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Laparoscopy versus laparotomy for FIGO stage I ovarian cancer (Review)

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Laparoscopy versus laparotomy for FIGO stage I ovarian cancer.
Cochrane Database of Systematic Reviews 2013, Issue 2. Art. No.: CD005344.
DOI: 10.1002/14651858.CD005344.pub3.

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[Intervention Review]

Laparoscopy versus laparotomy for FIGO stage I ovarian cancer

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Editorial group: Cochrane Gynaecological, Neuro-oncology and Orphan Cancer Group.
Publication status and date: Edited (no change to conclusions), comment added to review, published in Issue 6, 2015.
Review content assessed as up-to-date: 23 November 2012.

Citation: Lawrie TA, Medeiros LRF, Rosa DD, da Rosa MI, Edelweiss MI, Stein AT, Zelmanowicz A, Moraes AB, Zanini RR. Laparoscopy versus laparotomy for FIGO stage I ovarian cancer. *Cochrane Database of Systematic Reviews* 2013, Issue 2. Art. No.: CD005344. DOI: 10.1002/14651858.CD005344.pub3.

ABSTRACT

Background

This is an updated version of the original review that was first published in the Cochrane Database of Systematic Reviews 2008, Issue 4. Laparoscopy has become an increasingly common approach to surgical staging of apparent early-stage ovarian tumours. This review was undertaken to assess the available evidence on the benefits and risks of laparoscopy compared with laparotomy for the management of International Federation of Gynaecology and Obstetrics (FIGO) stage I ovarian cancer.

Objectives

To evaluate the benefits and risks of laparoscopy compared with laparotomy for the surgical treatment of FIGO stage I ovarian cancer (stages Ia, Ib and Ic).

Search methods

For the original review, we searched the Cochrane Gynaecological Cancer Group Trials (CGCRG) Register, Cochrane Central Register of Controlled Trials (CENTRAL 2007, Issue 2), MEDLINE, EMBASE, LILACS, Biological Abstracts and CancerLit from 1 January 1990 to 30 November 2007. We also handsearched relevant journals, reference lists of identified studies and conference abstracts. For this updated review, we extended the CGCRG Specialised Register, CENTRAL, MEDLINE, EMBASE and LILACS searches to 6 December 2011.

Selection criteria

Randomised controlled trials (RCTs), quasi-RCTs and prospective cohort studies comparing laparoscopic staging with open surgery (laparotomy) in women with stage I ovarian cancer according to FIGO.

Data collection and analysis

There were no studies to include, therefore we tabulated data from non-randomised studies (NRS) for discussion.

Main results

We performed no meta-analyses.

Authors' conclusions

This review has found no good-quality evidence to help quantify the risks and benefits of laparoscopy for the management of early-stage ovarian cancer as routine clinical practice.

PLAIN LANGUAGE SUMMARY

Laparoscopy versus laparotomy (open surgery) for early-stage ovarian cancer

Stage I ovarian cancer is diagnosed when the tumour is confined to one or both ovaries, without spread to lymph nodes or other parts of the body. Approximately 25% of women with ovarian cancer will be diagnosed at an early stage, thus the diagnosis often occurs due to an accidental finding. The intention of surgical staging is to establish a diagnosis, to assess the extent of the cancer and to remove as much tumour as possible. The latter is particularly important as women with ovarian cancer survive for longer when all visible tumour has been removed.

We conducted this review in an attempt to clarify whether laparoscopy (keyhole surgery) is as safe and effective as laparotomy (open surgery) for early-stage ovarian cancer. We intended to include only high-quality studies that compared the two types of surgery.

We wanted to know whether women having laparoscopy survived as long as those having open surgery and whether there were differences in the time it took for the cancer to get worse. We were also interested to see how these different surgeries compared with regard to blood loss and other complications.

Unfortunately, we were unable to find any high-quality randomised trials comparing these approaches. Further research is needed.

BACKGROUND

Description of the condition

This is an updated version of the original review that was first published in the Cochrane Database of Systematic Reviews 2008, Issue 4.

Ovarian cancer is the eighth most common cancer in women worldwide (Jemel 2011). A woman's risk of developing ovarian cancer before the age of 75 ranges from 0.5% in developing countries to 1% in developed countries (GLOBOCAN 2008; Jemel 2011). Just over a third of women with ovarian cancer are alive five years after diagnosis (EUROCARE 2003), largely because most women with ovarian cancer are diagnosed when the cancer is already at an advanced stage (Jemal 2008). International Federation of Gynaecology and Obstetrics (FIGO) stage I ovarian cancer (limited to the ovaries) is diagnosed in approximately 20% to 33% of women with ovarian cancer in developed countries (Maringe 2012) and diagnosis is usually made by accidental discovery at sonography, computerised tomography (CT scanning) or during laparoscopy. The incidence of accidental discovery of ovarian cancer at laparoscopy has been estimated to range from 0.65% (Wenzl 1996) to 0.9% (Muzii 2005) of premenopausal women and 3% of postmenopausal women who undergo the procedure for an adnexal mass (Muzii 2005), but may be higher depending on the selection criteria applied.

Most cancers of the ovary are epithelial (90%) with histological subtypes including serous (35%), endometrioid (10%), borderline (16%), mucinous (8%), clear cell (4%), undifferentiated and mixed epithelial (Kosary 2007). In general, the prognosis of ovarian tumours depends on the FIGO stage, tumour grade, histological subtype, age and the volume of residual disease after surgery (Benedet 2000), however for stage I tumours the most important prognostic indicators are considered to be the degree of differ-

entiation (grade) and the occurrence of tumour rupture (Vergote 2001).

The standard management of women with ovarian cancer is comprehensive surgical staging by laparotomy, a midline abdominal incision that allows exposure of the entire abdomen. Comprehensive surgical staging includes a total hysterectomy, bilateral salpingo-oophorectomy, removal of all obvious sites of tumour, aspiration of cytological washings or ascites, omentectomy, retroperitoneal (pelvic and para-aortic) lymph node dissection or sampling and biopsy of all suspicious-looking areas including mesentery, liver and diaphragm (Benedet 2000; Schorge 2012). Systematic retroperitoneal lymph node dissection (RLND) may improve survival in stage I ovarian cancer by detecting microscopic disease (Chan 2007) and is considered a standard procedure in some centres (Schorge 2012), however the UK National Institute for Clinical Excellence (NICE) guidelines currently do not recommend RLND in stage I disease (NICE 2011).

A meta-analysis of four randomised controlled trials (RCTs) of adjuvant platinum-based chemotherapy, which included data from the International Collaborative Ovarian Neoplasm 1 (ICON1) trial (Trimbos 2003) and the Adjuvant Chemotherapy in Ovarian Neoplasm (ACTION) trial (Trimbos 2004), found that adjuvant chemotherapy significantly improved overall survival (OS) and progression-free survival (PFS) in women with early ovarian cancer (Winter-Roach 2012). However, it was considered not to be necessary in women with comprehensively staged, stage Ia or 1b grade 1 to 2 tumours, as subgroup analyses suggested that women who were optimally staged were unlikely to benefit from adjuvant chemotherapy. Hence, comprehensive surgical staging has an important impact on the subsequent management of women with early ovarian cancer, with adjuvant chemotherapy indicated when staging is considered to be inadequate (Elit 2004; Winter-Roach 2012).

