

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## INTERVENTIONAL PROCEDURES PROGRAMME

### Interventional procedure overview of combined endoscopic and laparoscopic removal of colonic polyps

Colonic polyps are small growths on the inside lining of the large bowel. If left untreated, there is a small risk that polyps may develop into bowel cancer after several years. Combined endoscopic and laparoscopic removal of colonic polyps is done by using both keyhole surgery and a long flexible tube with a tiny camera on the end of it, which is inserted into the bowel through the anus.

#### Introduction

The National Institute for Health and Care Excellence (NICE) has prepared this overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

#### Date prepared

This overview was prepared in February 2014 and updated in May 2014.

#### Procedure name

- Combined endoscopic and laparoscopic removal of colonic polyps

#### Specialist societies

- The Association of Coloproctology of Great Britain and Ireland (ACPGBI)
- British Society of Gastroenterology (BSG)
- The Association of Surgeons of Great Britain and Ireland

## Description

### ***Indications and current treatment***

Colonic polyps are mucosal lesions that project into the lumen of the large bowel. Most colonic polyps cause no symptoms, but they may cause rectal bleeding, mucus in stools, abdominal pain and rarely diarrhoea or constipation. If left untreated, there is a small risk (approximately 1 in 10) that polyps may develop into bowel cancer after several years.

Colonic polyps are usually removed by an endoscopic snaring. Polyps that cannot be removed endoscopically are typically large, broad-based or situated in anatomically inaccessible areas (such as behind mucosal folds) where attempted endoscopic removal could result in bowel perforation. Polyps that are unsuitable for endoscopic removal need open or laparoscopic bowel resection.

### ***What the procedure involves***

Combined endoscopic and laparoscopic removal of colonic polyps is used to excise polyps that are unsuitable or high risk for endoscopic removal, without the need for open surgery or segmental laparoscopic resection. The procedure aims to provide enhanced visualisation and enable the colon to be manoeuvred and controlled during resection of the polyp.

The procedure is done with the patient under general anaesthesia. The position of the polyp is noted by making intraluminal and extraluminal marks around the polyp using endoscopic coagulation and laparoscopic diathermy respectively. Alternatively, the location of the polyp can be marked using endoscopic tattooing. Sutures are placed laparoscopically (extraluminally) at the marked sites around the polyp. The sutures are then drawn together to invert a fold, containing the polyp, into the colonic lumen. The inversion site is then laparoscopically oversewn and the protruding tissue, including the polyp, is removed endoscopically. Alternatively, a wedge excision of the marked polyp is done laparoscopically and the polyp retrieved and removed from one of the laparoscopic port sites. It is then sent for histopathological examination.

## Literature review

### *Rapid review of literature*

The medical literature was searched to identify studies and reviews relevant to combined endoscopic and laparoscopic removal of colonic polyps. Searches were conducted of the following databases, covering the period from their commencement to 21 May 2014: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

**Table 1 Inclusion criteria for identification of relevant studies**

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded if no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with colonic polyps.
Intervention/test	Combined endoscopic and laparoscopic removal.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

### *List of studies included in the overview*

This overview is based on 781 patients from 4 non-randomised comparative studies and 5 case series.

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

**Table 2 Summary of key efficacy and safety findings on combined endoscopic and laparoscopic removal of colonic polyps.**

Study details	Key efficacy findings	Key safety findings	Comments																												
<p>Abbreviations used: CELS, Combined endoscopic-laparoscopic surgery; EASR, Endoscopy-assisted segmental resection; EATR, Endoscopy-assisted transluminal resection; EAWR, Endoscopy-assisted wedge resection; EMR, Endoscopic mucosal resection; LAEP, Laparoscopic-assisted endoscopic polypectomy; LC, Laparoscopic colectomy; LMCP, Laparoscopic-monitored colonoscopic polypectomy; LRH, Laparoscopic right hemicolectomy; SBR, Segmental bowel resection,</p> <p>Cruz RA (2011) <sup>1</sup></p> <p><b>Non-randomised comparative study</b></p> <p>United States</p> <p>Recruitment period: January 2006 to July 2010</p> <p>Study population: patients with large or broad-based colonic polyps that were unsuitable for standard endoscopic polypectomy.</p> <p><b>n=123 (25 Laparoscopic-assisted endoscopic polypectomy [LAEP] vs 30 Endoscopic mucosal resection [EMR] vs 68 Laparoscopic colectomy [LC])</b></p> <p>Mean age: 61.5 years</p> <p>Sex: 46.3% female</p> <p>Patient selection criteria: patients with large or broad-based polyps, polyps located behind mucosal folds, polyps located in tortuous colonic segments, polyps that could</p>	<p>Number of patients analysed: <b>123 (25 LAEP vs 30 EMR vs 68 LC)</b></p> <p><b>Intraoperative and postoperative outcomes</b></p> <table border="1" data-bbox="607 518 1384 842"> <thead> <tr> <th></th> <th>LAEP (n=25)</th> <th>EMR (n=30)</th> <th>LC (n=68)</th> </tr> </thead> <tbody> <tr> <td>Successful removal (%)</td> <td>76.0</td> <td>76.7</td> <td>100</td> </tr> <tr> <td>Operative failure (%) <sup>a</sup></td> <td>24.0</td> <td>23.3</td> <td>0</td> </tr> <tr> <td>Mean polyp size (cm)</td> <td>2.4±0.9</td> <td>2.2±0.9</td> <td>2.9±1.2</td> </tr> <tr> <td>Mean operation time (minutes)</td> <td>92.7±31.0</td> <td>NR</td> <td>119.2±50.1</td> </tr> <tr> <td>Estimated blood loss (ml)</td> <td>20.0±23.8</td> <td>NR</td> <td>70.0±41.2</td> </tr> <tr> <td>Length of stay (days)</td> <td>1.5±0.8</td> <td>DOD <sup>b</sup></td> <td>3.5±1.6</td> </tr> </tbody> </table> <p><sup>a</sup> Operative failure was due to failed elevation of the polyp by submucosal saline injected.</p> <p><sup>b</sup> DOD - Discharged on the day NR – Not reported</p>		LAEP (n=25)	EMR (n=30)	LC (n=68)	Successful removal (%)	76.0	76.7	100	Operative failure (%) <sup>a</sup>	24.0	23.3	0	Mean polyp size (cm)	2.4±0.9	2.2±0.9	2.9±1.2	Mean operation time (minutes)	92.7±31.0	NR	119.2±50.1	Estimated blood loss (ml)	20.0±23.8	NR	70.0±41.2	Length of stay (days)	1.5±0.8	DOD <sup>b</sup>	3.5±1.6	<p><b>Conversion</b></p> <ul style="list-style-type: none"> <li>Conversion to LC was required in 4% (1/25) of patients treated by LAEP due to intraoperative diagnosis of adenocarcinoma.</li> <li>Conversion to LC was required in 3.3% (1/30) of patients treated by EMR due to intraoperative diagnosis of adenocarcinoma.</li> </ul> <p><b>Postoperative complications within 30 days of surgery</b></p> <ul style="list-style-type: none"> <li>No postoperative complications were observed in the EMR group.</li> <li>1 ileus and 1 abdominal abscess were observed in the LAEP group.</li> <li>3 ileuses, 2 surgical site infections and 2 anastomotic leaks were observed in the LC group.</li> </ul>	<p><b>Follow-up issues:</b></p> <ul style="list-style-type: none"> <li>None identified</li> </ul> <p><b>Study design issues:</b></p> <ul style="list-style-type: none"> <li>Each procedure was carried out by one of 3 colorectal surgeons.</li> <li>LAEP was offered to patients if EMR was attempted but failed due to technical limitations. LC was performed as a salvage procedure in a subset of patients in which EMR and LAEP was attempted but failed. LC was also performed if there was suspicion of malignancy.</li> </ul> <p><b>Study population issues:</b></p> <ul style="list-style-type: none"> <li>None identified</li> </ul> <p><b>Other issues:</b></p> <ul style="list-style-type: none"> <li>None identified</li> </ul>
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Study details	Key efficacy findings	Key safety findings	Comments
<p>not be elevated for complete resection or that were associated with increased risk of complication were included.</p> <p>Exclusion criteria: Not reported</p> <p>Technique: patients underwent LAEP, EMR or LC but technical descriptions were not provided in the text; instead, authors cited papers where descriptions can be obtained. EMR was offered to all patients as a primary intervention. LAEP was offered to patients if EMR was attempted but failed due to technical limitations. LC was performed as a salvage procedure in a subset of patients in which EMR and LAEP was attempted but failed. LC was also performed if there was suspicion of malignancy.</p> <p>Follow-up: <b>30 days</b></p> <p>Conflict of interest/source of funding: not reported</p>			

