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[Intervention Review]

Endoscopic mucosal resection for early gastric cancer

Cathy Bennett¹, Yiping Wang², Tao Pan²¹Systematic Research Ltd., Leicester, UK. ²Department of Gastroenterology, West China Hospital, Sichuan University, Chengdu, China**Contact address:** Cathy Bennett, Systematic Research Ltd., Leicester, Leicestershire, UK. info@systematicresearch.co.uk, info@systematicresearch.co.uk.**Editorial group:** Cochrane Upper GI and Pancreatic Diseases Group.**Publication status and date:** Stable (no update expected for reasons given in 'What's new'), published in Issue 10, 2014.**Citation:** Bennett C, Wang Y, Pan T. Endoscopic mucosal resection for early gastric cancer. *Cochrane Database of Systematic Reviews* 2009, Issue 4. Art. No.: CD004276. DOI: [10.1002/14651858.CD004276.pub3](https://doi.org/10.1002/14651858.CD004276.pub3).

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ABSTRACT

Background

The treatment of early gastric cancer (EGC) using endoscopy, namely endoscopic mucosal resection (EMR), has been adopted for about 20 years, but the effectiveness and safety of the modality are still controversial. Furthermore, the risk of bias of trials of this technique has not been assessed systematically.

Objectives

The purpose of this review was to compare the effectiveness and safety of endoscopic mucosal resection with gastrectomy for the treatment of early gastric cancer.

Search methods

Searches were conducted on the Cochrane Central Register of Controlled Trials (CENTRAL) which includes the Cochrane Upper Gastrointestinal and Pancreatic Diseases Group (UGPD) Trials Register (The Cochrane Library 2005, Issue 1), MEDLINE (1966 to March 2005), EMBASE (1980 to March 2005), CINAHL (1985 to March 2005) and CBM (Chinese BioMedical Database 1982 to 2002). The searches of CENTRAL, MEDLINE and EMBASE were updated in February 2006, January 2009 and January 2011. Reference lists from trials selected by electronic searching were handsearched to identify further relevant trials. Published abstracts from conference proceedings from the United European Gastroenterology Week (published in *Gut*) and Digestive Disease Week (published in *Gastroenterology*) were handsearched. Members of the Cochrane UGPD Group, and experts in the field were contacted and asked to provide details of outstanding clinical trials and any relevant unpublished materials.

Selection criteria

All randomised controlled trials of early gastric cancer patients involving a treatment arm of EMR and a comparison arm of gastrectomy were to be included, but no RCTs were found.

Data collection and analysis

The review authors independently assessed the eligibility of potential trials and extracted the data.

Main results

There were no randomised controlled trials identified for systematic review. Available evidence derived from non-randomised controlled trials is discussed in the main text of this review.

Authors' conclusions

There is a lack of randomised controlled trials in which endoscopic mucosal resection (EMR) is compared with gastrectomy for early gastric cancer. There is, therefore, a need for well-designed randomised controlled trials to determine the effects of EMR compared to gastrectomy.

PLAIN LANGUAGE SUMMARY**Endoscopic mucosal resection for early stomach cancer**

There is a lack of randomised controlled trials (RCTs) in which endoscopic mucosal resection (EMR) is compared with surgery for early stomach cancer. There is a need for well-designed randomised controlled trials to determine the effects of EMR compared to gastrectomy.

BACKGROUND

Description of the condition

Stomach cancer is the fourth most common cancer worldwide. In the UK, it is the eighth most common cancer in males in the UK and thirteenth in females (Cancer Research UK). It is the second most common cause of death from cancer worldwide. Geographically, there are some high risk areas, such as Eastern Asia (China, Japan, Republic of Korea, Democratic Republic of Korea and Mongolia), and lower rates of occurrence in North America, Australia and New Zealand (Parkin 2002). The lowest rates are found in Western and Northern Africa (Cancer Research UK 2007). Early gastric cancer (EGC) was defined in 1962 by the Japanese Research Society for Gastric Cancer as tumours with invasion limited to the mucosa or submucosa of the stomach irrespective of lymph node involvement (Kojima 1998).