Description of the intervention

The intention of surgical staging is to establish a diagnosis, to assess the extent of the disease and to remove as much gross tumour as possible (Schorge 2012). Surgical staging of ovarian cancer by laparoscopy is the same intra-abdominal procedure as that performed by laparotomy except that it involves two or more, much smaller, abdominal incisions, through which laparoscopic instruments are then inserted. Specimen retrieval bags are used to prevent spillage and possible seeding of cyst contents and to avoid contact with incision (port) sites. Cysts may be aspirated within the retrieval bag, or morcellated if solid, to facilitate extraction through the port sites (Ghezzi 2007). Larger specimens, like omentum, may be extracted through the vagina with the uterus after hysterectomy (Lee 2011; Park 2008a).

How the intervention might work

Several recent non-randomised studies (NRSs) in early ovarian cancer have reported that laparoscopic surgical staging is a safe and technically feasible procedure (Colomer 2008; Ghezzi 2009; Nezhat 2009; Park 2008b; Park 2010). The possible advantages of laparoscopy include smaller incisions, less blood loss, faster recovery, shorter hospital stay, fewer complications, less postoperative infection and a better visualisation of the tumour inside the abdomen as the laparoscopy image can be magnified (Gad 2011; Ghezzi 2007; Lee 2011). In addition, the shorter recovery period following laparoscopy means that chemotherapy can be commenced sooner compared with laparotomy (Ghezzi 2007; Nezhat 2009), potentially resulting in a favourable effect on survival.

However, laparoscopy has been associated with a higher rate of intraoperative cyst rupture for apparently benign (Muzii 2005) and borderline tumours (Fauvet 2005), which may result in upstaging of the unexpected ovarian cancer from stage Ia or 1b to Ic (Muzii 2005). It has been argued that some aspects of comprehensive surgical staging, particularly RLND, may be technically difficult to achieve via laparoscopy and, therefore, that laparoscopy should be restricted to women with pre-operative evidence of benign conditions only (Vergote 2004). Other disadvantages of laparoscopy may include longer operating times and the possibility of port-site metastases, although the risk of the latter in early disease is considered to be low (Schorge 2012). Furthermore, to facilitate laparoscopy, CO_2 is commonly used for pneumoperitoneum and has been shown to lower the peritoneal pH (Bergstrom 2008; Kuntz 2000) which may activate enzymes that increase tumour cell mitosis and growth factor production. In addition, mechanical damage to the mesothelium may occur with prolonged laparoscopic surgery, thereby increasing the risk of metastases in the abdominal cavity (Greene 1995; Volz 1999).

Why it is important to do this review

Laparoscopic surgical staging of stage I ovarian cancer remains controversial as it is unclear how the risks and benefits of this procedure compare with the conventional open approach by laparotomy. An earlier version of this systematic review, published in 2008, found insufficient evidence to evaluate laparoscopy for the management of early ovarian cancer as routine clinical practice. We continue to update this review with the aim of clarifying and consolidating the available evidence regarding this alternative surgical approach.

OBJECTIVES

To evaluate the benefits and harms of laparoscopy in the surgical treatment of FIGO stage I ovarian cancer (stages Ia, Ib and Ic)

when compared with laparotomy.

METHODS

Criteria for considering studies for this review

Types of studies

RCTs and quasi-RCTs. We also considered prospective cohort studies where the results had been adjusted for the baseline case mix using multivariate analyses, and excluded those with historical (non-concurrent) controls.

Types of participants

Women with stage I ovarian cancer defined by FIGO as follows.

- Stage Ia: unilateral tumours
- Stage Ib: bilateral tumours
- Stage Ic: identified tumour spillage, tumour capsular penetration, positive peritoneal cytology

Types of interventions

Surgical staging via laparoscopy (experimental group) versus laparotomy (control group) for stage I ovarian cancer.

Types of outcome measures

Primary outcomes

1. Overall survival (OS)
2. Progression free survival (PFS)

Secondary outcomes

1. Operating time
2. Intraoperative tumour rupture
3. Pelvic and para-aortic lymph node yield
4. Size of omental specimen
5. Estimated blood loss and the need for blood transfusion
6. Comprehensive staging achieved by the allocated procedure (conversion to laparotomy)
7. Surgical complications (immediate and delayed) including: injuries to the bladder, ureter, blood vessels, nerves, small bowel and colon; febrile morbidity; intestinal obstruction; haematomas and infections
8. Length of hospital stay
9. Time to adjuvant chemotherapy
10. Systemic complications
11. Abdominal wall recurrence: laparoscopy (port sites) and laparotomy (midline incision).
12. Quality of life

Search methods for identification of studies

Electronic searches

We conducted searches to identify all published and unpublished RCTs and NRSs that compared laparoscopy and laparotomy for stage I ovarian cancer. The search strategies identified studies in all languages and, when necessary, we translated non-English language papers so that they could be fully assessed for potential inclusion in the review.

We searched the Cochrane Gynaecological Cancer Review Group (CGCRG) Trials Register, Cochrane Central Register of Controlled Trials (CENTRAL 2007, Issue 2), MEDLINE (January 1990 to November 2007), EMBASE (1990 to November 2007), LILACS (1990 to November 2007), Biological Abstracts (1990 to November 2007) and CancerLit (1990 to November 2007). For this updated version of the review, we extended these searches to 6 December 2011. (See Appendix 1, Appendix 2, Appendix 3 and Appendix 4 for the search strategies).

Searching other resources

We handsearched the citation lists of relevant publications and included studies, and contacted experts in the field to identify further trials. For the original review we also handsearched the following conferences and publications: *Gynecologic Oncology*, *International Journal of Gynaecological Cancer*, *British Journal of Cancer*, British Cancer Research Meeting, Annual Meetings of the International Gynaecologic Cancer Society, Annual Meetings of the American Society of Gynecologic Oncologists, Annual Meetings of the European Society of Medical Oncology (ESMO), and Annual Meetings of the American Society of Clinical Oncology (ASCO).

Data collection and analysis

Selection of studies

Two review authors sifted the searches and identified potentially eligible studies. All authors assessed the methodology of these potentially eligible studies according to the specific inclusion criteria. Review authors were not blind to the authors, institutions or journals of potentially relevant studies.

Data extraction and management

No studies fulfilled the inclusion criteria for this review. For future versions of this review, two authors will independently extract data from included trials to a pre-designed data collection sheet that includes the following information:

- *Study methodology*: description of randomisation, blinding, number of study centres, study duration, length of follow-up and number of study withdrawals.
- *Participants*: number, mean age, mean risk score.
- *Intervention*: type of intervention, dose and schedule.
- *Outcomes:*

    - We will extract data to allow for intention-to-treat (ITT) analysis where possible.
    - For dichotomous outcomes (e.g. number of lymph nodes, complications or deaths), we will extract outcome rates to estimate a risk ratio (RR).
    - For continuous outcomes (e.g. quality of life (QoL) measures and duration of treatment) we will extract means and standard deviations (SD) to estimate a mean difference (MD).
    - For time-to-event outcomes (e.g. overall survival) we will extract the log of the hazard ratio (log(HR)) and its standard error from trial reports. If these are not reported, we will attempt to estimate the log (HR) and its standard error using Parmar's methods (Parmar 1998).