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Study details	Key efficacy findings	Key safety findings	Comments
<p>Wilhelm D (2013)<sup>2</sup></p> <p><b>Case series of various combined endoscopic and laparoscopic approaches</b></p> <p>Germany</p> <p>Recruitment period: January 1997 and December 2006</p> <p>Study population: Patients with large or broad-based colonic polyps that were unsuitable for standard endoscopic polypectomy.</p> <p><b>n=146 (Laparoscopic-assisted endoscopic polypectomy [LAEP], n=8; Endoscopy-assisted wedge resection [EAWR], n=72; Endoscopy-assisted transluminal resection [EATR], n=40; Endoscopy-assisted segment resection [EASR], n=26)</b></p> <p>Mean age: 64 Sex: : 53 % female</p> <p>Patient selection criteria: patients with large polyps or broad-based polyps, polyps with a base that could not be observed, polyps behind mucosal folds and polyps located in tortuous colonic segments were included. Exclusion criteria: Patients with biopsies consistent with invasive cancer were excluded from the combined laparoscopic-endoscopic</p>	<p>Number of patients analysed: <b>n=146 (LAEP, n=8; EAWR, n=72; EATR, n=40; EASR, n=26)</b></p> <p><b>Median operation time (minutes) [range]</b> Overall: 100 [40-272] LAEP: 75 [55-90] EAWR: 92 [40-170] EATR: 93 [50-150] EASR: 123 [75-272]</p> <p><b>Postoperative outcomes</b></p> <ul style="list-style-type: none"> <li>• The overall median length of stay was 8 days (range: 3-35 days).</li> <li>• 70% (102/146) of patients required opioid analgesia for a median of 1 day (range: 0-21 days).</li> <li>• 85% (124/146) of patients required opioid analgesia for a median of 3 days (range: 0-22 days).</li> <li>• Local relapse of tubulovillous adenoma was observed in 1 patient at mean follow-up of 2.9 years.</li> <li>• Invasive adenocarcinomas were observed in 11% (17/146) of patients.</li> </ul>	<p><b>Conversion</b></p> <ul style="list-style-type: none"> <li>• Conversion to open surgery was required in 5% (7/146) of patients due to: <ul style="list-style-type: none"> <li>– 3 lesions suspected of being malignant.</li> <li>– 1 bowel perforation during colonoscopy in a patient with severe adhesions.</li> <li>– 2 difficult closures of the colostomy site.</li> <li>– 1 incomplete resection of a polyp.</li> </ul> </li> </ul> <p><b>Postoperative complications</b></p> <ul style="list-style-type: none"> <li>• Complications were reported in 25% (36/146) of patients: <ul style="list-style-type: none"> <li>– Wound infections were observed in 9.6% (14/146) of patients.</li> <li>– Urinary tract infections were observed in 3.4% (5/146) of patients.</li> <li>– Intra-abdominal abscesses were observed in 2.7% (4/146) of patients.</li> <li>– Delayed bleeding was observed in 1.4% (2/146) of</li> </ul> </li> </ul>	<p><b>Follow-up issues:</b></p> <ul style="list-style-type: none"> <li>• 10% (15/146) of patients were lost to follow-up.</li> </ul> <p><b>Study design issues:</b></p> <ul style="list-style-type: none"> <li>• Unclear whether procedures were carried out by the same group of surgeons.</li> </ul> <p><b>Study population issues</b></p> <ul style="list-style-type: none"> <li>• All combined procedures were converted to open surgery if the operative appearance of the lesion was suspicious of malignant disease.</li> </ul> <p><b>Other issues</b></p> <ul style="list-style-type: none"> <li>• Patients were assessed for complications at the time of hospital discharge. The majority of outcome measures were not stratified according to the type of procedure performed.</li> <li>• Authors did not state if frozen section pathological analysis was carried out.</li> <li>• Poor reporting of outcome measures.</li> <li>• Poor reporting of</li> </ul>

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Study details	Key efficacy findings	Key safety findings	Comments
<p>approach.</p> <p>Technique: All procedures were performed under general anaesthesia. LAEP: laparoscopic manipulation of the relevant colon segment conferred endoscopic polypectomy using an electrosurgical snare.</p> <p>EAWR: Endoscopic localisation of the polyp conferred tangential excision of the polyp with a linear stapling device. For procedures affecting the cecal region, the colonoscope was passed into the terminal ileum.</p> <p>EATR: A small colotomy was performed for polyps located near the mesentry. The lesion was elevated and resected with a linear stapling device. Closure of the colotomy site was achieved using laparoscopic sutures or a linear stapling device. EASR: for polyps inaccessible to LAEP, EAWR or EATR, laparoscopic segmental colon resection was performed under endoscopic guidance.</p> <p>Follow-up: <b>mean follow-up of 2.9 years</b></p> <p>Conflict of interest/source of funding: Not reported</p>		<p>patients.</p> <ul style="list-style-type: none"> <li>– Phlegmon was observed in 1 patient.</li> <li>– Cardiac arrhythmias were observed in 1 patient during surgery.</li> </ul> <ul style="list-style-type: none"> <li>• Reoperation was necessary in 11% (16/146) of patients due to: <ul style="list-style-type: none"> <li>– 7 postoperative complications.</li> <li>– 9 patients with pathological confirmation of malignant disease.</li> </ul> </li> <li>• 29% (31/131) of patients with long term follow-up developed metachronous adenomas.</li> </ul>	<p>outcomes.</p> <ul style="list-style-type: none"> <li>• Authors did not state what proportion of patients, in each group, had their polyps successfully removed.</li> <li>• Authors reported the occurrence of adverse events for all combined procedures, rather than rates for each individual procedure</li> </ul>



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Study details	Key efficacy findings	Key safety findings	Comments
<p>Franklin ME (2009)<sup>3</sup></p> <p><b>Retrospective case series</b></p> <p>USA</p> <p>Recruitment period: May 1990 to January 2008</p> <p>Study population: Patients with large or broad-based colonic polyps that were unsuitable for standard endoscopic polypectomy.</p> <p><b>n=176</b></p> <p>Mean age: 74.7 years</p> <p>Sex: 49% female</p> <p>Patient selection criteria: patients with large or broad-based polyps, polyps that were behind mucosal folds or polyps that were located in tortuous colonic segments were included.</p> <p>Exclusion criteria: patients with contraindications to laparoscopic surgery such as intolerance to general anaesthesia and bleeding dyscrasias were excluded</p> <p>Technique: patients underwent laparoscopic-monitored endoscopic polypectomies. Procedures were carried out under general anaesthesia using CO2 insufflation. After the polyp was located with the colonoscope, its position was noted</p>	<p>Number of patients analysed: <b>176 patients (251 polyps)</b></p> <p><b>Operative characteristics:</b></p> <ul style="list-style-type: none"> <li>• Mean polyp size: 3.69 cm (range 2-6 cm)</li> <li>• Mean operation time: 96.5 minutes</li> <li>• Mean estimated blood loss: 46.03 ml</li> <li>• Mean length of stay: 1.1 days</li> <li>• Mean time taken to return to full activities: 2 days (range 1-10 days)</li> </ul> <p><b>Recurrence:</b></p> <p>With a median follow-up of 65 months, there was no recurrence of resected polyps</p>	<ul style="list-style-type: none"> <li>• 2.3% (4/176) of patients were converted to a 'formal resection' due to failure of the combined approach.</li> <li>• 8.5% (15/176) of patients with benign disease required full thickness resection (as part of the same procedure) because of polyp size/location, problems with the technique or positive margins.</li> <li>• 10.2% (18/176) of patients were converted to a 'formal resection' due to histopathological evidence of cancer.</li> <li>• Atelectasis was observed in 5.1% (9/176) of patients (time of occurrence not reported).</li> <li>• Seroma was observed in 1.7% (3/176) of patients (time of occurrence not reported).</li> <li>• Ileus was observed in 2.3% (4/176) of patients (time of occurrence not reported).</li> </ul>	<p><b>Follow-up issues:</b></p> <ul style="list-style-type: none"> <li>• All patients were followed-up for more than 6 months, 91.6% for more than 1 year, 81.6% for more than 2 years, 69.6% for more than 3 years, 57.6% for more than 4 years, and 47.6% for more than 5 years.</li> </ul> <p><b>Study design issues:</b></p> <ul style="list-style-type: none"> <li>• Unclear whether all procedures were performed by the same surgeon(s).</li> <li>• Study may include data from patients that have already been included in a previous study by the same author (Franklin 2000).</li> </ul> <p><b>Study population issues:</b></p> <ul style="list-style-type: none"> <li>• None identified</li> </ul> <p><b>Other issues:</b></p> <ul style="list-style-type: none"> <li>• Poor reporting of outcome measures: authors did not clearly state what proportion of patients had their polyps successfully removed.</li> <li>• Authors did not state whether formal resection was performed</li> </ul>

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Study details	Key efficacy findings	Key safety findings	Comments
<p>by laparoscopic visualisation using transillumination. Polypectomy was performed using an electro-surgical snare. Histopathological testing was then carried out by frozen section analysis. Depending on the pathology report, the procedure was concluded or converted to laparoscopic resection.</p> <p>Follow-up: <b>10 years</b></p> <p>Conflict of interest/source of funding: not reported</p>			laparoscopically or by open surgery.

