rate in the EMR group was 52.78% (95% CI 19.20–86.36; Table 3). The cumulative meta-analysis revealed that there was a significant difference in the ESD groups since 2010 in the second study (OR 5.08, 95% CI 1.45–17.78; Fig 2B). As time went on, the odds ratio further increased and the influence gradually stabilised (Fig 2B).

Complete resection rate

Complete resection was defined as the horizontal and vertical margins of resected specimens that were negative. The meta-analysis demonstrated that the complete resection rate was significantly higher in the ESD group when compared with the EMR group (OR 16.10, 95% CI 8.56–30.28, $p = 0.000$; Fig 2C). The result has heterogeneity and a random-effect model was applied ($I^2 = 58.0\%$, $p = 0.020$; Fig 2C). In the single-arm synthesis, the complete resection rate in the ESD group was 75.57% (95% CI 41.95–109.19), while the rate in the EMR group was 59.47% (95% CI 28.95–90.00; Table 3). The cumulative meta-analysis results of the eight studies were stable (Fig 2D).

Local recurrence rate

The meta-analysis revealed that the local recurrence rate was significantly lower in the ESD group when compared

with the EMR group (OR 0.08, 95% CI 0.04–0.19, $p = 0.000$; Fig 2E). Since there was no heterogeneity in the result, a fixed-effect model was applied ($I^2 = 0.0\%$, $p = 0.855$; Fig 2E). In the single-arm synthesis, the local recurrence rate in the ESD group was 0.08% (95% CI –24.15 to 24.31) while the rate in the EMR group was 2.66% (95% CI –19.06 to 24.37; Table 3). The cumulative meta-analysis demonstrated that there was a significant difference in ESD groups since 2010 in the third study (OR 0.14, 95% CI 0.03–0.59; Fig 2F). It can also be observed that the 95% CI become narrow, and the influence gradually stabilised (Fig 2F).

Complications

Both ESD and EMR have a degree of complications, and the comparison between these two surgical complications can reflect the safety of the operation. The meta-analysis demonstrated that the incidence of complications was

Table 1 Characteristics and quality assessment of the included retrospective studies (intervention: ESD versus EMR)

Study	Year	Country	Study period	Quality score ^a
Berger <i>et al</i> ¹²	2019	France	NA	7
Furue <i>et al</i> ¹³	2018	Japan	November 1999 – August 2015	7
Kinjo <i>et al</i> ¹⁴	2015	Japan	March 2004 – August 2012	8
Yamashita <i>et al</i> ¹⁵	2011	Japan	January 1997 – September 2009	7
Urabe <i>et al</i> ¹⁶	2011	Japan	October 2005 – March 2009	7
Teoh <i>et al</i> ¹⁷	2010	China	January 2002 – December 2007	7
Takahashi <i>et al</i> ¹⁸	2010	Japan	March 1994 – July 2007	8
Kubota <i>et al</i> ¹⁹	2010	Japan	January 1998 – December 2008	6
Ishihara <i>et al</i> ²⁰	2008	Japan	January 2002 – October 2007	8

NA, not available
^a Modified Newcastle–Ottawa scale

Table 2 Demographics of the included studies

Study	Patients (n)	Lesions (n)			Mean age (years)		Sex (male/female)	Tumour size (mm)
		ESD	EMR	ESD	EMR	Two-channel EMR		
Berger <i>et al</i> ¹²	139	68	80	65.7	61.8	–	108/31	ESD: 33.7 (15.0–94.3) EMR: 20.0 (5.0–70.0)
Furue <i>et al</i> ¹³	374	274	149	72.2 ± 7.2	67.6 ± 7.6	–	ESD: 204/36 EMR: 110/24	ESD: 20.7 ± 12.4 EMR: 16.5 ± 10.9
Kinjo <i>et al</i> ¹⁴	84	22	93	67 ± 7.4	66 ± 7.0	–	81/3	ESD: 13 (5–32) EMR: 11 (2–40)
Yamashita <i>et al</i> ¹⁵	112	71	56	-	-	–	-	ESD: 21.3 ± 11.1 EMR: 19.4 ± 11.2
Urabe <i>et al</i> ¹⁶	122	79	83	65.3 ± 9.2	63.8 ± 10.1	–	ESD: 50/9 EMR: 56/7	ESD (≤ 20/> 20): 48/31 EMR (≤ 20/> 20): 50/33
Teoh <i>et al</i> ¹⁷	28	22	13	67.5 ± 13.94	61 ± 12.44	–	ESD: 13/5 EMR: 7/3	ESD: 24.3 ± 9.8 EMR: 11.5 ± 3.5
Takahashi <i>et al</i> ¹⁸	300	116	184	67.1 ± 8.6	66.4 ± 8.0	–	ESD (ratio): 7.4/1 EMR (ratio): 9.2/1	ESD: 30 ± 16 EMR: 20 ± 11
Kubota <i>et al</i> ¹⁹	167	38	131	-	-	–	-	ESD: 31 (20–70) EMR: 30 (20–100)
Ishihara <i>et al</i> ²⁰	136	31	140	64	65	64	ESD: 25/4 EMRC: 50/8 Two-channel EMR: 54/7	ESD: 16 ± 4 EMRC: 13 ± 4 Two-channel EMR: 12 ± 5

