Laparoscopy versus laparotomy for benign ovarian tumour (Review)

Medeiros L, Rosa DD, Bozzetti MC, Fachel JMG, Furness S, Garry R, Rosa MINES, Stein AT

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Lidia Medeiros[1], Daniela D Rosa[2], Mary C Bozzetti[3], Jandyra MG Fachel[4], Sue Furness[5], Ray Garry[6], Maria INES Rosa[7], Airton T Stein[8]

[1]Social Medicine, Faculty of Medicine, Federal University of Rio Grande do Sul, Rio Grande do Sul, Brazil. [2]Hospital Femina - Grupo Hospitalar Conceicao, Porto Alegre, Brazil. [3]Social Medicine, Faculty of Medicine at Federal University of Rio Grande do Sul, Rio Grande do Sul, Brazil. [4]Departmento de Estatistica, Instituto de Matematica, Universidade Federal do Rio grande do Sul (UFRGS), Porto Alegre, Brazil. [5]Obstetrics & Gynaecology, University of Auckland , Auckland, New Zealand. [6]Gynaecological Surgery, University of Tesside and South Cleveland Hospital, Middlesbrough, Guisborough, UK. [7]Medical School, Universidade do Extremo Sul Catarinense, Criciuma , Brazil. [8]Department of Epidemiology, Fundacao Faculdade Federal de Ciencias Medicas de Porto Algre, Porto Alegre, Brazil

Contact address: Lidia Medeiros, Social Medicine, Faculty of Medicine, Federal University of Rio Grande do Sul, Ramiro Barcelos 2300, Porto Alegre, Rio Grande do Sul, 90035-000, Brazil. lidia.rosi@terra.com.br.

A B S T R A C T

Background

Over the last ten years laparoscopy and minilaparotomy have become increasingly common approaches for the surgical removal of benign ovarian tumours. However in the event that a tumour is found to be malignant, laparotomy is the appropriate procedure. Careful preoperative assessment including transvaginal ultrasound with morphological scoring, colour doppler assessment of vascular quality and a serum Ca125 level is desirable.

Objectives

To determine the benefits, harms and cost of laparoscopy or minilaparotomy compared with laparotomy in women with benign ovarian tumours.

Search strategy

We searched electronic databases, trials registers and reference lists of published trial reports. Reference lists from trials and review articles were also searched.

Selection criteria

All randomised controlled trials comparing either laparoscopy or minilaparotomy with laparotomy for benign ovarian tumours.

Data collection and analysis

Eight reviewers independently assessed the eligibility and quality of each study, and independently extracted the data.

Main results

The results of nine randomised controlled trials (n=482 women) showed that laparoscopic surgery was associated with fewer adverse events of surgery (surgical injury or post operative complications including fever or infection) (OR 0.3 95% CI 0.2 to 0.5), less post operative pain (VAS scores WMD -2.4 95% CI -2.7 to -2.0), greater likelihood of being pain free after 2 days (OR 7.42 95% CI 4.86 to 11.33) and fewer days in hospital (WMD -2.88 95%CI -3.1 to -2.7) .

In one study that reported costs, laparoscopy was associated with a significant reduction compared to laparotomy(WMD - $1045 95%CI -$1348 to -$742) in US $ in 1993. Very high levels of heterogeneity made it inappropriate to pool data on duration of surgery.

Three RCT's compared laparoscopy versus minilaparotomy and found that laparoscopy was associated with reduced odds of any adverse event (surgical injury or postoperative complications) (OR 0.10 95% CI 0 to 0.8) lower VAS scores for pain (WMD -1.0 95%CI -1.6 to -0.45). Duration of hospital stay ranged between 1 and 2.2 days with substantial heterogeneity.

Authors' conclusions

In women undergoing surgery for benign ovarian tumours, laparoscopy was associated with a reduction in fever, urinary tract infection, post operative complications, post operative pain, number of days in the hospital and total cost. These findings should be interpreted with caution since only a small number of studies were identified including a total of only 769 women and not all of the important outcomes were reported in each study.

P L A I N   L A N G U A G E   S U M M A R Y

Laparoscopic surgery for benign ovarian tumours is associated with less pain, shorter hospital stay and fewer adverse events.