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Study details	Key efficacy findings	Key safety findings	Comments
<p>Franklin ME (2000)<sup>4</sup></p> <p><b>Retrospective case series</b></p> <p>United states Recruitment period: May 1990 to September 1999 Study population: patients with inaccessible polyps that could not be removed colonoscopically.</p> <p><b>n=47 (60 polyps)</b></p> <p>Median age: 72 years</p> <p>Sex: 49% female</p> <p>Patient selection criteria: patients with large or broad based polyps, polyps that were located in inaccessible areas and polyps that could not be removed satisfactorily without the risk of full thickness thermal injury were included. Exclusion criteria: patients with contraindications for laparoscopy related to co-morbidities and intolerance to general anaesthesia were excluded. Some patients with a history of multiple gastrointestinal operations or the presence of adhesions were excluded at the discretion of the operating surgeon.</p> <p>Technique: All patients underwent mechanical and antibiotic bowel preparations prior to surgery. All patients underwent LAEP under general anaesthesia using CO<sub>2</sub></p>	<p>Number of patients analysed: <b>47</b></p> <ul style="list-style-type: none"> <li>• Margins were clear for all polyps removed.</li> <li>• 97% of patients reacted to the procedure as if they had undergone colonoscopy alone (numerator not reported).</li> <li>• Mean polyp size: 2.8cm</li> <li>• Mean length of stay: 21 hours (range: 8 hours – 5 days)</li> <li>• Return to liquid diet was started at 6 hours postoperatively.</li> <li>• 'Return to physical activity was usually within 2 days'</li> <li>• 1 patient had a new polyp at a different site.</li> <li>• No patients progressed to carcinoma at 6 month follow-up.</li> </ul>	<ul style="list-style-type: none"> <li>• Conversion to other types of surgical procedures was required in 10.6% (5/47) of patients. <ul style="list-style-type: none"> <li>– 3 patients underwent laparoscopic segmental resection for malignancy that had not been diagnosed preoperatively.</li> <li>– 2 patients with benign disease underwent laparoscopic segmental resection 'due to circumferential involvement'.</li> <li>– 2 patients with benign topathologic diagnosis underwent colotomy due to large polyps (&gt;6cm).</li> </ul> </li> <li>• Seroma was observed at the umbilical port site of 1 patient.</li> </ul>	<p><b>Follow-up issues:</b></p> <ul style="list-style-type: none"> <li>• Authors state that colonoscopy was performed 6 months after surgery and yearly afterwards but no follow-up period was reported.</li> </ul> <p><b>Study design issues:</b></p> <ul style="list-style-type: none"> <li>• Unclear whether procedures were carried out by the same group of surgeons.</li> <li>• Study may include data from patients included by another study by the same author (Franklin 2009).</li> </ul> <p><b>Study population issues:</b></p> <ul style="list-style-type: none"> <li>• Some patients with adhesions or a history of multiple gastrointestinal operations were excluded at the discretion of the operating surgeon.</li> </ul> <p><b>Other issues:</b></p> <ul style="list-style-type: none"> <li>• Poor reporting of outcomes.</li> <li>• Authors state that margins were clear for all polyps; however, there is no indication</li> </ul>

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Study details	Key efficacy findings	Key safety findings	Comments
<p>insufflation. The polyp was located intraluminally and its position was noted with direct vision using a laparoscope or via intense illumination by the colonoscope. Polyps were removed by an endoscopist using a surgical snare.</p> <p>Follow-up: <b>not reported</b></p> <p>Conflict of interest/source of funding: not reported</p>			<p>how many polyps were successfully removed using the approach the approach. Furthermore, authors state that conversion to other types of surgery was required in 10.6 % of patients.</p>

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Study details	Key efficacy findings	Key safety findings	Comments
<p>Goh C (2013)<sup>5</sup></p> <p><b>Retrospective case series</b></p> <p>Ireland</p> <p>Recruitment period: September 2010 to May 2013</p> <p>Study population: Patients with complex benign polyps that were unsuitable for colonoscopic removal.</p> <p><b>n=30</b></p> <p>Median age: 65 (range 62-74)</p> <p>Sex: 40% female</p> <p>Patient selection criteria: patients with large polyps or broad-based polyps, polyps with a base that could not be observed, polyps behind mucosal folds and polyps located in tortuous colonic segments were included.</p> <p>Exclusion criteria: patients with rectal polyps were excluded.</p> <p>Technique: patients underwent LAEP. All procedures were carried out under general anaesthesia using CO<sub>2</sub> insufflation. Polyps were exposed using laparoscopic manipulation and elevated with a sub-mucosal injection of adrenalin in saline. Polyps were then removed using a hot rotatable endoscopic</p>	<p>Number of patients analysed: <b>n=30</b></p> <ul style="list-style-type: none"> <li>73% (22/30) of patients successfully had their polyps removed by LAEP as intended. Of these patients all resection margins were clear.</li> <li>Median operation time: 105 minutes (range 75-125)</li> <li>Median length of stay, 2 days; range, 1-3 days.</li> <li>Median length of stay for converted patients, 5.5 days; range, 3.5-6.8 days.</li> <li>6.7% (2/30) of patients had new polyps distant from the initial polypectomy site at a median follow-up of 20 months.</li> </ul>	<p><b>Conversion</b></p> <ul style="list-style-type: none"> <li>26.6% (8/30) of procedures were converted to colotomy or laparoscopic colectomy due to the following: <ul style="list-style-type: none"> <li>2 patients with large polyps</li> <li>3 patients with polyps in difficult locations.</li> <li>2 failed polypectomies</li> <li>1 ulcer</li> </ul> </li> </ul> <p><b>Postoperative complications (time of occurrence not reported)</b></p> <ul style="list-style-type: none"> <li>Postoperative bleeding, that resolved with conservative treatment, was observed in 3.3% (1/30) of patients: details of treatment were not reported.</li> <li>Ileus was observed in 3.3% (1/30) of patients.</li> <li>Urinary retention was observed in 6.6% (2/30) of patients</li> </ul>	<p><b>Follow-up issues:</b></p> <ul style="list-style-type: none"> <li>None identified</li> </ul> <p><b>Study design issues:</b></p> <ul style="list-style-type: none"> <li>None identified</li> </ul> <p><b>Study population issues:</b></p> <ul style="list-style-type: none"> <li>Preoperatively, all patients were thought to have a benign polyp based on a review of colonoscopy images and histological examinations of colonoscopic biopsies.</li> </ul> <p><b>Other issues:</b></p> <ul style="list-style-type: none"> <li>None identified</li> </ul>

Abbreviations used: CELS, Combined endoscopic-laparoscopic surgery; EASR, Endoscopy-assisted segmental resection; EATR, Endoscopy-assisted transluminal resection; EAWR, Endoscopy-assisted wedge resection; EMR, Endoscopic mucosal resection; LAEP, Laparoscopic-assisted endoscopic polypectomy; LC, Laparoscopic colectomy; LMCP, Laparoscopic-monitored colonoscopic polypectomy; LRH, Laparoscopic right hemicolectomy; SBR, Segmental bowel resection,			
Study details	Key efficacy findings	Key safety findings	Comments
snare.  Follow-up: <b>6 months</b>  Conflict of interest/source of funding: not reported			