EMR, endoscopic mucosal resection; EMRC, EMR using a transparent cap; ESD, endoscopic submucosal dissection

higher in the ESD group when compared with the EMR group (OR 1.47, 95% CI 1.05–2.06, $p = 0.025$; Fig 3A). Since there was no heterogeneity in the study, a fixed-effect model was used ($I^2 = 43.7\%$, $p = 0.087$; Fig 3A). In the single-arm synthesis, the complication rate in the ESD group was 3.52% (95% CI –18.34 to 25.38), while the rate

in the EMR group was 2.3% (95% CI –19.61 to 24.21; Table 3). The results of the cumulative meta-analysis were not stable (Fig 3B).

In order to explore the reason of instability in the cumulative meta-analysis, a subgroup analysis of complications was performed. The incidence of major bleeding, perforation

Figure 2 Forest plot and cumulative meta-analysis of primary outcomes. A) Forest plot of en bloc resection rate. B) Cumulative meta-analysis of en bloc resection rate. C) Forest plot of complete resection rate. D) Cumulative meta-analysis of complete resection rate. E) Forest plot of local recurrence rate. F) Cumulative meta-analysis of local recurrence rate.

and stenosis were analysed in both procedures. The meta-analysis demonstrated that the incidence of perforation was obviously higher in the ESD group when compared with the EMR group (OR 2.82, 95% CI 1.43–5.56, $p = 0.003$; Fig 3D). Since there was no heterogeneity in the study, a fixed-effect model was used ($I^2=28.2\%$, $p=0.203$; Fig 3D). However, there were no differences in the incidence of major bleeding and stenosis in the ESD and EMR groups (Figures 3C and 3E).

Procedural time

The meta-analysis revealed that procedural time was significantly longer in the ESD group when compared with the EMR group (WMD 47.20, 95% CI 28.40–66.00, $p = 0.000$; Fig 4). The result has heterogeneity, and a random-effect model was applied ($I^2 = 95\%$, $p = 0.000$; Fig 4). In the single-arm synthesis, the procedural time in the ESD group was 74.33 minutes (95% CI 56.28–92.38) while the procedural time in the EMR group was 26.85 minutes (95% CI 16.88–36.81; Table 3).

Publication bias and sensitivity analysis

The funnel plots demonstrated that the included studies had a symmetrical distribution (Fig 5). The Harbord test, Peters test and Egger's test revealed that the included studies had no publication bias (Table 4). Furthermore, the sensitivity analysis has proven that these present results were robust and reliable (Fig 6).

Discussion

The present meta-analysis included the latest comparative study of ESD and EMR in the treatment of early oesophageal carcinoma from 2000 to 2019. Although all the included studies were retrospective studies, these articles had high quality scores (Table 1). The funnel plots and related statistical tests revealed that there was no publication bias in the present study (Fig 5, Table 4). The sensitivity analysis also revealed that individual research had no effect on the final results of the meta-analysis (Fig 6). In the present study, a total of 1,462 patients with 1,650 lesions (721 ESD/929 EMR) from nine articles were included in the meta-analysis.

In our study, the en bloc resection rate (ESD/EMR 67.94% compared with 52.78%, OR 19.79, $p = 0.000$) and complete resection rate (ESD/EMR 75.57% compared with 59.47%, OR 16.10, $p = 0.000$) were significantly higher in the ESD group when compared with the EMR group, which indicates that ESD is more effective than EMR in the treatment of early oesophageal carcinoma. Although the meta-analysis results of both indicators were heterogeneous, the cumulative meta-analysis by year of publication indicated that these results were stable.

The cumulative meta-analysis of the en bloc resection rate revealed that there was a significant difference in ESD groups since 2010 in the second study, which may due to the immaturity of the ESD technology at the beginning of

its invention. In recent years, some researchers have considered that EMR is ineffective in resecting lesions larger than 20mm in diameter, while ESD is suitable for lesions of all sizes.²¹ Our results validated these views and demonstrated that ESD was superior to EMR in the treatment of early oesophageal carcinoma in terms of en bloc and complete resection rates.

Local recurrence rate was another important index for evaluating the efficacy of surgery. The present study revealed that the local recurrence rate was significantly lower in the ESD group when compared with the EMR group (ESD/EMR 0.08% compared with 2.66%, OR 0.08, $p = 0.000$) with no heterogeneity. The cumulative meta-analysis demonstrated that there was a significant difference in the ESD groups since 2010 in the third study, which may due to the immaturity of the ESD technology at the time. ESD was a surgical method invented by Japanese researchers in the 1990s for the treatment of early gastric cancer.²² Its development had a long evolution, which may explain why the efficiency of ESD was not significantly improved when compared with EMR in earlier studies.