Description of the intervention

Surgical gastrectomy was the only method of treatment for EGC before endoscopic mucosal resection (EMR) or endoscopic mucosectomy was introduced in Japan (Hiki 1996). However, accumulated histopathological data on surgical gastric cancer specimens have revealed that many early gastric cancer patients did not have any metastatic lesions (Gotoda 2000; Tada 2000). That is, gastrectomy for resection of regional lymph nodes is not always required and the option of treating EGC using endoscopy, namely endoscopic mucosal resection (EMR), can be considered when the probability of lymph node metastasis is low.

The indications for EMR according to the Japanese Gastric Cancer Association Guidelines (Japanese GCA 1998; Eguchi 2003) include:

1. a tumour with a low risk of lymph node metastasis;
2. differentiated adenocarcinoma, intramucosal cancer;
3. a tumour of less than 20 mm in size, regardless of macroscopic type, and without ulcer findings.

How the intervention might work

EMR has the advantage of not only allowing the lesion to be examined histologically to reveal its extent and infiltration depth but also the outcome of treatment can be evaluated on the basis of macroscopic and histological findings. Therefore, EMR provides significant benefits for an accurate final diagnosis and eradication of submucosal lesions. The procedure is less invasive than surgical gastrectomy without sacrificing the possibility of a cure (Hiki 1996; Ono 2001). Because of this, EMR appears to be a good therapeutic modality for EGC, especially in patients at high risk of having severe complications or refusing surgery (Hamada 1996). Endoscopic treatment has become increasingly popular in recent years as an alternative to surgical treatment and with the hope of offering superior quality of life for the patient. EMR is considerably cheaper compared with conventional surgery (O'Mahony 2001). A low incidence of post-operative complaints and no severe complications have been reported (Takeshita 1997a; Suzuki 1999). No deaths related to complications of EMR were registered in a review of 1832 patients treated with EMR in Japan over 10 years (Kojima 1998). Due to technological advances in detection methods, almost 10,000 cases of early gastric cancer are diagnosed every year in Japan, corresponding to 40% to 50% of all gastric cancers (Kojima 1998). The five-year survival rate of patients with

EGC in that country is about 90% after gastrectomy and complete removal of primary and secondary lymph nodes (Ono 2001). Five and 10-year survival rates of EMR are similar to conventional surgery (Tada 2000). Thus, in differentiated gastric adenocarcinoma with minimal submucosal invasion and not accompanied by peptic ulcer or other risk factors, such as lymphatic invasion EMR alone may have a curative potential, without the necessity for further radical surgery (Kashimura 1999; Tada 2000).

Why it is important to do this review

Because of the excellent results of EMR, experts believe that early detection of cancerous lesions and their treatment using EMR is the ideal goal of cancer treatment in people with cancers of the gastrointestinal tract (Ono 2001; Inoue 2002). EMR for mucosal gastric carcinoma without lymph node metastasis is the currently accepted curative procedure in Japan. Many other countries have adopted EMR treatment for EGC, such as China, the Americas and Western countries (Zhou 1995; Giovannini 1999; Llorens 2000; Wehrmann 2001; Ahmad 2002).

There are numerous techniques and many published studies evaluating EMR available (Zhou 1995; Kajiyama 1996; Takeshita 1997b; Giovannini 1999; Suzuki 1999; Kim 2000; Wehrmann 2001; Yoshikane 2001; Ahmad 2002). However, the quality of these trials has not been assessed systematically even though the technique of EMR has been in use for about 20 years.

OBJECTIVES

The purpose of this review was to compare the effectiveness and the safety of EMR with gastrectomy for the treatment of EGC.

METHODS

Criteria for considering studies for this review

Types of studies

We searched for all randomised and quasi-randomised controlled trials of EGC patients involving a treatment arm of EMR and a comparison arm of gastrectomy. Abstracts or unpublished articles were included.

Types of participants

Participants included patients with EGC defined as tumours with invasion limited to the intermucosa and submucosa, using the Japan or Vienna Criteria (Schlemper 2000; Eguchi 2003), as these types of lesions have a low risk of metastasis (Yamao 1996).

Types of interventions

Endoscopic mucosal resection (EMR) was compared with gastrectomy (including partial, distal and total gastrectomy) in the treatment of EGC.

Types of outcome measures

Primary outcomes

Five-year survival rate.

Secondary outcomes

- Recurrence.
- Metastasis after therapy.

- Failure cases of EMR (patients whose EGC is not resected by EMR).
- Reports of complications, including bleeding, perforation and death associated with EMR.
- Quality of life measures.