Assessment of risk of bias in included studies

For future versions of this review we will assess the risk of bias in included studies using The Cochrane Collaboration's tool (Higgins 2011) and the following criteria:

1. selection bias: random sequence generation and allocation concealment;
2. performance bias: blinding of participants and personnel (patients and treatment providers);
3. detection bias: blinding of outcome assessment;
4. attrition bias: incomplete outcome data;
5. reporting bias: selective reporting of outcomes;
6. other possible sources of bias.

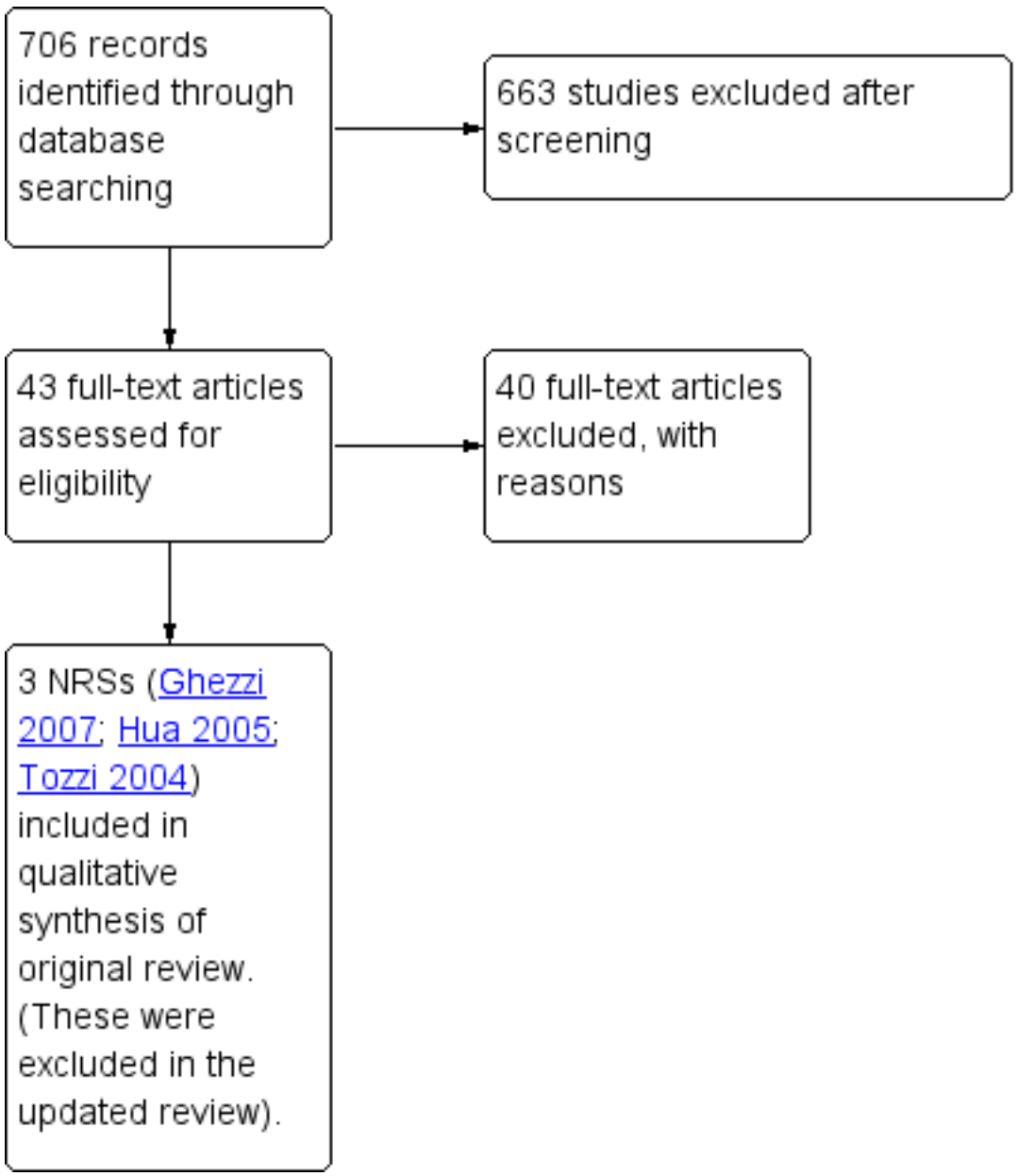
RESULTS

Description of studies

Results of the search

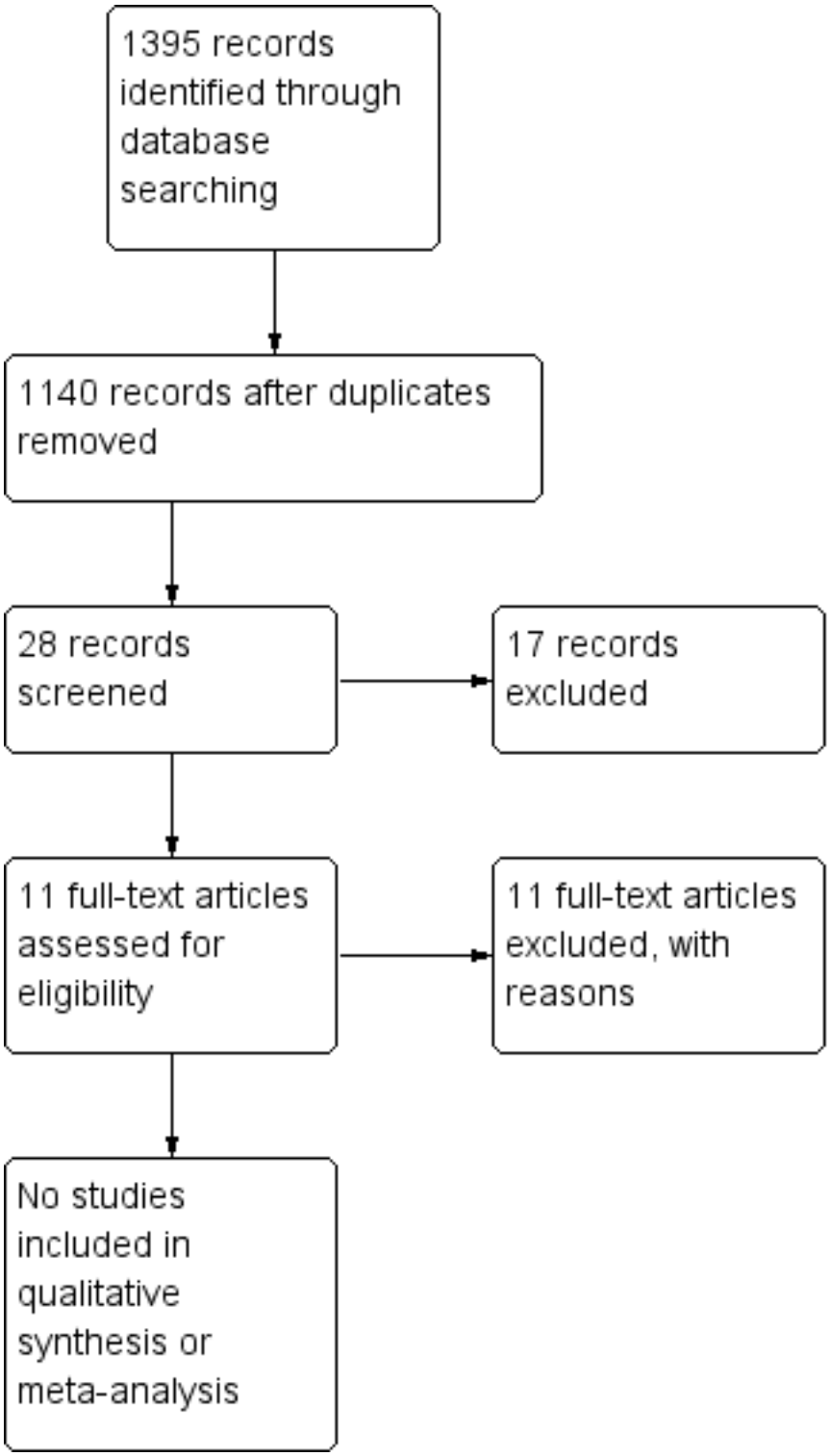
The original search identified 706 citations, of which we retrieved 43 for detailed examination. We subsequently excluded 40 of these records and three NRSs (two case-control studies and one case series) were included in the original review (Ghezzi 2007; Hua 2005; Tozzi 2004; Figure 1). For this updated review, we excluded these NRSs but tabled their findings with other similar studies that were identified by the updated search (see Differences between protocol and review).