Complications were important for evaluating the safety of surgery. In the present study, the incidence of complications was higher in the ESD group when compared with the EMR group (ESD/EMR 3.52% compared with 2.30%, OR 1.47, $p = 0.025$). A subgroup analysis was performed because the results of the cumulative meta-analysis were unstable. For a long time, researchers have considered that the incidence of major bleeding and stenosis in ESD was higher than in EMR, resulting in their reluctance to use this new surgical method.²³ The present analysis results revealed that there were no differences in the incidence of major bleeding and stenosis between the ESD and EMR groups, while the incidence of perforation in the ESD group was higher than in the EMR group. Furthermore, major bleeding and perforation were more serious complications of endoscopic surgery than stenosis.²⁴

Table 3 Single-arm meta-analysis of outcomes

Outcomes	ESD	EMR
En bloc resection rate	67.94% (45.48, 90.40)	52.78% (19.20, 86.36)
Complete resection rate	75.57% (41.95, 109.19)	59.47% (28.95, 90.00)
Local recurrence rate	0.08% (–24.15, 24.31)	2.66% (–19.06, 24.37)
Complications	3.52% (–18.34, 25.38)	2.30% (–19.61, 24.21)
Procedural time (minutes)	74.33 (56.28, 92.38)	26.85 (16.88, 36.81)

EMR, endoscopic mucosal resection; ESD, endoscopic submucosal dissection

In clinical practice, these complications can be effectively controlled by proper prevention, diagnosis and management.²⁴

In the present study, procedural time was significantly longer in the ESD group when compared with the EMR group (ESD/EMR 74.33 minutes compared with 26.85 minutes, WMD 47.20, $p = 0.000$). Although the heterogeneity of this study was a little high, the results were still credible, because the procedural time in the ESD group all included on the right side of the ineffective line. Long procedural time and high technical difficulty may be another two reasons why some doctors are reluctant to use ESD.

Using the clinical trial database clinicaltrials.gov, we discovered that a cohort study of early oesophageal carcinoma treatment with ESD is underway (NCT03377972), which indicates that there are still international doubts about the effectiveness and safety of ESD for early oesophageal carcinoma. In the meta-analysis, it was observed that the ESD group had a higher en bloc resection rate, complete resection rate and lower local recurrence rate when compared with the EMR group, which demonstrates that ESD is superior to traditional EMR in the treatment of early oesophageal carcinoma.

Figure 3 Forest plot, cumulative meta-analysis and subgroup analysis of complications. A) Forest plot of complications. B) Cumulative meta-analysis of complications. C) Forest plot of major bleeding. D) Forest plot of perforation; E) Forest plot of stenosis.

Figure 4 Forest plot of procedural time

Figure 5 Funnel plot of all outcomes. A) En bloc resection rate. B) Complete resection rate. C) Local recurrence rate. D) Complications. E) Procedural time.

In fact, in recent years, more and more digestive physicians in China have regarded ESD as the first choice for the treatment of early oesophageal carcinoma. Many researchers have considered that the incidence of serious complications, such as perforation and bleeding, can be controlled at a significantly low level with the development and improvement of ESD, and that the effectiveness of ESD in the treatment of early oesophageal carcinoma is credible.^{25–27}

Limitations

There are some limitations in the present meta-analysis. First, all the included articles were retrospective, rather than randomised controlled studies. Hence, our results may have potential selection bias. Second, there was a slight difference in treatment. The study conducted by Ishihara *et al* compared the related indicators of ESD, EMRC (EMR using a transparent cap) and two-channel

EMR in the treatment of oesophageal carcinoma. Our study combined the results of EMRC and two-channel EMR as the results of EMR, which may affect the final results.

Most of the included studies lacked follow-up results, which made it impossible for us to have sufficient data for performing a meta-analysis for the long-term prognosis of ESD and EMR. Nevertheless, these present results are reliable in terms of published bias detection and sensitivity analysis.

Conclusion

In conclusion, ESD is more effective than EMR in the treatment of early oesophageal carcinoma, which was determined by its high en bloc resection rate, high complete resection rate and low local recurrence rate. Although ESD

Table 4 Quantitative assessment for publication bias

	En bloc resection rate	Complete resection rate	Local recurrence rate	Complications	Procedural time
Studies (n)	9	8	9	8	4
Harbord tests	0.806	0.670	0.385	0.952	–
Peters tests	0.845	0.931	–	0.615	–
Egger's tests	–	–	–	–	0.791

Note: $p < 0.1$ indicates that there is publication bias

Figure 6 Sensitivity analysis of all outcomes. A) En bloc resection rate. B) Complete resection rate. C) Local recurrence rate. D) Complications. E) Procedural time.

has a higher risk of perforation and longer procedural time than EMR, these are controllable and acceptable. These results indicate that ESD should be considered as a better treatment approach for early oesophageal carcinoma.

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