Cost assessments were not performed.

Search methods for identification of studies

Electronic searches

Searches were conducted on the Cochrane Central Register of Controlled Trials (CENTRAL) which includes the Cochrane Upper Gastrointestinal and Pancreatic Diseases Group (UGPD) Trials Register (The Cochrane Library 2005, Issue 1), MEDLINE (1966 to March 2005), EMBASE (1980 to March 2005), CINAHL (1985 to March 2005) and CBM (Chinese BioMedical Database 1982 to 2002). The searches of CENTRAL, MEDLINE and EMBASE were updated in February 2006, January 2009 and January 2011. Reference lists from trials selected by electronic searching were handsearched to identify further relevant trials. Published abstracts from conference proceedings from the United European Gastroenterology Week (published in Gut) and Digestive Disease Week (published in Gastroenterology) were handsearched. Members of the Cochrane UGPD Group, and experts in the field were contacted and asked to provide details of outstanding clinical trials and any relevant unpublished materials.

The Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE, Sensitivity maximising version, Ovid format (Higgins 2008), was combined with the search terms in Appendix 1 to identify randomised controlled trials in MEDLINE. The MEDLINE search strategy was adapted for use in the other databases searched.

Searches were conducted to identify all published and unpublished randomised controlled trials. Articles published in any language were included.

Searching other resources

Reference lists from trials identified by electronic searching were handsearched to identify further relevant trials. Published abstracts of conference proceedings from the United European Gastroenterology Week and British Society of Gastroenterology (published in Gut) and Digestive Disease Week (published in Gastroenterology) were handsearched. The authors also handsearched conference abstracts from the World Congress of Gastroenterology, Digestive Disease Week of China and the International Gastric Cancer Congress.

In addition, members of the Cochrane UGPD Group and experts in the field were contacted and asked to provide details of outstanding clinical trials and any relevant unpublished materials.

Data collection and analysis

Selection of studies

All identified trials were reviewed to determine if they were RCTs or quasi-RCTs. The review of eligibility was carried out independently by three authors (YP Wang, C Bennett and T Pan). There was no difference in opinion. Trials published only in abstract form

were included if full details of the protocol were given. Duplicate publications were excluded.

Data extraction and management

Studies were assessed for eligibility by T Pan, checked by YP Wang and independently assessed by C Bennett. We did not identify any studies which met the inclusion criteria. If updated searches retrieve any reports of studies which meet the inclusion criteria for this review, they will be analysed using the methods detailed in Appendix 2.

RESULTS

Description of studies

Results of the search

Electronic searches retrieved a total of 746 reports of studies from literature searches conducted in 2005, and updated in 2006, 2009 and 2011.

Included studies

No studies fitted the inclusion criteria.

Excluded studies

None of the reports of studies retrieved was suitable for inclusion. None of these excluded studies was an RCT; they were retrospective reviews of therapy for EGC, either single arm or controlled against other modalities of EMR or against surgery. There were only six studies which directly compared EMR with surgery (Mizumoto 1992; Nishida 1993; Fukase 1994; Tada 1998; Kim 2000; Fukase 2004). One further trial reviewed EMR and surgery cases retrospectively but this was not a direct comparison as it reported lymph node metastasis and mode of invasion in the EMR cases and background factors and treatment results in the surgery cases (Misumi 1991). Please see (Characteristics of excluded studies).

Risk of bias in included studies

There were no included studies.

Effects of interventions

There were no included studies.

DISCUSSION

Many studies of EMR have been published, particularly in the Japanese literature. There are currently no randomised controlled trials (RCTs) which evaluate the efficacy and safety of endoscopic mucosal resection (EMR) for early gastric cancer (EGC), or which compare EMR to gastrectomy for EGC. This discussion is, therefore, based on available evidence derived from reports of non-randomised studies. It is difficult to draw conclusions from the data obtained from non RCTs as selection bias in the series quoted will be present.

Indications for endoscopic mucosal resection

Based on the Japanese classification of gastric carcinoma (Japanese GCA 1998), the indications for endoscopic therapy are (Tada 2000) as follows.

1. Well-differentiated adenocarcinoma.

2. A tumour of size 20 mm or less in elevated types.
3. A tumour of size 10 mm or less in depressed types.
4. Not associated with peptic ulcer.
5. Invasion limited to the mucosa.