Abbreviations used: CELS, Combined endoscopic-laparoscopic surgery; EASR, Endoscopy-assisted segmental resection; EATR, Endoscopy-assisted transluminal resection; EAWR, Endoscopy-assisted wedge resection; EMR, Endoscopic mucosal resection; LAEP, Laparoscopic-assisted endoscopic polypectomy; LC, Laparoscopic colectomy; LMCP, Laparoscopic-monitored colonoscopic polypectomy; LRH, Laparoscopic right hemicolectomy; SBR, Segmental bowel resection,			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Yan J (2011) <sup>6</sup></p> <p><b>Retrospective case series</b></p> <p>USA</p> <p>Recruitment period: January 2003 to July 2008</p> <p>Study population: patients with 'complex' right colon polyps unsuitable for removable colonoscopically.</p> <p>n=23</p> <p>Mean age: 70 years</p> <p>Sex: 39% female</p> <p>Patient selection criteria: Inclusion criteria: patients with large or sessile polyps (<math>\leq 5</math>cm), polyps that were not removed after multiple attempts of standard endoscopic snare polypectomy or polyps located in the right colon that were not suitable for endoscopic removal were included. Preoperative endoscopic biopsies established that all polyps were benign but including high-grade dysplasia.</p> <p>Exclusion criteria: patients with multiple or familial adenomatous polyposis, Irritable Bowel Disease that required surgery, simultaneous left colon or rectal cancer, other abdominal malignant diseases, appendiceal masses or a history of</p>	<p>Number of patients analysed: n=23</p> <ul style="list-style-type: none"> <li>87% (20/23) of patients successfully underwent combined endoscopic and laparoscopic removal of polyps.</li> <li>Mean polyp size: 3.0 cm</li> <li>Median length of stay, 2 days; range, 1-5 days.</li> <li>Recurrence of resected polyps was observed in 13% (3/23) of patients at follow-up.</li> <li>17.4% (4/23) of patients had de novo polyps.</li> </ul>	<ul style="list-style-type: none"> <li>13% (3/23) of patients were converted to laparoscopic resection after laparo-endoscopic evaluations. <ul style="list-style-type: none"> <li>2 patients due to failed elevation of the polyp.</li> <li>1 patient due to the identification of a polyp &gt;5 cm in diameter.</li> </ul> </li> <li>No organ damage, perforation, haemorrhage or serosal tears were observed during surgery.</li> <li>13% (3/23) of patients required precautionary sutures to reinforce the colon wall because it appeared to be thin.</li> <li>30.4% (7/23) of patients required precautionary sutures even though there was no evidence of colon wall thinning.</li> </ul>	<p><b>Follow-up issues:</b></p> <ul style="list-style-type: none"> <li>None identified</li> </ul> <p><b>Study design issues:</b></p> <ul style="list-style-type: none"> <li>None identified</li> </ul> <p><b>Study population issues:</b></p> <ul style="list-style-type: none"> <li>None identified</li> </ul> <p><b>Other issues:</b></p> <ul style="list-style-type: none"> <li>None identified</li> </ul>

Abbreviations used: CELS, Combined endoscopic-laparoscopic surgery; EASR, Endoscopy-assisted segmental resection; EATR, Endoscopy-assisted transluminal resection; EAWR, Endoscopy-assisted wedge resection; EMR, Endoscopic mucosal resection; LAEP, Laparoscopic-assisted endoscopic polypectomy; LC, Laparoscopic colectomy; LMCP, Laparoscopic-monitored colonoscopic polypectomy; LRH, Laparoscopic right hemicolectomy; SBR, Segmental bowel resection,			
Study details	Key efficacy findings	Key safety findings	Comments
<p>previous major multiple abdominal surgeries were excluded.</p> <p>Technique: Polyps were removed either by LAEP or EAWR. All procedures were performed under general anaesthesia using CO2 insufflation. In patients that received LAEP, polyps were elevated with submucosal injections of indigo carmine blue solution and removed using electro-surgical snares. Polyps were then extracted transanally and sent to pathology for frozen-section analysis. In patients that received EAWR, colonoscopy was used to locate the polyp and monitor adequate surgical margin when excision of the polyp was performed.</p> <p>Follow-up: <b>12 months</b></p> <p>Conflict of interest/source of funding: not reported</p>			



Abbreviations used: CELS, Combined endoscopic-laparoscopic surgery; EASR, Endoscopy-assisted segmental resection; EATR, Endoscopy-assisted transluminal resection; EAWR, Endoscopy-assisted wedge resection; EMR, Endoscopic mucosal resection; LAEP, Laparoscopic-assisted endoscopic polypectomy; LC, Laparoscopic colectomy; LMCP, Laparoscopic-monitored colonoscopic polypectomy; LRH, Laparoscopic right hemicolectomy; SBR, Segmental bowel resection,																															
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<p>Jang H (2013) /</p> <p><b>Non-randomised comparative study</b></p> <p>USA</p> <p>Recruitment period: not reported</p> <p>Study population: patients with benign polyps that were unsuitable for endoscopic polypectomy.</p> <p><b>n=26 (13 Laparoscopic-assisted endoscopic polypectomy [LAEP] vs 4 Endoscopy-assisted wedge resection [EAWR] vs 9 Segmental bowel resection [SBR])</b></p> <p>Mean Age: 60.7 years</p> <p>Sex: 61.5% female</p> <p>Patient selection criteria: patients with benign polyps which were unsuitable for endoscopic polypectomy were included. Exclusion criteria: patients with polyps containing invasive carcinoma, high grade dysplasia or carcinoma in situ were excluded. Patients with familial adenomatous polyposis or other polyposis syndromes were also excluded.</p> <p>Technique: All combined procedures were carried out under general anaesthesia using CO<sub>2</sub> insufflation. LAEP: endoscopic polypectomy was</p>	<p>Number of patients analysed: <b>26 (13 LAEP vs 4 EAWR vs 9 SBR)</b></p> <table border="1"> <thead> <tr> <th>Outcome</th> <th>LAEP</th> <th>EAWR</th> <th>SBR</th> <th>p value</th> </tr> </thead> <tbody> <tr> <td>Mean operation time (minutes±SD)</td> <td>185.3±59.8</td> <td>225.3±80.9</td> <td>282.7±95.6</td> <td>N/A</td> </tr> <tr> <td>Median length of stay (days) [range]</td> <td>3 [2.0-4.3]</td> <td>5 [2.4-7.1]</td> <td>5 [4.1-6.1]</td> <td>0.0037<sup>a</sup></td> </tr> <tr> <td>Median time to first flatus (days) [range]</td> <td>1 [1.0-2.1]</td> <td>2 [0.7-3.3]</td> <td>3 [2.2-3.3]</td> <td>0.0099<sup>a</sup></td> </tr> <tr> <td>Median time to first bowel movement (days) [range]</td> <td>2 [1.3-2.3]</td> <td>2 [0.2-4.3]</td> <td>3 [2.2-3.8]</td> <td>0.0118<sup>a</sup></td> </tr> </tbody> </table> <p><sup>a</sup> Statistically significant differences were observed between groups.</p> <ul style="list-style-type: none"> <li>Residual adenoma was reported in 15.4% (2/13) of LAEP patients.</li> </ul>				Outcome	LAEP	EAWR	SBR	p value	Mean operation time (minutes±SD)	185.3±59.8	225.3±80.9	282.7±95.6	N/A	Median length of stay (days) [range]	3 [2.0-4.3]	5 [2.4-7.1]	5 [4.1-6.1]	0.0037 <sup>a</sup>	Median time to first flatus (days) [range]	1 [1.0-2.1]	2 [0.7-3.3]	3 [2.2-3.3]	0.0099 <sup>a</sup>	Median time to first bowel movement (days) [range]	2 [1.3-2.3]	2 [0.2-4.3]	3 [2.2-3.8]	0.0118 <sup>a</sup>	<ul style="list-style-type: none"> <li>Prolonged ileus was observed in 15.4% (2/13) of LAEP patients and 25% (1/4) of EAWR patients.</li> <li>38% (5/13) of LAEPs were converted to SBRs.</li> <li>23% (3/13) of LAEPs were converted to EAWRs.</li> <li>Small foci of invasive carcinoma were found in 23% (3/13) of polyps of patients from the LAEP group whose frozen section analyses had shown adenoma only. Patients underwent subsequent SBR and pathology revealed no cancer in the bowel wall or in the lymph nodes.</li> </ul>	<p><b>Follow-up issues:</b></p> <ul style="list-style-type: none"> <li>None identified</li> </ul> <p><b>Study design issues:</b></p> <ul style="list-style-type: none"> <li>Small study sample size may result in low statistical power.</li> </ul> <p><b>Study population issues:</b></p> <ul style="list-style-type: none"> <li>None identified</li> </ul> <p><b>Other issues:</b></p> <ul style="list-style-type: none"> <li>Frozen section pathological analysis was carried out immediately. If invasive cancer was found the procedure was converted to a segmental bowel resection.</li> <li>Authors did not explicitly state what proportion of patients, in each group, had their polyps successfully removed. They reported that all polyps were removed successfully but subsequently state that 38% (5/13) of LAEPs were converted to SBRs and 23% (3/13) of LAEPs were converted to EAWRs.</li> </ul>
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Study details	Key efficacy findings	Key safety findings	Comments
<p>performed using a saline lift followed by removal with a standard surgical snare or removal in a piecemeal fashion.</p> <p>EAWR: wedge resection was carried out on polyps not suitable for LAEP. Tattoos alerted the surgeon of the polyp's location and resection was carried out using a laparoscopic stapling device under endoscopic guidance.</p> <p>SBR: a standard oncological segmental bowel resection was performed on polyps judged inappropriate for LAEP or EAWR.</p> <p>Follow-up: <b>22 months</b></p> <p>Conflict of interest/source of funding: not reported</p>			