Laparoscopy is modern surgical technique in which operations are performed through small incisions (usually 2-3cm) using a laparoscope: a telescopic rod lens system, that is usually connected to a video camera. In 12 studies identified was associated with reduced risk of any adverse events from surgery, less pain, and fewer days in the hospital when compared to laparotomy, the traditional surgical technique.There was no difference between the procedures with regard to outcomes of fever, post operative infections and tumour recurrence.

B A C K G R O U N D

The ovary is a complex embryological, histological and physiological structure that is capable of developing over fifty types of primary neoplasm variants from benign to borderline and malignant tumours (Barber 1984). Functional and benign ovarian cysts are the most frequent abnormal gynaecological structural finding in women in the reproductive ages, and are among the five main causes of hospitalisation for gynaecological disease in the United States and England (Westhoff 1992). Data from the National Hospital Discharge Survey from 1988 to 1990 showed that the average annual rates of hospitalizations for benign ovarian cysts was 32.7 (95% CI 28.8-36.6) per 10,000 women in reproductive age, and 68% of these patients were submitted to surgical procedure (Velebil 1995). Approximately 80% of ovarian tumours can be successfully surgically treated using an endoscopic technique(Canis 1994). Many advantages of laparoscopic gynae-

cologic surgery have clearly been demonstrated including shorter length of hospital stay, and decreased postoperative pain and recovery time, and less adhesion formation (Canis 1994; Lundorff 1991).

Malignant ovarian neoplasms are responsible for 4% of all malignant tumours affecting women and are the second most common cause of death from gynaecological cancer and the fourth most common cause of death from all types of cancer affecting women (Ekerhovd 2001). The incidence of ovarian tumours progressively increases with age with 3.2 cases per 100.000 person between the ages of 15 to 39 and 54 cases per 100.000 person above the age of 70 (Yancik 1993). The ovary is involved in approximately half of all women with endometriosis (Jenkins 1986). However, a malignant ovarian tumour has been documented clinically to arise in 0.3% to 0.8% of patients with ovarian endometriosis (Heaps 1990; Hitti 1990). Dermoid cysts are the most prevalent germ

cell tumour and account for up to 25% of ovarian neoplasms in premenopausal women. Malignancy occurs in less than 3% and is most frequent in postmenopausal women (Chistopherson 1989; Woodruff 1968). Benign, borderline and malignant lesions have been identified in the same surgical specimen. The frequency and speed of the evolution from dysplasia into cancer remains unknown (Scully 2000).

When an ovarian tumour is detected, it is necessary to establish whether it is likely to be malignant or benign as this diagnosis will guide the decision making on the surgical approach. This cannot be determined with 100% accuracy until inspection of the abdominal cavity, cytological examination of the peritoneal liquid and histological examination of the surgical specimens are performed (Canis 1994). However, a number of criteria can facilitate preoperative diagnosis:

(1) Transvaginal ultrasonography with the use of a morphological scoring system (internal borders, septations, papillary projections, tissue echogenicity and volume) (Sassone 1991) is of value. An ovarian volume of above 20 cm^3 in the reproductive age group and above 10 cm^3 in the postmenopausal group may indicate a need for further investigation (Van Nagell 2000).

(2) Colour Doppler ultrasonography (US) allows vascular quality to be assessed by vascular resistance index (RI) and the pulsatility index (PI) with cut-off for values for malignancy to be less than 0.4 and 1, respectively (Brown 1994). However for ovarian masses it is still not known if benign and malignant lesions can be differentiated with the use of colour and pulsed Doppler US.

(3) CA 125 may be detected in the serum of up to 86% of patients with ovarian neoplasms, with levels of 35 U/ml or higher being suspicious (Chou 1994; Maggino 1987).

In a study of 191 women with ovarian tumours (Timmerman 1999), logistic regression was used to develop an algorithm to distinguish preoperatively between benign and malignant ovarian tumours. The most useful variables in the logistic regression analysis were menopausal status, serum Ca125 level, the presence of 1 or more papillary growth(s) of greater than 3 mm, and a colour score indicative of tumour vascularity and blood flow. The optimised algorithm had a sensitivity of 95.9% and a specificity of 87.1% in the group studied. A subsequent publication attempting to validate this model and others using a large heterogeneous data set, found few models to be robust and generalisable, perhaps due to the subjective nature of some of the component assessments (Van Holsbeke 2007). It is generally accepted that ovarian malignancy can seldom be absolutely excluded prior to surgery.