The incidence of lymph node metastasis from intramucosal EGCs fulfilling these criteria is small, reported as only 0.36% (Yamao 1996).

EMR can be used to completely resect small EGCs restricted to the mucosa or can be considered when the degree of invasion into the submucosa is minute (Noda 1997). In this review the participants' characteristics were predetermined by the characteristics of patients who were enrolled by the individual studies. Perhaps as a result of this, most of the trials we assessed only included people who had tumours with apparently limited local invasion and low risk of metastasis. The true depth of invasion is not normally known at the time of EMR and one of the advantages of EMR is that it provides detailed information on depth of invasion and risk of lymph node metastasis. If cases in which lesions were found to invade deeper than expected are excluded from studies, the potential advantage of EMR in such cases cannot be assessed. Some studies do report the application of EMR to patients with such expanded criteria (Kojima 1998). Kajiyama et al 1996 evaluated the diagnostic accuracy and therapeutic value of EMR for the treatment of sub-mucosal lesions in the gastrointestinal tract. In a series of 77 patients, they concluded that EMR can be used to eradicate some types of sub-mucosal lesions (Kajiyama 1996). In an assessment of local curability of early gastric cancer, that is, no recurrence of tumour in the stomach two years after treatment, patients who did not satisfy then current therapeutic indications were treated by EMR. These patients should have been treated by surgery but had severe concomitant disease. Local cure rate in these cases was only 67% compared with a 98% local cure rate for tumours that met the standard criteria (Amano 1998). Noda 1997 cautions that as surgical gastrectomy has a five-year survival rate of 98%, any expansion of endoscopic therapy in EGC should at present only be in cases where there are clinical contraindications for surgical treatment. However, results from studies which support the use of EMR in patients having larger, well-differentiated mucosal carcinomas and developments in EMR techniques may influence widening the present indications for EMR. One report of long term outcomes for early gastric cancer patients treated with EMR that had completely removed tumours of less than 2cm without ulcerative change. The overall disease specific 5 and 10 year survival rates were 99% and 99% retrospectively. The authors concluded that *en bloc* EMR ensured an excellent prognosis in patients with small differentiated mucosal early gastric cancers (Uedo 2006). Conversely, Kang 2010 et al conducted a review of review of 478 pathological specimens from participants who had undergone gastrectomy with lymph node dissection for the treatment of both mucosal and submucosal EGC. In that study, lymph node metastasis was demonstrated in some cases that appeared to meet established criteria for extended endoscopic submucosal dissection. Although the results may partly be explained by differences between pathologists in the diagnostic criteria and definition of EGC, the authors of Kang 2010 suggest that it may be necessary to re-evaluate whether the current literature, based on large Japanese datasets (for example Gotoda 2000), provides an accurate representation of the risk of LN metastasis in EGC lesions that apparently fall within current criteria for ESD of EGC.

Rabenstein 2008, reviewed the status of minimally invasive therapies for early gastric cancer outside Japan and stated that currently, these therapies should not be employed by inexperienced institutes outside of prospective studies.

Resection rates

Reported resection rates varied. In a review of 1832 cases in the Japanese literature, Kojima 1998 reported that complete resection was achieved in 73.9% of cases (Kojima 1998). Higher rates have been reported: 90.4% (Giovannini 1999), 97.7% (Tani 1997) and Oizumi et al report only 9.7% residual lesions in patients with standard indications for EMR (Oizumi 1991). Lower rates of complete resection have been noted in series which expanded the indications for EMR (Hiki 1995). A large study, which prospectively recruited patients with early gastric cancer for treatment with EMR, gave an overall complete excision rate of 71.9% for patients who completed the study and had small, moderately to well-differentiated intramucosal carcinomas but only 46.3 % for cases with larger differentiated carcinomas of size 2.1 to 4 cm. Completeness of resection was assessed histopathologically and suitable incompletely resected cases underwent additional endoscopic treatment. Subsequent endoscopic findings, including biopsies, showed no residual tumour, indicating that in some cases of incomplete EMR repeat treatment can be successful in eliminating tumours (Ida 2004).

Factors which influence incomplete resection by EMR are probably related to the resection technique used, the definition of clear margins and the inclusion of patients with expanded criteria, for example patients who have tumours with some degree of submucosal invasion (Kojima 1998).