Abbreviations used: CELS, Combined endoscopic-laparoscopic surgery; EASR, Endoscopy-assisted segmental resection; EATR, Endoscopy-assisted transluminal resection; EAWR, Endoscopy-assisted wedge resection; EMR, Endoscopic mucosal resection; LAEP, Laparoscopic-assisted endoscopic polypectomy; LC, Laparoscopic colectomy; LMCP, Laparoscopic-monitored colonoscopic polypectomy; LRH, Laparoscopic right hemicolectomy; SBR, Segmental bowel resection,																									
Study details	Key efficacy findings		Key safety findings	Comments																					
<p>Lee MK (2013)<sup>8</sup></p> <p><b>Non-randomised comparative study</b></p> <p>USA</p> <p>Recruitment period: August 2008 to October 2013</p> <p>Study population: Patients with large colonic polyps that were unsuitable for standard endoscopic polypectomy.</p> <p><b>n=14 (5 Combined endoscopic-laparoscopic surgery [CELS] vs 9 bowel resection)</b></p> <p>Age: CELS group, 64.9 years; resection group, 68.3 years</p> <p>Sex: not reported</p> <p>Patient selection criteria: patients with large polyps not suitable for removal by endoscopy, polyps that appeared to be benign during endoscopy and polyps that were biopsied and found to be benign or exhibit high grade dysplasia were included.</p> <p>Exclusion criteria: not reported.</p> <p>Technique: All CELS procedures were carried out under general anaesthesia using CO<sub>2</sub> insufflation. Endoscopic polypectomy was performed using a saline lift followed</p>	<p>Number of patients analysed: <b>14 (5 CELS vs 9 resection)</b></p> <p><b>Intra-operative and postoperative outcomes</b></p> <table border="1"> <thead> <tr> <th>Outcome</th> <th>CELS</th> <th>Resection</th> </tr> </thead> <tbody> <tr> <td>Successful removal (%) [n]</td> <td>100 [5]</td> <td>N/A*</td> </tr> <tr> <td>Mean polyps size (cm)</td> <td>2.3</td> <td>2.9</td> </tr> <tr> <td>Mean operation time (minutes)</td> <td>159</td> <td>205</td> </tr> <tr> <td>Mean Length of stay (days)</td> <td>1</td> <td>5</td> </tr> <tr> <td>Residual polyp at follow-up (%) [n]</td> <td>40 [2]</td> <td>N/A*</td> </tr> <tr> <td>De novo polyp at follow-up (%) [n]</td> <td>40 [2]</td> <td>N/A*</td> </tr> </tbody> </table> <p>* N/A – Not available</p>		Outcome	CELS	Resection	Successful removal (%) [n]	100 [5]	N/A*	Mean polyps size (cm)	2.3	2.9	Mean operation time (minutes)	159	205	Mean Length of stay (days)	1	5	Residual polyp at follow-up (%) [n]	40 [2]	N/A*	De novo polyp at follow-up (%) [n]	40 [2]	N/A*	<ul style="list-style-type: none"> <li>No postoperative complications were observed in the CELS group.</li> <li>2 wound infections and 1 ileus was observed in the resection group (time of occurrence was not reported).</li> </ul>	<p><b>Follow-up issues:</b></p> <ul style="list-style-type: none"> <li>No patients were lost to follow-up.</li> </ul> <p>Study design issues:</p> <ul style="list-style-type: none"> <li>Unclear whether procedures were carried out by the same group of surgeons.</li> </ul> <p><b>Study population issues:</b></p> <ul style="list-style-type: none"> <li>Study sample size was too small to carry employ inferential statistics.</li> </ul> <p><b>Other issues:</b></p> <ul style="list-style-type: none"> <li>Authors did not give any details about what surgical approach was used to perform bowel resections.</li> </ul>
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Study details	Key efficacy findings	Key safety findings	Comments
<p>by removal with a surgical snare, under laparoscopic visualisation. Laparoscopic manipulation of the serosal surface of the colon wall was carried out if needed. After completion of the polypectomy, a frozen section analysis was performed. Authors did not give any details about what surgical approach was used to perform bowel resections.</p> <p>Follow-up: <b>Up to 12 months</b></p> <p>Conflict of interest/source of funding: not reported</p>			

Abbreviations used: CELS, Combined endoscopic-laparoscopic surgery; EASR, Endoscopy-assisted segmental resection; EATR, Endoscopy-assisted transluminal resection; EAWR, Endoscopy-assisted wedge resection; EMR, Endoscopic mucosal resection; LAEP, Laparoscopic-assisted endoscopic polypectomy; LC, Laparoscopic colectomy; LMCP, Laparoscopic-monitored colonoscopic polypectomy; LRH, Laparoscopic right hemicolectomy; SBR, Segmental bowel resection,			
Study details	Key efficacy findings	Key safety findings	Comments
Franklin ME (2013) <sup>9</sup>  <b>Abstract of non-randomised comparative study</b>  USA  Recruitment period: 1991 to 2012  Study population: patients with right colon polyps that were unsuitable for endoscopic removal.  <b>n = 196 (119 Laparoscopic-monitored colonoscopic polypectomy [LMCP] vs 77 Laparoscopic right hemicolectomy [LRH])</b>  Age: not reported  Sex: not reported  Patient selection criteria: not reported  Technique: not reported  Follow-up: <b>up to 196 months</b>  Conflict of interest/source of funding: not reported	<b>Efficacy data not reported as this study was published as a conference abstract.</b>	<ul style="list-style-type: none"> <li>5.8% (7/119) of LMCP procedures were converted to LRH due to intra-operative pathological findings of adenocarcinoma.</li> <li>4.2% (5/119) of patients in the LMCP group underwent partial cecectomy or primary repair due to colonic wall damage during polypectomy.</li> </ul>	<b>Follow-up issues:</b> <ul style="list-style-type: none"> <li>None identified</li> </ul> <b>Study design issues:</b> <ul style="list-style-type: none"> <li>None identified</li> </ul> <b>Study population issues:</b> <ul style="list-style-type: none"> <li>None identified</li> </ul> <b>Other issues:</b> <ul style="list-style-type: none"> <li>None identified</li> </ul>

## **Efficacy**

### **Successful removal of polyps**

In a non-randomised comparative study of 123 patients treated by laparoscopic-assisted endoscopic polypectomy (n=25), endoscopic mucosal resection (n=30) or laparoscopic colectomy (n=68) successful removal of polyps was reported in 76%, 76% and 100% of patients respectively<sup>1</sup>.

In a case series of 47 patients treated by laparoscopic-assisted endoscopic polypectomy resection margins were clear for all polyps removed<sup>4</sup>.

In a case series of 30 patients treated by laparoscopic-assisted endoscopic polypectomy successful removal of polyps was reported in 73% (22/30) of patients. In these patients, all resection margins were clear<sup>5</sup>.

In a case series of 23 patients treated either by laparoscopic-assisted endoscopic polypectomy or endoscopy-assisted laparoscopic wedge resection successful removal of polyps was reported in 87% (20/23) of all patients<sup>6</sup>.

In a non-randomised comparative study of 26 patients treated by laparoscopic-assisted endoscopic polypectomy (n=13), endoscopy-assisted wedge resection (n=4) or segmental bowel resection (n=9) residual adenoma was reported in 15.4% (2/13) of patients in the laparoscopic-assisted endoscopic polypectomy group. Percentages were not stated for other groups<sup>7</sup>.

### **Recurrence**

In a case series of 146 patients treated by various combined endoscopic and laparoscopic approaches (including laparoscopic-assisted endoscopic polypectomy [n=8], endoscopy-assisted wedge resection [n=72], endoscopy-assisted transluminal resection [n=40] and endoscopy-assisted segmental resection [n=26]) 1 recurrence of a tubulovillous adenoma was reported at mean follow-up of 2.9 years<sup>2</sup>.

In a case series of 176 patients treated by laparoscopic-monitored endoscopic polypectomy no recurrence of resected polyps was observed at median follow-up of 65 months<sup>3</sup>.

In the case series of 23 patients treated either by laparoscopic-assisted endoscopic polypectomy or endoscopy-assisted laparoscopic wedge resection recurrence of resected polyps was observed in 13% (3/23) of all patients<sup>6</sup>.

### **Operating times**

In the case series of 146 patients treated by various combined endoscopic and laparoscopic approaches, median operating times were 75 minutes for laparoscopic-assisted endoscopic polypectomy (n=8), 92 minutes for endoscopy-assisted wedge resection (n=72), 93 minutes for endoscopy-assisted transluminal resection (n=40) and 123 minutes for endoscopy-assisted segmental resection (n=26)<sup>2</sup>.

In the non-randomised comparative study of 26 patients treated by laparoscopic-assisted endoscopic polypectomy (n=13), endoscopy-assisted wedge resection (n=4) or segmental bowel resection (n=9) mean operating times were 185.3, 225.3 and 282.7 minutes respectively<sup>7</sup>.