McDowell reported the first successful removal of an ovarian tumour in 1817 (McDowell 1817). The laparotomy approach was the only option until the end of the twentieth century. The first surgical laparoscopic procedure was performed by Semm and Met-

tler in 1980 (Semm 1980). This approach was thought to be associated with less surgical trauma and lower hospital cost (Canis 2000; Kehlet 1999; Lorenz 1999; Maiman 1991). Approximately 80% of ovarian tumours can be successfully resected using an Laparoscopic (endoscopic) technique (Canis 2000). The potential advantages of this approach include; improved magnification, that makes the diagnosis of peritoneal metastases more certain, the avoidance of an inappropriate transverse laparotomy incision in cases with a malignant tumour and, most important, the prevention of unnecessary laparotomies in patients with benign ovarian tumours (Canis 2000). The laparoscopic approach is used in patients whose adnexal mass is less than 10 cm in diameter, whatever the ultrasonographic appearance. Masses of more than 8 cm are managed more cautiously and evaluated by laparoscopy when unilocular, bilocular or when calcifications are identified) (Canis 1994a, Wong 2000). An alternative minimally invasive procedure to laparoscopy for the management of ovarian cysts is minilaparotomy (3-7 cm transverse skin incision, 2 to 4cm above the pubic symphysis) (Panici 2007). For dermoid cysts and endometriomata, special attention is necessary during the procedure to avoid spillage and the consequent chemical peritonitis and increased risk of subsequent postoperative adhesions. In the case of dermoid cysts, there is a risk of granulomatous reaction (Nissole 1994).

Postoperative adhesions are sequelae from ovarian surgery and may result in mechanical infertility in women in reproductive age (Bassil 1994). Laparoscopic ovarian cystectomy is associated with decreased postoperative adhesion formation when compared with laparotomy (Lundorff 1991).

Some endoscopic procedures are performed using carbon dioxide (CO_2) techniques, and this is considered by some authors to increase the risk of activating cell enzymes which may lead to mitosis and an increase in the production of tumour growth factor as has been shown in an animal model (Greene 1995). An increasing rate of trocar-site recurrences and intraabdominal growth of metastases after laparoscopic surgery in patients with malignant intraabdominal tumours has been reported(Martinez 1995). For this reason, if a tumour turns out to be malignant during laparoscopy, the procedure should be immediately converted to a laparotomy. In these cases, if laparotomy is delayed for more than 8 days, progression from stage Ic to stage II may occur (Kindermann 1995). If a tumour turns out to be malignant during laparoscopy and inadvertent rupture occurs, the procedure should be converted to a laparotomy with a longitudinal medial incision to allow the appropriate necessary surgical staging and debulking procedures.

As it is not yet established whether laparoscopy or laparotomy or minilaparotomy is the best approach for ovarian tumours assumed to be benign, we have performed a systematic review of all randomised controlled trials in which laparoscopy and laparotomy or minilaparotomy were compared for the treatment of benign ovarian tumours.

OBJECTIVES

To determine the benefits, harms and cost of laparoscopic surgery compared with laparotomy or minilaparotomy in women with ovarian tumours assumed to be benign.

METHODS

Criteria for considering studies for this review

Types of studies

All randomised controlled trials (RCTs) which compared laparoscopic surgery with laparotomy (or minilaparotomy) as a treatment for ovarian tumours assumed to be benign.

Types of participants

Inclusion criteria:
We considered three groups of women with benign ovarian tumours who were treated surgically by either laparoscopy, minilaparotomy or laparotomy in this analysis; those with any type of benign ovarian tumour, those with dermoid cysts and those with endometriomata. We have only included trials where women have been investigated in the preoperative setting with transvaginal and/ or transabdominal ultrasonography for analysis of the morphological scoring (internal borders, septations, papillary projections, echogenicity and volume) in order to exclude from the trial women with tumours that are likely to be malignant.
We have noted whether trials reported
(1) The use of Colour Doppler transvaginal ultrasonography to assess vascular quality by vascular resistance index (RI) and pulsatility index (PI).
(2) preoperative estimation of serum CA 125 levels. Levels greater than 35 U/ml are suggestive of malignancy
Exclusion criteria:
(1)Women with ovarian tumours having features suggestive of malignancy during preoperative assessment.
(2)Women with gynaecological cancer.
(3)Trials where the author did not describe the preoperative assessment performed.