Techniques

Numerous types of and modifications to the technique of EMR have been described (Takeshita 1997b; Chonan 1998) and discussed in Tanabe et al (Tanabe 1999). Additionally, there is debate over single fragment or piecemeal resection with it being suggested that EMR for EGC be performed *en bloc* rather than by dividing the lesion (Miyata 2000; Ono 2001; Eguchi 2003). Resection rates are reduced in lesions that are difficult to remove as a result of their size or location on the anterior or posterior wall rather than the lesser curvature of the stomach (Takekoshi 1994). To ensure adequate resection, it is suggested that a 'security margin' of 2 mm between the edge of the resected specimen and the margin of cancer should be preserved (Mizumoto 1992; Hamada 1996).

Residual and recurrent cancers

Incomplete resection may result in persistence or reappearance of a tumour. Clinicians then need to explore the options of further endoscopic therapy, observation or surgery depending on the status and fitness of the patient for major surgery and the degree of invasiveness of the tumour (Kojima 1998). Tada 2000 discussed this and reported the development of a protocol to follow up incomplete resection.

Endoscopic re-treatment of recurrences after EMR can result in local cure. In one study the patients were followed up by endoscopic examination up to five years after the completion of initial treatment (and extended for a further three years after endoscopic re-treatment for recurrence). With respect to small, moderately to well-differentiated intramucosal carcinomas, in

patients that completed the study "the long term results, including cases of additional treatment for residual cancer following the original EMR, showed that recurrence occurred in 8 out of 199 cases (4.0%) in five of whom local cure was achieved with endoscopic treatment, giving a local final cure of 98.5%". The remaining three recurrent tumour patients, who underwent surgery, had no lymph node metastases (Ida 2004).

Local recurrence may occur in completely resected cases and may be explained by the inappropriate assessment of multi-fragment specimens (Ono 2001). In a large prospective study (Ida 2004), there were no cases of recurrence following complete excisions in a single procedure. The authors do, however, conclude that in the cases of incomplete resection there were still recurrences after additional treatments and that in order to achieve radical cure by EMR the lesion must be initially detected and treated at the stage of local intramucosal disease. Recently there have been reports that endoscopic submucosal dissection has the advantage of reducing the risk of local residual or recurrent tumour (Oda 2006) and that it is effective in treating locally recurrent tumours after conventional EMR (Yokoi 2006). These studies were both retrospective in design. Yokoi 2006 reported a retrospective uncontrolled series of patients who developed local recurrence of EGC after initial EMR treatment; these patients were then re-treated with ESD. The participants were treated with ESD rather than EMR as EMR causes local scarring of the submucosa whereas ESD through the fibrosis can resect the tumour en bloc, there were also three perforations in this small series of 46 patients.

A retrospective review of patients who had been treated by EMR for early gastric cancer, suggested that the eradication of *Helicobacter pylori* "may help reduce the incidence of metachronous cancer" (Nagawa 2006). In an randomised controlled trial of patients who had undergone endoscopic mucosal resection (EMR) for early gastric cancer and who were treated with eradication of *Helicobacter pylori*, the incidence of metachronous gastric cancer in those participants who did not receive eradication therapy was significantly higher in control group (Fukase 2008).

Endoscopic monitoring may reveal the development of metachronous cancers, but the appropriate follow up interval has not yet been determined. Endoscopic surveillance of patients treated by EMR is recommended with suggested schedules of every six months for five years (Miyata 2000) or every three to six months for the first year and yearly thereafter (Kondo 2001). In order to detect metachronous lesions at an early enough stage for curative EMR, Nakajima 2006 suggested that endoscopic surveillance at one-year intervals was practical and effective.

Complications and mortality due to endoscopic mucosal resection

Mortality due to EMR is low. No cases were reported by Kojima 1998. Complications associated with EMR include bleeding and perforation (Nelson 2000). Bleeding and haemorrhage are managed by local coagulation therapy. Bleeding is more frequent when large lesions are removed or piecemeal resection techniques are employed (Noda 1997; Tanabe 1999). Rates of bleeding vary from 1.2% (Oizumi 1991) to 20.5% (Tanabe 1999) and are also described as 'frequent' (Ono 2001).