### **Safety**

#### **Conversion to other types of surgery**

Conversion to open surgery was needed in 5% (7/146) of patients in the case series of 146 patients treated by various combined endoscopic and laparoscopic approaches. The reasons for conversion to open surgery were 3 incidents of suspected malignant tumours, 1 bowel perforation, 2 difficult closures of the resection site and 1 incomplete resection of a polyp<sup>2</sup>.

Conversion to laparoscopic colectomy was needed in 4% (1/25) of patients treated by laparoscopic-assisted polypectomy, because of intraoperative diagnosis of adenocarcinoma, in the non-randomised comparative study of 123 patients treated by laparoscopic-assisted endoscopic polypectomy (n=25), endoscopic mucosal resection (n=30) or laparoscopic colectomy (n=68)<sup>1</sup>.

Conversion to a 'formal resection' was needed in 2.3% (4/176) of patients in the case series of 176 patients treated by laparoscopic-monitored endoscopic polypectomy, because of failure of the combined approach: the authors did not state whether formal resection was performed laparoscopically or by open surgery. In the same

study, 10.2% (18/176) of patients were converted to a 'formal resection' due to histopathological evidence of cancer<sup>3</sup>.

Conversion to colotomy or laparoscopic celectomy was needed in 26.6% (8/30) of patients in the case series of 30 treated by laparoscopic-assisted endoscopic polypectomy because of 2 cases of large polyps, 3 cases of polyps located in difficult anatomical locations, 2 failed polypectomies and the presence of 1 ulcer<sup>5</sup>.

Conversion to laparoscopic right hemicolectomy was needed in 5.8% (7/119) of patients treated by laparoscopic-monitored endoscopic polypectomy, because of intraoperative pathological diagnosis of adenocarcinoma, in a non-randomised comparative study of 196 patients treated by laparoscopic-monitored endoscopic polypectomy or laparoscopic right hemicolectomy<sup>9</sup>.

### **Infection**

Wound infections were observed in 9.6% (14/146) of patients in the case series of 146 patients treated by various combined endoscopic and laparoscopic approaches. In the same study, intra-abdominal abscesses were reported in 2.7% (4/146) of patients: CT-guided drainage of abscesses was needed in 3 patients and 1 patient needed re-operation<sup>2</sup>.

### **Other adverse events**

Small foci of invasive carcinoma were found in 23% (3/13) of polyps from patients in the laparoscopic-assisted endoscopic polypectomy group whose frozen section analyses had shown adenoma only in the non-randomised comparative study of 26 patients treated by laparoscopic-assisted endoscopic polypectomy (n=13), endoscopy-assisted wedge resection (n=4) or segmental bowel resection (n=9). These patients underwent subsequent segmental bowel resection (in another procedure) and pathology revealed no cancer in the bowel wall or in the lymph nodes<sup>7</sup>.

Postoperative bleeding, which resolved with conservative treatment, was reported in 3.3% (1/30) of patients in the case series of 30 patients treated by laparoscopic-assisted endoscopic polypectomy: details of treatment were not provided. In the same study, urinary retention was observed in 6.6% (2/30) of patients<sup>5</sup>.



Delayed bleeding was reported in 1.4% in (2/146) of patients in the case series of 146 patients treated by various combined endoscopic and laparoscopic approaches. In the same study, cardiac arrhythmia was reported in 1 patient during surgery and phlegmon was reported in 1 patient postoperatively<sup>2</sup>.

Atelectasis was reported in 5.1% (9/176) of patients in a case series of 176 patients treated by laparoscopic-monitored endoscopic polypectomy (time of occurrence not reported). In the same study, seroma was observed in 1.7% (3/176) of patients and ileus was observed in 2.3% (4/176) of patients<sup>3</sup>.

Precautionary sutures were needed to reinforce the colon wall of 13% (7/23) of patients in the case series of 23 patients treated either by laparoscopic-assisted endoscopic polypectomy or endoscopy-assisted laparoscopic wedge resection<sup>6</sup>.

### ***Validity and generalisability of the studies***

- Various combined endoscopic and laparoscopic approaches can be used to remove colonic polyps.
- In some studies different types of combined approaches were grouped together and outcome measures were reported as if they were the same procedure<sup>2,6</sup>.
- In some studies, authors did not explicitly state what proportion of patients had their polyps successfully removed using combined endoscopic and laparoscopic approaches<sup>2,3,4,7</sup>. Authors reported the proportion of procedures that were converted to other types of surgery or the number of residual polyps identified at follow-up endoscopy; however, it is left down to the reader to conclude what proportion of combined procedures were successful.
- Some of the studies adopted a 'cross over' design in which unsuccessful endoscopic polypectomies were converted to combined endoscopic and laparoscopic approaches. If combined procedures were unsuccessful they were converted to open or laparoscopic segmental resections.
- The majority of studies did not employ any inferential statistics and results were mainly described in prose rather than tables or graphs.
- It was difficult to identify any strengths or weaknesses in the available literature because of brief methods sections and limited or unstructured reporting of outcome measures.

### ***Existing assessments of this procedure***

There were no published assessments from other organisations identified at the time of the literature search.

### ***Related NICE guidance***

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

#### **Interventional procedures**

- Endoscopic submucosal dissection of lower gastrointestinal lesions. NICE interventional procedure guidance 335 (2010). Available from: [www.nice.org.uk/guidance/IPG335](http://www.nice.org.uk/guidance/IPG335)
- Computed tomographic colonography (virtual colonoscopy). NICE interventional procedure guidance 129 (2005). Available from: [www.nice.org.uk/guidance/IPG129](http://www.nice.org.uk/guidance/IPG129)

#### **Clinical guidelines**

- Colonoscopic surveillance for prevention of colorectal cancer in people with ulcerative colitis, Crohn's disease or adenomas. NICE clinical guideline 118 (2011). Available from: [www.nice.org.uk/guidance/CG118](http://www.nice.org.uk/guidance/CG118)

### **Specialist advisers' opinions**

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and does not represent the view of the society.

Mr Charles Maxwell-Armstrong and Mr John I Jenkins (Association of Coloproctology of Great Britain and Ireland); Dr Sunil Dolwani, Professor Matt Rutter and Professor Brian Saunders (British Society of Gastroenterology)

- Three specialist advisers perform the procedure regularly, 2 specialist advisers have never performed the procedure.

- Two specialist advisers described the procedure as novel and of uncertain safety and efficacy, 3 specialist advisers described the procedure as a minor variation on an existing procedure that is unlikely to alter that procedure's safety and efficacy
- Four specialist advisers stated that fewer than 10% of specialists are engaged in this area of work. The other specialist adviser could not give an estimate of the proportion of doctors who perform the procedure.
- Comparator treatments include endoscopic mucosal resection, colectomy and laparoscopic colonic resection.
- The specialist advisers did not highlight any additional adverse events reported in literature.
- One specialist adviser stated that inflammatory responses to tattoo ink in adjacent tissues, difficulty with laparoscopy as a result of gross colonic distension from colonoscopy and bleeding after polypectomy bleeding were anecdotal adverse events.
- The specialist advisers listed theoretical adverse events as incomplete resection, bleeding that may be difficult to control intraluminally, bowel perforation, anastomotic leak, faecal contamination, infection, missed malignancy, tumour spillage and loss of colonic circumference rendering simple closure difficult or impossible.
- The specialist advisers listed key efficacy outcomes as complete polyp excision allowing for complete pathological assessment, recurrence rates, morbidity compared against standard laparoscopic resection or traditional surgery, avoidance of major laparoscopic resection and maintenance of bowel function.
- Specialist advisers stated that the main uncertainties surrounding the procedure involve the recurrence of resected polyps, excision at the mesenteric border, accurate assessment of likely nodal disease involvement in early malignant polyps, closure of defect, optimal localisation techniques and optimal wall excision techniques.
- One specialist adviser considered the procedure to have a moderate impact on the NHS and 4 specialist advisers considered the procedure to have a minor impact.

## Patient commentators' opinions

NICE's Public Involvement Programme sent 9 questionnaires to 1 NHS trust for distribution to patients who had the procedure (or their carers). NICE received 2 completed questionnaires.

The patient commentators' views on the procedure were consistent with the published evidence and the opinions of the specialist advisers.

## Issues for consideration by IPAC

Ongoing trials:

- NCT01986699: Laparoscopic-assisted colonoscopic polypectomy; type, randomised controlled trial; location, United States; estimated enrolment, 34; estimated completion date, October 2013.