Types of interventions

Two surgical approaches used for the management of ovarian tumours assumed to be benign were compared - laparoscopy and laparotomy. Laparotomy was further defined as either 'standard laparotomy' with a Pfannansteil incision or 'minilaparotomy' where the transverse incision was 3-7 cm.

Whenever possible the results were analysed by type of surgeon: gynaecological versus general surgeons.

Types of outcome measures

The major outcome measures were:
1 *Surgical*
- mean duration of surgery
- change of diagnosis from benign to malignant tumour

2 *Adverse events*
- surgical injury - bladder
- surgical injury - ureter
- surgical injury - vascular
- surgical injury - small bowel
- surgical injury - colon

3 *Post operative complications*
- requirement for blood transfusion
- haematoma
- fever
- incision infection
- urinary tract infection
- thromboembolism
- perioperative mortality

4 *Any other adverse event*
- urinary retention
- chemical peritonitis
- intestinal obstruction

5 *Any adverse events of surgery* (either surgical injury, post operative complication or other adverse events of surgery)

6 *Short-term outcomes*
- pain - VAS scores
- pain - pain free at 24-48 hrs post operation
- pain - requirement for analgesia
- length of hospital stay
- recurrence rate after 6-12 months
- blood loss by haemoglobin levels

7 *Economic measure*
- direct cost of surgical procedures

Search methods for identification of studies

For the update of this review in 2007 we searched strategy Cochrane Menstrual Disorders and Subfertility Group Trials Specialised Register (search November 2007) which is submitted as part of the Cochrane Central Register of Controlled Trial (CENTRAL) (The Cochrane Library) MEDLINE (1966 to November 2007), EMBASE (1985 to November 2007), CINAHL (1984 to November 2007), SciSearch (1991 to November 2007), and

LILACS (1982 to November 2007).Appendix 1; Appendix 2; Appendix 3; Appendix 4

The citation list of relevant publications, abstracts of scientific meetings and list of included studies were checked through hand-searching and experts in the field were contacted to identify further reports trials.

A prospective handsearch of publication from 1980 to 2007 on the surgical treatment for benign ovarian tumours in the following journals was carried out: American Journal of Obstetrics and Gynecology, British Journal of Obstetrics and Gynaecology Cancer, Gynecology Oncology, Obstetrics and Gynecology, International Journal Gynecologic Cancer, Gynaecological Endoscopy, Journal American Association Gynecologic Laparoscopists, European Journal Obstetric Gynaecologic, Journal Reproduction Medicine, Reference Gynecologie Obstetrique, Fertility and Sterility, Human Reproduction and Journal of Gynecologic Surgery. Abstracts presented to the following international societies were handsearched: British Society for Gynaecological Endoscopy, European Society for Gynaecological Endoscopy, International Society for Gynecologic Endoscopy, Australian Gynaecological Endoscopy Society, Hong Kong Gynaecological Endoscopy Society, Italian Society for Gynaecological Endoscopic and American Association of Gynecologic Laparoscopists.

Data collection and analysis

Selection of studies
In this update all studies were assessed according the inclusion criteria above. Four reviewers (LRM, JF, MIR,DDR) worked in pairs and agreement on eligibility was reached. A standard checklist was used to guide this process. No effort was made to blind the reviewers from names of authors, institutions or journals. The reasons for this was that the reviewers were very familiar with the literature on surgical treatment for benign ovarian tumours and would recognise most studies even if they were blinded. For this update, two reviewers (MCB and ATS) independently assessed citations for inclusion. Any discrepancies were resolved by a co-reviewer (RG and SF). When eligibility could not be determined from the published study the authors were contacted for clarification. There were no language restrictions.