Perforation rates vary from 0.4% (Oizumi 1991) to 5.2 % (Kondo 2001), this being managed by clipping or surgery. A multi-centre collaborative prospective study of endoscopic treatment of early gastric cancer reported haemorrhage rates of 1.7% (7/409) and only one case of perforation (0.2%) (Ida 2004). Only one trial reported a comparison of complications of surgery compared with EMR. In a report comparing EMR with 256 radical surgery cases, postoperative complications occurred in 7.8% with an operative mortality of 0.78% in the radical surgery group. In the 56 EMR cases, nine experienced slight bleeding which was treated by ethanol injection using endoscopy (Mizumoto 1992). An RCT comparing pre-operative PPI use with no pre-operative PPI use indicated that it is useful for controlling and preventing bleeding and that artificial ulcers created by EMR healed more quickly in participants who received preoperative PPIs (Watanabe 2006).

Survival and long term outcomes

Only one death after EMR was due to gastric cancer in the series reported by Kojima et al (Kojima 1998); with survival rates nearing 100% for small tumours with minimal submucosal invasion (Ponchon 2001). In a retrospective evaluation of endoscopic treatment (116 cases) for gastric cancer compared with surgical treatment (59 cases), survival rates with Kaplan-Meier curves were calculated. In patients who were younger than 65 years, five-year survival was 92.8% for EMR cases and 100% for surgery cases. The 10-year survival rates for patients less than 65 years of age were 92.8% for EMR treated cases and 91.7% for surgery cases. In patients older than 65 years of age, five-year survival was 80.8% for EMR treated cases and 100% for surgery cases. The 10-year survival rates for patients older than 65 years of age were 80.8% for EMR and 75.0% for surgery cases. There were no significant differences between the results for patients older or younger than 65 or between the survival of EMR treated cases and surgically treated cases and this trend continued when the case were followed up after a further 10 years. (Fukase 1994; Fukase 2004). Similar rates were noted by (Kim 2000), that is two and five-year survival rates for EMR were 95% and 100% respectively and 100% and 100% respectively for surgically treated patients. Nishida et al (Nishida 1993) showed that in elderly patients (older than 75 years of age) endoscopic therapy showed better results than conventional surgery in the first two years and almost the same results after three years. Tada et al (Tada 1998, summarised in Tada 2000) looked at survival in 410 patients treated over a 15-year period by strip EMR and 56 patients with the same types of lesion treated by surgery. Survival rates over five and ten years for EMR compared with surgery were 84.9% and 83.5% and 90.9% and 87.4% respectively, with no significant differences between the two groups.

Quality of life (QoL)

Only one study discussed quality of life. Takeshita 1997a referred to a report which indicated poor quality of life after gastrectomy. These authors suggested that QoL after EMR was favourable in terms of healing, diet, ability to work, drug therapy and performance status. Tada 1998 reported that "the therapy (EMR) is considered excellent from the viewpoint of quality of life".

Cost

A cost assessment was not included in the protocol for this review as it was considered to be outside the scope of a Cochrane review. In the trials assessed, no data regarding cost were reported.

The EMR procedure requires a shorter hospital stay than surgical gastrectomy but the cost saving may be offset by the need for long-term endoscopic surveillance post EMR.

AUTHORS' CONCLUSIONS

Implications for practice

We found no evidence from RCTs to evaluate the safety and efficacy of endoscopic mucosal resection (EMR compared with gastrectomy for early gastric cancer (EGC). It is difficult to draw too many conclusions from the data obtained from non-RCTs as selection bias in the series quoted will be present.

As patients with EGC can expect a five-year survival of greater than 90% with surgical gastrectomy, and there are no prospective randomised controlled studies that evaluate the effectiveness of EMR compared with gastrectomy in EGC, it is difficult to assess if EMR should be adopted as the primary method of treatment for small EGCs. In terms of quality of life after treatment and its utility in patients who are unfit for surgery EMR does seem to be an attractive alternative (O'Mahony 2001). However, complications are not infrequent and there is a risk of incomplete resection or the development of recurrent or new cancers at a later date. Long-term regular endoscopic surveillance may be unacceptable to patients and would incur costs to the provider. Wide uptake of this technique in the West may require the provision of specialist centres with appropriately trained personnel. While EMR is the method of choice for early gastric cancer in Japan, in the West, for those institutions inexperienced in the diagnosis and therapy of

gastrointestinal neoplasms, minimally invasive surgical procedures should be carried out on an individual basis or with the remit of a prospective study (Rabenstein 2008).