## References

1. Cruz, R. A., Ragupathi, M., Pedraza, R., Pickron, T. B., Le, A. T., Haas, E. M. (2011) Minimally invasive approaches for the management of "difficult" colonic polyps. *Diagnostic & Therapeutic Endoscopy* 2011 682793-2011.
2. Wilhelm, D., von, Delius S., Weber, L., Meining, A., Schneider, A., Friess, H., Schmid, R. M., Frimberger, E., Feussner, H. (2009) Combined laparoscopic-endoscopic resections of colorectal polyps: 10-year experience and follow-up. *Surgical Endoscopy* 23 (4): 688-693.
3. Franklin, Jr and Portillo, G. (2009) Laparoscopic monitored colonoscopic polypectomy: Long-term follow-up. *World Journal of Surgery* 33 (6): 1306-1309.
4. Franklin, M. E., Jr., Diaz-E JA, Abrego, D., Parra-Davila, E., Glass, J. L (2000) Laparoscopic-assisted colonoscopic polypectomy: the Texas Endosurgery Institute experience. *Diseases of the Colon & Rectum* 43 (9): 1246-1249.
5. Goh, C., Burke, J. P., McNamara, D. A., Cahill, R. A., Deasy, J. (2013) Endolaparoscopic removal of colonic polyps. *Colorectal Dis.* 2013.

6. Yan, J., Trencheva, K., Lee, S. W., Sonoda, T., Shukla, P., Milsom, J. W. (2011) Treatment for right colon polyps not removable using standard colonoscopy: combined laparoscopic-colonoscopy approach. *Diseases of the Colon & Rectum* 54 (6): 753-758.
7. Jang, J. H., Kirchoff, D., Holzman, K., Park, K., Grieco, M., Cekic, V., Naffouje, S., Kluft, J., Whelan, R. L. (2013) Laparoscopic-facilitated endoscopic submucosal dissection, mucosal resection, and partial circumferential ("wedge") colon wall resection for benign colorectal neoplasms that come to surgery. *Surgical Innovation*. 20 (3): 234-240.
8. Lee, M. K., Chen, F., Esrailian, E., Russell, M., Sack, J., Lin, A. Y., Yoo, J. (2013) Combined endoscopic and laparoscopic surgery may be an alternative to bowel resection for the management of colon polyps not removable by standard colonoscopy. *Surgical Endoscopy* 27 (6): 2082-2086.
9. Franklin, Jr, Liang, S., Glass, J. L. (2013) Laparoscopic monitored colonoscopic polypectomy vs laparoscopic right hemicolectomy: A comparative analysis on 187 patients with polyps in the right colon. *Surgical Endoscopy and Other Interventional Techniques*. Conference: 2013

## Appendix A: Additional papers on combined endoscopic and laparoscopic removal of colonic polyps

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Albert, M., Larach, S., Atallah, S. (2010) Transanal minimally invasive surgery (TAMIS). Diseases of the Colon and Rectum. Conference: Annual Meeting of the American Society of Colon and Rectal Surgeons, ASCRS Minneapolis, MN United States. Conference publication.	Conference proceeding of a case series.  n=15  Follow-up: not reported	Successful removal of 'neoplasms' was reported in all patients and all margins were clear. One patient was readmitted with self-limited bleeding. A second patient had an anterior entry into the peritoneal cavity which was closed without incident.	Study was published as a conference proceeding. Other studies with similar safety and efficacy outcome measures were available.
Agrawal, D., Chak, A., Champagne, B. J., Marks, J. M., Delaney, C. P. (2010) Endoscopic mucosal resection with full-thickness closure for difficult polyps: a prospective clinical trial. Gastrointestinal Endoscopy 71 (6): 1082-1088.	Case series  n=16  Follow-up: 3 months	Successful removal of polyps, using the combined approach, was reported 11 patients. In 5 patients, the procedure was converted to a laparoscopic or open colectomy owing to incomplete polyp resection.	Larger case series were available.
Benedix, F., Kockerling, F., Lippert, H., Scheidbach, H. (2008) Laparoscopic resection for endoscopically unresectable colorectal polyps: analysis of 525 patients. Surgical Endoscopy 22 (12): 2576-2582	Case series  n=525  Follow-up: median 2.8 years	Conversion to laparotomy became necessary in 17 (3.2%) cases. The perioperative morbidity rate was 20.8%, and malignant transformation occurred in a total of 18.1% of the adenomatous polyps.	Study combined data from laparoscopic resections and laparoscopic-assisted procedures (n=61) making it difficult to evaluate the outcomes of laparoscopic-assisted procedures.
Chang, P. F., Lin, Y. C., Chen, Y., Yeh, S. J. (2007) Laparoscopic-assisted colonoscopic polypectomy for juvenile polyp in children: a new minimal-invasive therapeutic approach. Surgical Laparoscopy, Endoscopy & Percutaneous Techniques 17 (5): 442-443.	Case report  n=1  Follow-up: not reported	The polyp was removed successfully and no intra-operative or postoperative complications were reported.	Larger case series were available.
Hensman, C., Luck, A. J., Hewett, P. J. (1999) Laparoscopic-assisted colonoscopic polypectomy: technique and preliminary experience. Surgical Endoscopy 13 (3): 231-232.	Case series  n=6  Follow-up: 12 months	Successful removal was reported in all patients. All polyps were benign on histological examination. The patients were discharged on the day following the procedure. There were	Larger case series with longer follow-up periods were available.

		no intra-operative or postoperative complications.	
Filograna, M. A., Lattarulo, S., Pezzolla, A., Fabiano, G., Palasciano, N., Ugenti, I. (2008) Laparoscopy-assisted endoscopic mucosal resection in the colon: a preliminary report. <i>Chirurgia Italiana</i> 60 (2):279-284	Case series n=2 Follow-up: 24 months-	Successful removal of polyps was reported in both patients. The patients presented no complications and no recurrence was observed during the subsequent follow-up.	Larger case series with longer follow-up periods were available.
Grunhagen, D. J., van Ierland, M. C., Doornebosch, P. G., Bruijninx, M. M., Winograd, R., de Graaf, E. J. (2011) Laparoscopic-monitored colonoscopic polypectomy: a multimodality method to avoid segmental colon resection. <i>Colorectal Disease</i> 13 (11): 1280-1284	Case series n=10 Follow-up: 27 months	Successful removal of polyps by laparoscopic-monitored colonoscopic polypectomy was reported in 90% (9/10) of patients. Conversion to laparoscopic segmental resection was required in 1 patient. There were no recurrences of polyps during a follow-up period of 4 to 27 months.	Larger case series with longer follow-up periods were available.
Giavarini, L., Boni, L., Cortellezzi, C. C., Segato, S., Cassinotti, E., Rausei, S., Dionigi, G., Rovera, F., Marzorati, A., Spampatti, S., Sambucci, D., Dionigi, R. (2011) Laparoscopic caecal wedge resection with intraoperative endoscopic assistance. <i>International Journal Of Surgery</i> 11 S58-S60	Case series n=15 Follow-up: not reported	All procedures were completed without complications and in all cases complete resection of the polyps was achieved. There were no intra-operative or postoperative complications.	Larger case series were available.
Prohm, P., Weber, J., Bonner, C (1998) Laparoscopic-assisted coloscopic polypectomy. <i>Diseases of the Colon &amp; Rectum</i> 44 (5): 746-748	Case series n=6 Follow-up: not reported	Successful removal was reported in all patients. The operation averaged 57 minutes, and no operation-specific complications were observed. Postoperative recovery in the hospital averaged 2.5 days.	Larger case series with longer follow-up periods were available.
Smedh, K., Skullman, S., Kald, A., Anderberg, B., Nystrom, P. (1997) Laparoscopic bowel mobilization combined with intraoperative colonoscopic polypectomy in patients with an inaccessible polyp of the colon. <i>Surgical Endoscopy</i> 11 (6): 643-644.	Case series n=2 Follow-up: not reported	Polyps were removed successfully and no intra-operative or postoperative complications were reported.	Larger case series were available.
Wood, J. J., Lord, A. C., Wheeler, J. M., Borley, N. R. (2011) Laparoscopic resection for extensive and inaccessible colorectal polyps: a feasible and safe procedure. <i>Annals of the Royal College of Surgeons of England</i> 93	Case series n=13 Follow-up: not reported	Successful removal of polyps was reported in 76.9% (10/13) of patients. In 3 patients the combined approach was converted to 2 laparoscopic right hemicolectomies and , a segmental traverse	Larger case series were available.

(3): 241-245.2011.		colectomy. There were no perforations or serious complications.	
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## Appendix B: Related NICE guidance for combined endoscopic and laparoscopic removal of colonic polyps.