Figure 1. Study flow diagram of original search 17 May 2007



From the updated search we identified 1395 records (1140 after de-duplication), 28 of which we screened for possible relevance. Of these, 11 new studies were identified for classification (Chen 2010; Chi 2005; Colomer 2008; Ghezzi 2009; Lee 2011; Nezhat 2009; Park 2008a; Park 2008b; Park 2010; Park 2011; Wu 2010; Figure 2). Park 2008b, Park 2010 and Park 2011 are extensions of the same series.

Figure 2. Study flow diagram of updated search 30 November 2011



Included studies

There were no studies that met the inclusion criteria.

Excluded studies

Altogether we excluded 54 studies. None of these studies met the inclusion criteria in Types of studies. We have summarised the results of the relevant case series, case-control studies and retrospective cohort studies in three tables: Table 1, Table 2 and Table 3, respectively. None of the comparative NRSs reported adjusting results for baseline characteristics and we considered all of them to be at a high risk of selection bias and other bias (e.g. outcome assessment bias).

Risk of bias in included studies

Not applicable.

Effects of interventions

There were no studies to include therefore no meta-analyses could be performed. Table 2 and Table 3 present the available data from the case-control and retrospective studies to date.

DISCUSSION

Stage I ovarian cancer is a rare disease and the use of laparoscopy for surgical staging thereof is a relatively new field of clinical study, therefore data are scarce. Recent UK guidelines on the management of ovarian cancer do not consider laparoscopy as an approach to the surgical staging of early ovarian cancer (NICE 2011); however, the German Gynaecological Oncology Group (AGO) have cautiously included the option of this procedure in their recent guidelines, for selected patients and only when performed by expert laparoscopic oncology surgeons, pending further evidence (Mettler 2009).

Summary of main results

We found no randomised controlled trials (RCTs) to include in this review and from which to compare the risks and benefits of laparoscopy with the conventional open approach. Existing non-randomised evidence comparing these interventions is extremely limited and is particularly at risk of selection bias. We considered including case-control non-randomised studies (NRSs) in meta-analyses, however sample sizes were small, none of these studies reported performing statistical adjustments for baseline case mix using multivariate analyses (e.g. age, final FIGO stage, grade, tumour size, co-morbidity and adjuvant chemotherapy), the duration of follow-up varied widely, and the primary outcomes of this review (OS and PFS) were not consistently reported.

Overall completeness and applicability of evidence

Survival

According to Surveillance Epidemiology and End Results (SEER; Kosary 2007), five-year OS rates for stage Ia, Ib and Ic ovarian adenocarcinoma (excluding borderline tumours) are about 94%, 91% and 80% respectively. However, survival data relating to the surgical approach (laparoscopy versus laparotomy) in the existing literature are extremely limited: comparative studies of laparoscopy versus laparotomy for early ovarian cancer to date include three case-control studies (Table 2; Chi 2005; Ghezzi 2007; Hua 2005) and five retrospective cohort studies (Table 3; Lee 2011; Park 2008a; Park 2008b; Park 2010; Park 2011), three of which are expansions of the same case series (Park 2008b; Park 2010; Park 2011). Of these eight studies, six reported survival data but the length of follow-up varied widely or was not reported. Lee 2011 reported higher PFS rates in the laparoscopy group (100% for laparoscopy versus 91% for laparotomy) and did not report OS, however median follow-up was much shorter in the laparoscopy group compared with the laparotomy group (12 versus 25 months) and mean tumour size was significantly larger in the laparotomy group (P = 0.01). Park 2011 reported OS of 89% and 86% for laparoscopy and laparotomy respectively and PFS rates of 78% in each group, but did not report the duration of follow-up in each group. Ghezzi 2007 reported 100% OS in both groups, however the median duration of follow-up differed substantially between the groups (16 months in the laparoscopy group compared with 60 months in the laparotomy group).

Two studies conducted in women with early ovarian cancer (Park 2008a; Wu 2010) have reported unfavourable survival outcomes with laparoscopy. In Park 2008a (OS = 88% in the laparoscopy group versus 100% in the laparotomy group; Table 3), one woman who was diagnosed with FIGO stage Ia grade 1 ovarian cancer was shown to have severely disseminated disease at seven months and died of the disease 15 months later; the other woman had stage Ia grade 2 ovarian cancer at laparoscopy and developed recurrence at the vaginal stump. The extent of laparoscopy surgical staging was considered sufficient in the latter case, the tumour was not ruptured and retrieval bags were used. Wu 2010 reported data from a cohort of women with stage 1 ovarian cancer treated between

1984 and 2006 and found that those in whom the initial surgical approach was laparoscopic had significantly worse PFS and OS than those who underwent laparotomy (OS hazard ratio (HR) = 3.52), however, comprehensive staging was not the purpose of the laparoscopy in most of these women, therefore these results are difficult to interpret. In general, we consider the available survival data to be of a very low quality, hence it is not possible draw any conclusions regarding the relative effect of laparoscopic surgical staging compared with laparotomy on ovarian cancer survival from the existing literature.

Feasibility

Measures of the technical feasibility of laparoscopy have included pelvic and para-aortic lymph node yields, the size of the omental specimen, operating times and intra-operative tumour spillage. All case-control and cohort studies identified have reported statistically similar yields of retroperitoneal lymph nodes between their laparoscopy and laparotomy groups. Only two comparative studies (Chi 2005; Park 2008b) have reported mean omental specimen volumes, which were not statistically significantly different. With regard to operating times, some studies report significantly longer times with laparoscopy (Chi 2005; Ghezzi 2007; Hua 2005; Lee 2011) whilst others have reported significantly shorter times with laparoscopy (Park 2008b; Park 2010; Park 2011). These differences probably reflect differences in surgeons' skills and laparoscopic techniques between investigator teams.