Implications for research

There is a wide variation in the range of results reported in published non-randomised studies, the reasons for this being unclear. A review of the different recurrence rates, metastasis rates and complication rates with the reasons for this variation is outside the scope of this review but if undertaken elsewhere could provide useful background information for practitioners and patients and may inform the design of properly controlled trials. It is recommended that future trials should analyse survival, employing Kaplan Meier curves and hazard ratios, this being a more powerful tool than assessment of survival at five and ten years only. Quality of life and cost effectiveness should also be investigated. The condition of patients and different modalities of EMR should be considered, if possible. Ideally, production of guidelines for the management of EGCs, including protocols for treatment of patients who are unsuitable for EMR or whose tumours are not completely resected, should be guided by results from properly designed controlled trials conducted by individuals who have had proper training in EMR.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Fukase 1994	Non-randomised study (retrospective case review)

Study	Reason for exclusion
Fukase 2004	Non-randomised study (retrospective case review)
Kim 2000	Non-randomised study (retrospective case review)
Misumi 1991	Retrospective review of cases
Mizumoto 1992	Retrospective review of cases
Nishida 1993	Non-randomised study (retrospective case review)
Tada 1998	Non-randomised study (retrospective case review), reported in Tada 2000

APPENDICES

Appendix 1. MEDLINE search strategy

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized.ab.
4. placebo.ab.
5. drug therapy.fs.
6. randomly.ab.
7. trial.ab.
8. groups.ab.
9. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8
10. humans.sh.
11. 9 and 10
12. exp gastrectomy/
13. gastrectom\$.tw.
14. (gastr\$ adj10 resect\$).tw.
15. (stomach adj10 resect\$).tw.
16. or/12-15
17. (endoscop\$ adj5 mucosa\$ adj5 resect\$).tw.
18. (endoscop\$ adj3 mucosectom\$).tw.
19. or/17-18
20. 16 and 19
21. 11 and 20
22. limit 21 to yr="2006-2009"

Appendix 2. Methods to be used in future versions of the review

Data extraction and management

Two authors will independently extract the data using a specially designed data extraction form. A third team member will resolve any differences in opinion. Two authors will independently check and enter the data into RevMan5.

Assessment of risk of bias in included studies

We shall describe each study in a 'Risk of bias' table, and address the following issues, which may be associated with biased estimates of treatment effect, that is, sequence generation, allocation sequence concealment, blinding, incomplete outcome data, selective outcome reporting and other potential sources of bias (Higgins 2008). We shall report specifically on:

- (a) the method of generation of the randomisation sequence;
- (b) the method of allocation concealment - it will be considered 'adequate' if the assignment could not be foreseen;
- (c) who was blinded and not blinded (participants, clinicians, outcome assessors) if this is appropriate;
- (d) how many participants were lost to follow up in each arm, and whether reasons for losses were adequately reported;
- (e) whether all participants were analysed in the groups to which they were originally randomised (intention to treat principle).

In addition we may report on:

- (f) the baseline assessment of the participants for age, sex, duration, location and stage of cancer
- (h) whether outcome measures were described and their assessment was standardised;
- (j) the use and appropriateness of statistical analyses, where tabulated data cannot be extracted from the original publication.

We shall record information on all these components in a 'Risk of bias' table. We shall also summarise the general quality of all the studies in the section on 'Risk of bias in the included studies'.

Measures of treatment effect

For studies of a similar type of radical endoscopic therapy (that is endoscopic therapy with curative intent) versus surgery, if sufficient trials are available and their populations are clinically similar, meta-analyses of primary and secondary end-points will be carried out.

For the time-to-event outcomes (survival), these outcomes may be reported as hazard ratio (HR) or log rank test and where these measures are provided in a trial report, they will be used.

For meta-analyses of dichotomous outcomes, relative risks (RR) or odds ratios (OR) will be calculated with 95% confidence intervals (CIs) and combined for meta-analysis with RevMan5 software. Data will be combined for the same duration of follow up rounded to the nearest 6 months.

Continuous data will be combined for meta-analysis. We will use mean and standard deviations to derive a weighted mean difference (WMD) with 95% CIs using a fixed effect model.