Guidance	Recommendations
Interventional procedures	<p data-bbox="528 432 1302 533"><b>Endoscopic submucosal dissection of lower gastrointestinal lesions. NICE interventional procedure guidance 335 (2010)</b></p> <p data-bbox="528 584 1350 846">1.1 Current evidence on endoscopic submucosal dissection (ESD) of lower gastrointestinal lesions shows that it is efficacious, but evidence on long-term survival when used to treat malignant lesions is limited in quantity. There are some concerns about safety with regard to the risk of perforation and bleeding. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.</p> <p data-bbox="528 869 1270 936">1.2 Clinicians wishing to undertake ESD of lower gastrointestinal lesions should take the following actions.</p> <ul data-bbox="576 943 1337 1328" style="list-style-type: none"> <li data-bbox="576 943 1283 976">• Inform the clinical governance leads in their trusts.</li> <li data-bbox="576 987 1337 1216">• Ensure that patients understand the uncertainty about the procedure's safety and efficacy in relation to the risks of perforation and bleeding, and that conversion to open surgery may be necessary. Patients should be provided with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended.</li> <li data-bbox="576 1227 1267 1328">• Audit and review clinical outcomes of all patients having ESD of lower gastrointestinal lesions (see section 3.1).</li> </ul> <p data-bbox="528 1346 1329 1541">1.3 Endoscopic submucosal dissection of lower gastrointestinal lesions is a technically challenging procedure and should only be carried out by clinicians with specific training in the technique. The Joint Advisory Group on Gastrointestinal Endoscopy intends to prepare training standards on this procedure.</p> <p data-bbox="528 1563 1283 1664">1.4 Patient selection should be carried out either by a colorectal surgeon or by both a colorectal surgeon and an endoscopist who are experienced in this technique.</p> <p data-bbox="528 1682 1337 1877">1.5 NICE encourages further research into ESD of lower gastrointestinal lesions. There should be clear documentation of the incidence of complications including perforation, haemorrhage and need for open surgery (with the reasons for this), rates of complete resection, and long-term outcomes including local recurrence and survival.</p>

	<p><b>Computed tomographic colonography (virtual colonoscopy). NICE interventional procedure guidance 129 (2005).</b></p> <p>1.1 Current evidence on the safety and efficacy of computed tomographic colonography (virtual colonoscopy) appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit and clinical governance.</p>	
Clinical guidelines	<p><b>Colonoscopic surveillance for prevention of colorectal cancer in people with ulcerative colitis, Crohn's disease or adenomas. NICE clinical guideline 118 (2011)</b></p> <p><b>People with adenomas</b></p> <p>1.1.6 Consider colonoscopic surveillance for people who have had adenomas removed and are at low risk of developing colorectal cancer (see table 2).</p> <p>1.1.7 Offer colonoscopic surveillance to people who have had adenomas removed and are at intermediate or high risk of developing colorectal cancer (see table 2).</p> <p>1.1.8 Use the findings at adenoma removal to determine people's risk of developing colorectal cancer (see table 2).</p> <p>Table 2 Risk of developing colorectal cancer in people with adenomas</p> <table border="1" data-bbox="531 1189 1347 1525"> <tr> <td> <p>Low risk:</p> <ul style="list-style-type: none"> <li>• 1 or 2 adenomas smaller than 10 mm.</li> </ul> <p>Intermediate risk:</p> <ul style="list-style-type: none"> <li>• 3 or 4 adenomas smaller than 10 mm or</li> <li>• 1 or 2 adenomas if one is 10 mm or larger.</li> </ul> <p>High risk:</p> <ul style="list-style-type: none"> <li>• 5 or more adenomas smaller than 10 mm or</li> <li>• 3 or more adenomas if one is 10 mm or larger.</li> </ul> </td> </tr> </table> <p>1.1.9 Offer the appropriate colonoscopic surveillance strategy to people with adenomas based on their risk of developing colorectal cancer as determined at initial adenoma removal (see table 2).</p> <ul style="list-style-type: none"> <li>• Low risk: consider colonoscopy at 5 years: <ul style="list-style-type: none"> <li>– if the colonoscopy is negative (that is, no adenomas are found) stop surveillance</li> <li>– if low risk, consider the next colonoscopy at 5 years (with follow-up surveillance as for low risk)</li> <li>– if intermediate risk, offer the next colonoscopy at 3 years (with follow-up surveillance as for intermediate risk)</li> </ul> </li> </ul>	<p>Low risk:</p> <ul style="list-style-type: none"> <li>• 1 or 2 adenomas smaller than 10 mm.</li> </ul> <p>Intermediate risk:</p> <ul style="list-style-type: none"> <li>• 3 or 4 adenomas smaller than 10 mm or</li> <li>• 1 or 2 adenomas if one is 10 mm or larger.</li> </ul> <p>High risk:</p> <ul style="list-style-type: none"> <li>• 5 or more adenomas smaller than 10 mm or</li> <li>• 3 or more adenomas if one is 10 mm or larger.</li> </ul>
<p>Low risk:</p> <ul style="list-style-type: none"> <li>• 1 or 2 adenomas smaller than 10 mm.</li> </ul> <p>Intermediate risk:</p> <ul style="list-style-type: none"> <li>• 3 or 4 adenomas smaller than 10 mm or</li> <li>• 1 or 2 adenomas if one is 10 mm or larger.</li> </ul> <p>High risk:</p> <ul style="list-style-type: none"> <li>• 5 or more adenomas smaller than 10 mm or</li> <li>• 3 or more adenomas if one is 10 mm or larger.</li> </ul>		

	<ul style="list-style-type: none"> <li>– if high risk, offer the next colonoscopy at 1 year (with follow-up surveillance as for high risk).</li> <li>• Intermediate risk: offer colonoscopy at 3 years: <ul style="list-style-type: none"> <li>– if the colonoscopy is negative, offer the next colonoscopy at 3 years. Stop surveillance if there is a further negative result</li> <li>– if low or intermediate risk, offer the next colonoscopy at 3 years (with follow-up surveillance as for intermediate risk)</li> <li>– if high risk, offer the next colonoscopy at 1 year (with follow-up surveillance as for high risk).</li> </ul> </li> <li>• High risk: offer colonoscopy at 1 year. <ul style="list-style-type: none"> <li>– if the colonoscopy is negative, or low or intermediate risk, offer the next colonoscopy at 3 years (with follow-up surveillance as for intermediate risk)</li> <li>– if high risk, offer the next colonoscopy at 1 year (with follow-up surveillance as for high risk).</li> </ul> </li> </ul> <p>1.1.10 Offer a repeat colonoscopy if any colonoscopy is incomplete. Consider whether a more experienced colonoscopist is needed.</p> <p>1.1.11 Consider computed tomographic colonography<sup>1</sup> (CTC) as a single examination if colonoscopy is not clinically appropriate (for example, because of comorbidity or because colonoscopy cannot be tolerated).</p> <p>1.1.12 Consider double contrast barium enema as a single examination if CTC is not available or not appropriate.</p> <p>1.1.13 Consider CTC or double contrast barium enema for ongoing surveillance if colonoscopy remains clinically inappropriate, but discuss the risks and benefits with the person and their family or carers.</p>
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<sup>1</sup> Computed tomographic colonography (virtual colonoscopy). NICE interventional procedure guidance 129 (2005).

## Appendix C: Literature search for combined endoscopic and laparoscopic removal of colonic polyps

Database	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	21/05/2014	Issue 5 of 12, May 2014
Database of Abstracts of Reviews of Effects – DARE (CRD website)	21/05/2014	Issue 2 of 4, April 2014
HTA database (CRD website)	21/05/2014	Issue 2 of 4, April 2014
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	21/05/2014	Issue 4 of 12, April 2014
MEDLINE (Ovid)	21/05/2014	1946 to May Week 1 2014
MEDLINE In-Process (Ovid)	21/05/2014	May 20, 2014
EMBASE (Ovid)	21/05/2014	1974 to 2014 Week 20
PubMed	21/05/2014	n/a
JournalTOCS	21/05/2014	n/a

Trial sources searched on 03/02/2014:

- National Institute for Health Research Clinical Research Network Coordinating Centre (NIHR CRN CC) Portfolio Database
- Current Controlled Trials *meta*Register of Controlled Trials – *m*RCT
- Clinicaltrials.gov

Websites searched on 03/02/2014:

- National Institute for Health and Clinical Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) - MAUDE database
- French Health Authority (FHA)
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- Conference websites
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1	Laparoscopy/
2	laparoscop*.tw.
3	1 or 2
4	Colonoscopy/
5	colonoscop*.tw.
6	4 or 5
7	3 and 6
8	((laparoendoscopic or laparo-endoscopic or (laparo* adj4 endoscop*)) adj4 (resect* or excis* or surger* or procedure* or polypectom*)).tw.
9	("FLEX" and ("full thickness" or full-thickness)).tw.
10	("FLEX" adj4 procedure*).tw.
11	or/7-10
12	Colonic Polyps/
13	((colon* or colorect* or rectal* or rectum* or bowel* or hyperplastic* or neoplastic* or ademomat* or homartomat*) adj4 (polyp* or lesion* or growth*)).tw.
14	((colon* or colorect* or rectal* or rectum* or bowel*) adj4 adenom*).tw.
15	12 or 13 or 14
16	11 and 15
17	animals/ not humans/
18	16 not 17