Rupture or spillage of ovarian tumours during surgery has been reported to occur more frequently with laparoscopy than laparotomy (Romagnolo 2006) and has been identified as a prognostic indicator of disease-free survival (Vergote 2001). To date, six out of eight NRSs have compared rates of tumour spillage between laparoscopy and laparotomy groups (Hua 2005;Lee 2011; Park 2008a; Park 2008b; Park 2010; Park 2011). Five of these studies reported no significant difference between the two groups, and one study (Lee 2011) reported a statistically significantly higher rate of spillage in the laparotomy group (0% versus 14.9%; P = 0.037) which also had a significantly larger mean tumour size compared with the laparoscopy group. The definitions of spillage vary and the distinction between tumour rupture and puncture is not detailed in most studies (Ghezzi 2009). To properly assess these outcomes, technique and definitions need to be clearly defined in future studies. However, these limited data suggest that laparoscopy staging of early ovarian cancer is technically feasible when performed by experienced laparoscopic gynaecology oncology surgeons.

An inherent shortcoming of laparoscopy for surgical staging is the inability to palpate lymph nodes and other peritoneal surfaces (Colomer 2008; Park 2008a), however Chi 2010 argues that intra-operative direct visualisation and evaluation of nodes by palpation is inherently subjective. In a recent prospective study, of 111 women with apparent early ovarian cancer who underwent comprehensive staging by laparotomy that included retroperitoneal lymph node dissection (RLND), retroperitoneal nodal metastases were present in 13.5% of the women (Ditto 2012), which suggests that without RLND many women would be under-staged. However, systematic RLND may be associated with significant morbidity and is not a routine part of staging for early ovarian cancer in the UK, where clinical guidelines currently recommend retroperitoneal lymph node assessment with sampling of suspicious nodes (NICE 2011). Therefore, where RLND is not routine, lymph node palpation may play a crucial role in the decision-making process with regard to sampling. Another technically difficult part of the surgical staging procedure is the examination of the diaphragmatic peritoneum behind the liver and spleen and the dome of the liver (Park 2008a); this may be more difficult with laparoscopy, although it has been argued that isolated metastases to these areas are rare (Ghezzi 2009).

Safety

Surgical staging for ovarian cancer is a radical procedure that may be associated with severe intra-operative vascular, nerve, lymphatic, bowel and urinary tract complications. Common postoperative complications include wound infection, ileus, febrile morbidity and lymphoceles (Ghezzi 2007; Lee 2011; Park 2008a; Park 2008b). Three comparative studies in early ovarian cancer have reported significantly fewer postoperative complications with laparoscopy compared with laparotomy (Hua 2005; Lee 2011; Park 2011). The following complications have been reported in the laparoscopy participants of studies in early ovarian cancer: umbilical hernias (Lee 2011), retroperitoneal haematoma (Ghezzi 2007), vascular injury (Colomer 2008; Ghezzi 2007; Park 2008b), lymphoceles (Lee 2011; Nezhat 2009), obturator nerve damage (Hua 2005), bowel injury or obstruction (Nezhat 2009; Park 2008a) and ureter injury (Park 2008b). Estimated blood loss (EBL) in all case-control (Table 2) and comparative cohort studies (Table 3) has been statistically significantly less than in the laparoscopy groups compared with laparotomy groups, with the exception of one study (Ghezzi 2007). In these studies, rates of blood transfusion in laparoscopy groups ranged from 0% to 15%, whereas transfusions were necessary in up to 30% (Park 2010) of women who underwent laparotomy.

There have been several reports of the occurrence of abdominal wall metastases following laparoscopy for ovarian cancer (Childers 1994; Gleeson 1993; Leminen 1999). However, in the studies of laparoscopy in stage I ovarian cancer that have reported this outcome, no port-site metastases had occurred by the time of reporting in Chi 2005 (20 women), Park 2008a (17 women), Park 2008b (19 women), Nezhat 2009 (36 women) and Lee 2011 (26 women). Port-site metastases may be technique-related and limited mostly to patients with advanced disease (Chi 2005; Nezhat 2009). In a study of laparoscopic cytoreductive surgery for advanced ovarian cancer and in which no port-site metastases

occurred, the authors attributed their results to a surgical technique that employed endoscopic bags to retrieve intact specimens and a layered closure of the trocar site (Nezhat 2010). Lee 2011 and Chi 2005 have also reported employing this technique to prevent port-site metastases.

Other outcomes

Lee 2011 evaluated the relative cost of laparoscopy compared with open surgery in women with early ovarian cancer and found that laparoscopy resulted in higher costs due to the cost of disposable instrumentation and direct material/operating room costs, but the cost of hospital stay was higher in the laparotomy group because the stay was longer. Where bed costs are higher, this difference in cost might be eliminated, however the median lengths of hospital stay in the laparotomy groups in most of the studies reporting this outcome seem excessive with a range of up to 14.5 days (Table 2; Table 3). Literature on the quality of life for women undergoing laparoscopy compared with laparotomy is scant, however Lee 2011 reported significantly lower postoperative pain scores in the laparoscopy group.

Agreements and disagreements with other studies or reviews

A meta-analysis of eight RCTs comparing laparoscopic surgical staging with laparotomy for endometrial cancer has shown the laparoscopic approach to be safe, with statistically significantly fewer postoperative complications than laparotomy, and similar rates of intra-operative complications (Zullo 2012). It is possible that similar conclusions may, in time, be drawn about laparoscopy and laparotomy for stage I ovarian cancer, however the evidence for this is not currently in the literature.

AUTHORS' CONCLUSIONS

Implications for practice

Due to technological advancements in instrumentation and an increase in laparoscopic surgical expertise, the role of laparoscopy in gynaecological cancers is expanding, however there is still wide regional variation in the laparoscopic skills and competence of gynaecological-oncology surgeons. We did not find any good evidence to recommend laparoscopy for the routine management of women with stage I ovarian cancer.

Implications for research

Survival data for patients with gynaecological malignancies managed by laparoscopy are still lacking. A major barrier to conducting randomised controlled trials (RCTs) in early ovarian cancer is the anticipated difficulty in recruiting sufficient numbers of participants (Ghezzi 2009). Other difficulties include standardising the quality of the surgery and the skill of the surgeons. Subsequent results from such trials may only be applicable to expert laparoscopic oncology surgeons. However, we understand, from a personal communication, that the Korean Gynecologic Oncology Group (KGOG) is currently developing a protocol for a RCT comparing laparoscopy with laparotomy for early ovarian cancer. Two recently reported Korean cohort studies (Lee 2011; Park 2011) recruited 325 women between them within the same six-year period (2004 to 2010), suggesting that a multicentre RCT is feasible. Participating institutions should be subgrouped according to whether retroperitoneal lymph node dissection or lymph node assessment with sampling is performed routinely. Outcomes of RCTs should include overall and progression-free survival, complications (intraoperative and postoperative), the use of adjuvant chemotherapy, patient satisfaction, quality of life and costs. It would be helpful if costs are reported separately for the preoperative, intraoperative and postoperative periods.

ACKNOWLEDGEMENTS

We would like to thank Jo Morrison, Gail Quinn, Clare Jess and Tracey Bishop of the Cochrane Gynaecological Cancer Review Group team that is based at the Royal United Hospital, Bath, UK for their help, advice and support throughout the review process; Jane Hayes for performing the updated search; and the library staff at the Royal United Hospital, Bath, UK, who obtained many articles for us. We would also like to thank Lidia Medieros for acting as the Contact Author on the original review.