Unit of analysis issues

We will seek input from the Cochrane Upper Gastrointestinal and Pancreatic Diseases Group editorial base for analysis issues involving any included trials with multiple treatment groups, and cluster randomised designs. We do not expect to identify any cross over trials as this design is inappropriate for this type of intervention, given that surgery and endoscopic therapies are intended to have a curative rather than temporary effect.

Dealing with missing data

We shall contact trial authors or sponsors of studies less than 10 years old to provide missing data. Where there is uncertainty about the specifics of a trial, we shall contact the trial authors for clarification.

Assessment of heterogeneity

Heterogeneity will be assessed with (I²), which provides a measure of the degree of inconsistency in the studies' results with 95% uncertainty intervals (Higgins 2008). A value of 0% indicates no heterogeneity and a value greater than 50% is considered to be substantial heterogeneity.

Assessment of reporting biases

We shall test publication bias by the use of a funnel plot when adequate data are available for similar types of endoscopic therapies. If our analysis contains sufficient trials to make visual inspection of the plot meaningful (there is no standard for this, but we will assume that five trials is the minimum), and if the presence of asymmetry in the inverted funnel suggests a systematic difference between large and small trials in their estimates of treatment effect, we may comment on this in the Discussion section.

Data synthesis

As a general rule, a fixed effect model will be used for calculations of summary estimates and their 95% CIs unless there is significant heterogeneity, in which case results will be confirmed using a random effects statistical model (DerSimonian 1986). We will compare relative risk of surviving in the endotherapy group compared with surgery at one or more years depending on the data available.

Subgroup analysis and investigation of heterogeneity

Subgroup analysis

We plan to perform subgroup analyses where adequate information is given in reports of studies. The groups will be different types of disease (mucosal cancer, submucosal cancer), and the age of participants as described by the trial authors. We may also consider subgroup analysis for types of endoscopic therapies or surgical techniques and on the basis of study design and reporting (adequate versus unclear allocation concealment for RCTs).

Investigation of heterogeneity

If substantial heterogeneity ($I^2 > 50\%$) exists between studies for the primary outcome, we shall explore the reasons for heterogeneity; such as age, cancer stage, histological type and treatment type. If it is inappropriate to pool the data because of clinical or statistical heterogeneity a systematic review without meta-analysis will be performed or a meta-analysis excluding outlying studies will be performed.

Sensitivity analysis

We plan to conduct sensitivity analyses to examine the effects of excluding studies defined as those with a moderate or high risk of bias as described in the Cochrane Handbook of Systematic Reviews of Interventions (Higgins 2008).

Adverse outcomes

We shall record:

1. the appropriateness of the methods used to detect adverse events;
2. the adequacy of reporting.

We shall describe the information qualitatively.

WHAT'S NEW

Date	Event	Description
1 October 2014	Amended	Contact details updated.
18 April 2011	Review declared as stable	Review declared stable as new evidence is unlikely.

HISTORY

Protocol first published: Issue 3, 2003

Review first published: Issue 1, 2006

Date	Event	Description
27 March 2011	New search has been performed	Updated with new search results and minor text edits, no new included studies, no other changes.
20 September 2010	Amended	Contact details updated.
10 May 2010	Amended	Contact details updated
28 June 2009	New citation required but conclusions have not changed	Updated, no new studies included

Date	Event	Description
18 April 2006	Amended	Minor update, converted to new format.

CONTRIBUTIONS OF AUTHORS

YP Wang conceived the topic and designed the review.

C Bennett, YP Wang and T Pan, screened the papers against inclusion criteria, appraised the quality of the papers and extracted data from the papers.

C Bennett and YP Wang wrote the review.

C Bennett updated the review (February 2006, June 2009, March 2011)

DECLARATIONS OF INTEREST

None known

SOURCES OF SUPPORT

Internal sources

- Chinese Cochrane Center, Chinese Center of Evidence-based Medicine, West China Hospital of Sichuan University, China.

External sources

- China Medical Board of New York (Grant number 98-680), China.

INDEX TERMS

Medical Subject Headings (MeSH)

Gastrectomy; Gastric Mucosa [*surgery]; Gastroscopy [adverse effects] [*methods]; Stomach Neoplasms [pathology] [*surgery]

MeSH check words

Humans