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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
Amara 1996	A case series of 11 women with stage Ia to IIIc ovarian cancer who underwent laparoscopy staging
Berman 2003	Narrative review
Bristow 2000	Narrative review
Canis 1994	Narrative review
Canis 1997	A case series of 10 cases of laparoscopy for low malignant potential tumour and 15 cases of cancer, but stage not described
Canis 2000	A series of laparoscopy for 28 cases of cancer and borderline tumour; stage not described
Chapron 1998	Narrative review
Chen 2010	A case series of 43 women who underwent laparoscopic surgical staging for apparent early ovarian cancer (see Table 1)
Chi 2005	A retrospective case-control study of 50 women who underwent laparoscopic or open surgical staging for apparent early ovarian cancer (see Table 2)
Childers 1995	A prospective case series of second-look laparoscopy to evaluate both intraperitoneal cavity and retroperitoneal lymph nodes and laparoscopic surgical staging. 14 women underwent laparoscopic staging of apparent early ovarian cancer; metastatic disease was discovered in 8 of these women (see Table 1).
Childers 1996	A series of 138 cases of laparoscopy for suspicious ovarian masses (not surgical staging). Malignancies were discovered in 19 women
Colomer 2008	A prospective case series of laparoscopic surgical staging of 20 women with apparent early ovarian cancer (18 EOCs and 2 dysgerminomas) (see Table 1)
Darai1998	A retrospective case series of 25 women with borderline ovarian tumours
de Poncheville 2001	Retrospective study of surgery without para-aortic lymphadenectomy in stage I ovarian cancer. Investigators advocate surgery without lymphadenectomy for women with early ovarian cancer
Dottino 1999	Retrospective case series of 94 laparoscopic lymphadenectomies for gynaecological malignancies, including 14 women with ovarian cancer
Ghezzi 2007	A case-control study of 15 women who underwent laparoscopic staging for early ovarian cancer versus 19 historical controls who had open surgery (see Table 2)

(*Continued*)

Ghezzi 2009	A case series of 26 women who underwent laparoscopic staging for early ovarian cancer (see Table 1)
Goff 2006	Narrative review
Hua 2005	A small, prospective, case-control study of 10 women who underwent laparoscopic staging for early ovarian cancer versus 11 women who underwent laparotomy (see Table 2). No adjustments were made for baseline case mix.
Kadar 1995	Included other cancers (endometrial, cervical, ovarian)
Klindermann 1995	A survey conducted on laparoscopy in Germany
Leblanc 2004	Cohort with other types of cancer (fallopian tube carcinoma) and in patients that were inadequately staged at the time of initial surgery for invasive ovarian carcinoma
Leblanc 2006	Narrative review
Lee 2011	A retrospective cohort study of laparoscopy in 26 women with early ovarian cancer versus 87 women who underwent open surgery (see Table 3). No adjustments were made for baseline case mix. Women in the laparotomy group had significantly larger tumours and longer follow-up
Lécuru 2004	Retrospective study of 105 women who underwent surgery for stage I ovarian cancer. 14 underwent laparoscopy only, 13 had a laparoscopy converted to laparotomy and 78 had a laparotomy. Comprehensive staging was less frequent in the laparoscopy group
Maiman 1991	Members and candidate members of the Society of Gynecologic Oncologists responded to a survey concerning the "laparoscopy management of ovarian neoplasm subsequently found be malignant"
Malik 1998	Unexpected ovarian tumours were discovered in 11/292 women who underwent laparoscopy to evaluate adnexal masses
Maneo 2004	Criteria for exclusion: 62 patients had fertility-sparing after surgery
Manolitsas 2001	Narrative review
Mehra 2004	A prospective case series of 32 women with ovarian and other gynaecological cancers who underwent laparoscopic retroperitoneal para-aortic lymphadenectomy
Nezhat 1992	Series of cases
Nezhat 2009	A case series of 36 women with early ovarian cancer who underwent complete laparoscopic staging (see Table 1)
Nezhat 2010	A case series of women with advanced ovarian cancer who underwent complete laparoscopic staging
Park 2008a	A retrospective cohort study of 17 versus 19 women with early ovarian cancer who underwent laparoscopic staging and laparotomy respectively (see Table 3). No adjustments were made for baseline case mix.

(*Continued*)

Park 2008b	A retrospective cohort study of 19 versus 33 women with early ovarian cancer who underwent laparoscopic staging and laparotomy respectively (see Table 3)
Park 2010	An expansion of the earlier study (Park 2008b; see Table 3)
Park 2011	An expansion of Park 2008b and Park 2010 retrospective studies (see Table 3)
Parker 1990	This study only included women with benign ovarian cysts
Pomel 1995	A series of women with stage I ovarian carcinoma who underwent a laparoscopic procedure to complete their staging
Querleu 2003	A retrospective study of laparoscopic restaging of 30 women with borderline ovarian tumours
Querleu 2006a	Narrative review
Querleu 2006b	Many types of tumours (cervical, vaginal, endometrial and ovarian carcinoma)
Reich 1990	A case report
Romagnolo 2006	A series of cases where laparoscopy was performed for suspected borderline ovarian tumours, and included fertility-sparing procedures
Rouzier 2005	Narrative review
Spirtos 2005	A case series of laparoscopy for all stages of ovarian cancer and other types of cancers
Tozzi 2004	A case series of laparoscopic staging for early ovarian cancer (see Table 1)
Tozzi 2005	Narrative review
Tropé 2006	Narrative review
Vaisbuch 2005	Narrative review
Vergote 2003	Narrative review
Vinatier 1996	Narrative review
Volz 1997	Narrative review
Wenzl 1996	A questionnaire was sent to all 97 Departments of Gynaecology in Austria to determine the frequency of discovering a malignant ovarian mass when laparoscopy is used to manage an adnexal mass
Wu 2010	A retrospective cohort study of laparoscopy versus laparotomy, however surgical staging was not always the aim of the initial laparoscopy

EOC = epithelial ovarian cancer

DATA AND ANALYSES

This review has no analyses.

ADDITIONAL TABLES

Table 1. Case series of comprehensive laparoscopic staging of early ovarian cancer (including fallopian tube cancer)

	No. of women	Mean pelvic nodes (n)	Mean para-aortic nodes (n)	Median follow-up (months)	Recurrences (n)	PFS (%)	OS (%)
Querleu 1994	8	-	8.6	-	-	-	-
Pomel 1995	8	7.5	8.5	-	-	-	-
Childers 1995	14	-	-	-	-	-	-
Tozzi 2004	24	19.4	19.6	46	2	92	100
Leblanc 2004	42	14	20	54	3/34 [1]	91	98
Colomer 2008	20	18	11.3	24.7	1	95	100
Ghezzi 2009	26	24.5	9.8	26.7	1	96	96
Nezhat 2009	36	14.8	12.2	55.9 [2]	3	92	100
Chen 2010	43	16.6	6.5	24.7	3	93	-

Abbreviations: PFS = progression-free survival; OS = overall survival; n = number

[1]Leblanc 2004 reported recurrences in confirmed stage I women only, i.e. excluding 8 women who were upstaged.

[2]Mean follow-up.

Table 2. Case-control studies of laparoscopic surgical staging versus open surgical staging of early ovarian cancer

Study name	Hua 2005			Chi 2005			Ghezzi 2007		
Period	2002-2004			2000-2003			2003-2006		
Design	Prospective cohort			Retrospective case-control			Case-control (with historical controls 1997-2003)		
Intervention	LPS	LPT	P value	LPS	LPT	P value	LPS	LPT	P value
Number of women	10	11	-	20	30	-	15	19	-

Table 2. Case-control studies of laparoscopic surgical staging versus open surgical staging of early ovarian cancer (*Continued*)

Mean age	40	42	-	47.3	50.6	0.31	55	61	0.05
BMI (kg/m²)	-	-	-	24.6	25.4	0.64	23.8	25.8	0.19
Mean operating time (min)	298	182	**< 0.05**	321	276	**0.04**	377	272	**0.002**
Mean blood loss (ml) (SD)	280	346	**< 0.05**	235	367	**0.003**	250	400	0.28
Blood transfusion n (%)	-	-	-	-	-	-	1 (6.7)	2 (10.5)	1.0
Pelvic lymph nodes, n	25 [1]	27 [1]	NS	12.3	14.7	NS	25.2	25.1	0.96
Para-aortic nodes, n	-	-	-	6.7	9.2	NS	6.5	7	0.78
Omental specimen (cm³)	-	-	-	186	347	0.09	-	-	-
Intra-operative tumour spillage, n (%)	0	0	-	-	-	-	3 (20)	2 (10.5)	0.63
Postoperative complications n (%)	2 (20%) [2]	7 (72.7%)	**< 0.01**	0 (0)	3 (10)	-	2 (13.3%)	8 (42.1%)	0.13
Hospital stay (days)	-	-	-	3.1	5.8	**< 0.001**	3	7	**0.001**
Final diagnosis = stage I, n (%)	-	-	-	-	-	-	11 (73.3)	13 (68.4)	-

Table 2. Case-control studies of laparoscopic surgical staging versus open surgical staging of early ovarian cancer (*Continued*)

Tumour upstaged, n (%)	0	0	-	-	-	-	4 (26.7)	6 (31.6)	1.0
Conversion to LPT, n	-	-	-	0	NA	-	0	NA	-
Adjuvant chemotherapy, n (%)	-	-	-	-	-	-	11 (73.3)	13 (68.4)	-
Time to adjuvant chemotherapy (days)	-	-	-	-	-	-	-	-	-
Median follow-up in months (range)	-	-	-	-	-	-	16 (4-34)	60 (32-108)	-
Port-site/ abdominal wound metastasis, n	-	-	-	0	-	-	-	-	-
Recurrences, n (%)	-	-	-	-	-	-	0	4 (21)	-
OS, n (%)	-	-	-	-	-	-	15 (100)	19 (100)	-

Abbreviations: LPS = laparoscopy; LPT, laparotomy; BMI = body mass index; PFS = progression-free survival; OS = overall survival; n = number; NA = not applicable; SD = standard deviation; NS = not specified.

[1]Lymph nodes not specified as pelvic or para-aortic in origin.

[2]Right obturator nerve damaged and repaired in one patient.

Table 3. Retrospective cohort studies of laparoscopic surgical staging versus open surgery for early ovarian cancer

Study name	**Park 2008a**			**Park 2008b**			**Park 2010***			**Park 2011***			**Lee 2011**		
Study period	2001-2006			2004-2007			2004-2008			2004-2010			2005-2010		
Intervention	**LPS**	**LPT**	P value	**LPS**	**LPT**	P value	**LPS**	**LPT**	P value	**LPS**	**LPT**	P value	**LPS**	**LPT**	P value
Number of women	17	19	-	19	33	-	40	76	-	84	128	-	26	87	-
Mean age (years)	43.2	48.9	0.155	43.9	45.4	0.614	-	-	NS	-	-	NS	42	44.4	0.437
BMI (kg/m²)	22.8	24.2	0.247	23.2	22.7	0.578	-	-	NS	-	-	NS	21.9	23.3	0.185
Mean operating time (min)	303.8	290.4	0.706	221	275	**0.012**	230	278	**0.001**	207	262	**< 0.001**	228	184	**0.016**
Mean blood loss (ml)	231	505	**0.001**	240	569	**0.005**	301	494	**0.004**	252	454	**< 0.001**	230	475	**< 0.001**
Blood transfusion, n (%)	0 (0)	2 (11)	-	1 (5)	10 (30)	**0.04**	6 (15)	23 (30)	0.071	6 (13)	36 (28)	**0.012**	0 (0)	20 (23)	**0.006**
Median pelvic lymph nodes, n	13.7	19.3	0.052	27.2	33.9	0.079	-	-	NS	-	-	NS	23.5	22.8	0.867

Table 3. Retrospective cohort studies of laparoscopic surgical staging versus open surgery for early ovarian cancer (*Continued*)

Median paraaortic nodes, n	8.9	6.4	0.187	6.6	8.8	0.324	-	-	NS	-	-	NS	9.9	4.8	**0.003**
Omental specimen (cm^3)	-	-	-	160	274	0.113	-	-	NS	-	-	NS	-	-	-
Tumour size, mean (cm)	4.0	4.5	0.618	8.9	11.0	0.254	-	-	-	-	-	-	**9.1**	**14.0**	**0.010**
Complications n (%)	0 (0)	4 (21)[1]	-	2[2]	9[1]	0.290	-	-	-	6 (7.1)	25 (19.5)	**0.013**	2	20[4]	-
Return to bowel movement (days)	3.8	2.0	**< 0.001**	1.3	3.6	**< 0.001**	1.7	3.6	**< 0.001**	1.8	3.1	**< 0.001**	-	-	-
Hospital stay (days)	9.4	14.1	**0.002**	8.9	14.5	**0.002**	7.9	14.5	**0.002**	6.3	13.5	**< 0.001**	6.4	12.4	**< 0.001**
Final diagnosis = stage I, n	16[3]	13	-	15	26	0.936	-	-	-	-	-	-	25	82	0.212
Intraoperative tu-	0	0	-	2	4	1.000	-	-	NS	-	-	NS	0	13 (14.9)	**0.037**

Table 3. Retrospective cohort studies of laparoscopic surgical staging versus open surgery for early ovarian cancer (*Continued*)

mour spillage n (%)															
Adjuvant chemotherapy, n (%)	10 (59)	17 (89)	0.196	15 (79)	26 (79)	-	-	-	-	-	-	-	17 (65.4)	65 (74.7)	0.453
Time (days) to adjuvant chemotherapy	11.1	14.3	0.140	12.8	17.6	**0.049**	12.8	13.9	**< 0.001**	15.8	20.7	**< 0.001**	8.5	10.3	**0.007**
Upstaged, n (%)	1	6	0.092	4 (21)	-	-	-	-	-	-	-	-	-	-	-
Conversion to LPT, n	0	NA	-	1	NA	-	-	-	-	-	-	-	-	-	-
Portsite/abdominal wound metastases	0	-	-	0	-	-	-	-	-	-	-	-	0	0	-
Median follow-up in months (range)	19 (5 to 56)	14 (5 to 61)	-	17 (2 to 40)	23 (1 to 44)	-	-	-	-	-	-	-	12 (1 to 42)	25 (1 to 74)	-

Table 3. Retrospective cohort studies of laparoscopic surgical staging versus open surgery for early ovarian cancer (*Continued*)

PFS, n (%)	15 [5] (88)	19 (100)	-	19 (100)	33 (100)	-	37 (92)	71 (93)	0.876	66 (78)	100 (78)	0.873	26 (100)	79 (91)	0.195
OS, n (%)	16 (94)	19 (100)	-	19 (100)	33 (100)	-	38 (96)	71 (94)	0.841	75 (89)	110 (86)	0.731	-	-	-

Abbreviations: LPS = laparoscopy; LPT, laparotomy; BMI = body mass index; PFS = progression-free survival; OS = overall survival; n = number; NA = not applicable; NS = not specified.

*These studies are expansions of the original data set (Park 2008b).

[1]Wound infections, fever, ileus.

[2]Including one intra-operative great vessel injury repaired via a small abdominal incision.

[3]All these women were staged Ia/b compared with only five Ia/b and eight Ic cases in the LPT group.

[4] Including 10 lymphoceles in the LPT group. Two umbilical hernias occurred in the LPS group.

[5] One woman diagnosed as FIGO stage Ia grade 1 had severely disseminated disease 7 months postoperatively and died of the disease 15 months later. The other woman was stage Ia grade 2 at LPS and developed recurrence at the vaginal stump.

APPENDICES

Appendix 1. CENTRAL search strategy

#1 MeSH descriptor Ovarian Neoplasms explode all trees
#2 ovar* near/5 (cancer* or tumor* or tumour* or neoplas* or carcinoma* or malignan* or adenocarcinoma*)
#3 (#1 OR #2)
#4 MeSH descriptor Laparoscopy explode all trees
#5 laparoscop* or celioscop* or peritoneoscop* or (endoscop* near/5 abdom*)
#6 MeSH descriptor Laparotomy, this term only
#7 laparotom* or (abdom* near/5 (surg* or incision))
#8 (#4 OR #5 OR #6 OR #7)
#9 (#3 AND #8)

Appendix 2. MEDLINE search strategy

1 exp Ovarian Neoplasms/
2 (ovar* adj5 (cancer* or tumor* or tumour* or neoplas* or carcinoma* or malignan* or adenocarcinoma*)).mp.
3 1 or 2
4 exp laparoscopy/
5 (laparoscop* or celioscop* or peritoneoscop* or (endoscop* adj5 abdom*)).mp.
6 Laparotomy/
7 (laparotom* or (abdom* adj5 (surg* or incision))).mp.
8 4 or 5 or 6 or 7
9 3 and 8
10 randomized controlled trial.pt.
11 controlled clinical trial.pt.

12 randomized.ab.
13 placebo.ab.
14 clinical trials as topic.sh.
15 randomly.ab.
16 trial.ti.
17 exp cohort studies/
18 exp case-control studies/
19 comparative study/
20 (cohort* or prospective* or retrospective* or control* or longitudinal or follow-up).mp.
21 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20
22 9 and 21
key: [mp = protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]

Appendix 3. EMBASE search strategy

1 exp ovary tumor/
2 (ovar* adj3 (cancer* or tumor* or tumour* or neoplas* or carcinoma* or malignan* or adenocarcinoma*)).ti,ab.
3 1 or 2
4 laparoscopy/
5 (laparoscop* or celioscop* or peritoneoscop* or (endoscop* adj3 abdom*)).ti,ab.
6 laparotomy/
7 (laparotom* or (abdom* adj3 (surg* or incision))).ti,ab.
8 4 or 5 or 6 or 7
9 exp controlled clinical trial/
10 cohort analysis/
11 exp case control study/
12 exp comparative study/
13 (randomized or randomly or trial* or cohort* or prospective* or retrospective* or control* or longitudinal or follow-up).ti,ab.
14 9 or 10 or 11 or 12 or 13
15 3 and 8 and 14
key: [mp = title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]

Appendix 4. LILACS search strategy

(MH:"ovarian neoplasms" or (ovar$ and (cancer$ or tumor$ or tumour$ or tumour$ or neoplas$ or carcinoma$ or malignan$ or adenocarcinom$))) and (MH:"laparoscopy" or laparoscop$ or MH:"laparotomy" or laparotom$)

F E E D B A C K

Definition of studies, 7 June 2015

Summary

Name: Alexander Melamed
Comment: The term “prospective case-control” is used in this study is confusing. Case-control studies by definition are retrospective. A case-control study is one where patients with and without an outcome of interest are identified, and the presence or absence of a putative causal exposure is investigated among these “cases” and “controls.” Perhaps what the authors of this study are referring to is what would conventionally be called a cohort study. For a useful discussion of the confusion in regarding the terminology please see Marshall T. What is a case-control study? International Journal of Epidemiology 2004;33:612-617.
I agree with the conflict of interest statement below:
I certify that I have no affiliations with or involvement in any organization or entity with a financial interest in the subject matter of my feedback.

Reply

The authors would like to thank Dr Melamed for taking the time to write, and we accept his suggestion. We have amended the term prospective case-control to prospective cohort studies throughout the review.

Contributors

Theresa A Lawrie on behalf of the author team.

WHAT'S NEW

Last assessed as up-to-date: 23 November 2012.

Date	Event	Description
16 June 2015	Feedback has been incorporated	Feedback received and responded too.
1 April 2015	Amended	Contact details updated.

HISTORY

Protocol first published: Issue 3, 2005

Review first published: Issue 4, 2008

Date	Event	Description
11 February 2015	Amended	Contact details updated.
27 March 2014	Amended	Contact details updated.

(*Continued*)

20 December 2012	Amended	Authorship order amended
12 September 2012	New citation required but conclusions have not changed	Eleven newly identified studies excluded, no studies included. Conclusions unchanged
30 November 2011	New search has been performed	Search updated.
9 November 2010	Amended	Author contact details amended.
14 May 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

Lidia Medieros (LM), Daniela Rosa (DR), Mary Bozetti (MB), Maria Ines Rosa (MR), Alice Zelmanowicz (AZ) and Airton Stein (AS) contributed to the writing of the protocol and the original review. LM, DR, MR, MB and Maria Edelweiss sifted the searches, selected studies and extracted data for the original review (which included NRSs). Anaelena Ethur (AE) and Roselaine Zanini (RZ) contributed to the protocol and methods section. Tess Lawrie (TL) sifted the updated search and wrote the first draft of the updated review. All authors approved the final version.

DECLARATIONS OF INTEREST

None.

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

- National Institute for Health Research (NIHR), UK.

This review received methodological, statistical and editorial support as part of the 10/4001/12 NIHR Cochrane Programme Grant Scheme: Optimising care, diagnosis and treatment pathways to ensure cost effectiveness and best practice in gynaecological cancer: improving evidence for the NHS.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

For the original review (Medeiros 2008), we included NRSs and evaluated the quality of three studies (Ghezzi 2007; Hua 2005; Tozzi 2004) according to the STROBE and NOS tools. For the updated review, these studies were excluded, but we tabulated and discussed the data with other NRSs.

INDEX TERMS

Medical Subject Headings (MeSH)

*Laparoscopy; *Laparotomy; Early Detection of Cancer [*methods]; Neoplasm Staging; Ovarian Neoplasms [pathology; *surgery]

MeSH check words

Female; Humans