Methodological quality and data extraction
Included trials were analysed for the following specific criteria and methodological details. Using a standard checklist to guide this process, the reviewers collected information on study design for each trial. Differences in data extraction were resolved by consensus, referring back to the original article. When trials were reported in more than one publication, data were extracted from the most recent article, referring to other articles for methodological details, baseline characteristics or further outcomes when appropriate.

Data extraction
Data regarding details on the study population, intervention and outcomes were extracted by one reviewer (LRM, DDR, MIR)

and checked independently by other three reviewers (MCB, JF, ATB) using a data extraction form. This included the following information:

Trial characteristics
(1) Method of randomisation
(2) Presence or absence of blinding to treatment allocation
(3) Quality of allocation concealment
(4) Number of patients randomised, excluded or lost from follow-up
(5) Whether an intention-to -treat analysis was performed
(6) Whether a power calculation was done
(7) Duration, timing and location of the study

Characteristics of the women participants
(1) Age and any other baseline characteristics of women in the study
(2) Method used to define ovarian cysts in the laparoscopy surgery
(3) Details of the preoperative assessment
(4) Other inclusion criteria
(5)Exclusion criteria
(6)Histological type of ovarian tumour (endometrioma, dermoid cyst, or other)

Interventions used
(1) Laparoscopy - ovarian cystectomy (unilateral and bilateral) or oophorectomy (unilateral and bilateral), number of ports, type of anaesthesia.and histological types (endometriosis, dermoid cysts and others).
(2) Laparotomy - ovarian cystectomy (unilateral and bilateral) or oophorectomy (unilateral and bilateral), type and length of incision.
(3) Minilaparotomy - where the transverse incision was 3-7 cm, ovarian cystectomy (unilateral and bilateral) or oophorectomy (unilateral and bilateral).

Outcomes
The major outcome measures were:
(1) Surgical duration
(2) Adverse events - surgical injury
(3) Post operative complications
(4) Any other adverse events
(5) Any adverse events from surgery (either surgical injury, post operative complication or other adverse events)
(6) Short-term outcomes
(7) Economic measure

Assessment of methodological quality of included studies
All assessments of the quality of trial and data extraction were performed independently by five reviewers (LRM, DDR, MIR, MCB, ATS) using forms designed by Cochrane. The quality of allocation concealment was assigned for each trial, using the following criteria:
- Grade A: Adequate concealment
- Grade B: Uncertain concealment
- Grade C: Clearly inadequate concealment

Trials with quasi-randomisation designs were excluded.

Attrition bias (loss of participants)

We described completeness of follow up for each trial and include reasons for loss of participants, for example, withdrawals, dropouts and protocol deviations when reported.

Performance bias (blinding of participants, researchers and outcome assessment)

Blinding of participants, caregivers and outcome assessment were assessed and described, or reported as 'not stated'.

Analysis

Statistical analysis was performed in accordance with the guidelines for statistical analysis developed by the Menstrual Disorders and Subfertility Group. All trials were initially included in the analysis. Subgroup analysis was performed looking separately, at dermoid cysts and endometriomata ovarian cysts.

For categorical outcomes (surgical injuries, change of diagnosis from benign to malignant tumour, postoperative complications, any adverse events of surgery, pain free at 24-48 hours, readmission rates) we extracted the numbers reported for each outcome for each group of women. Results for each study were expressed as an odds ratio (OR) with 95% confidence intervals and combined for meta-analysis with the RevMan software using the Peto-modified Mantel-Haenszel method.

Statistical heterogeneity among the results of different studies was examined by inspecting the both the scatter points in the graphs and the overlap in their confidence intervals and, more formally, by checking the results of chi-square tests. Because there were few studies, a p-value for chi-square tests of less than 0.10 was used to indicate heterogeneity. The outcomes were pooled statistically when no clinical heterogeneity was apparent. However, since clinical and methodological diversity always occur in a meta-analysis, statistical heterogeneity is inevitable. An alternative approach that quantifies the effect of heterogeneity is inconsistency (I^2), providing a measure of the degree of inconsistency in the results of the studies with 95% uncertainty intervals (Higgins 2003). This describes the percentage of the variability in the effect estimates that is due to heterogeneity rather than sampling error (chance). A value of 0% indicates no observed heterogeneity and a value greater than 50% may be considered substantial heterogeneity. When it is inappropriate to pool the data due to clinical or statistic heterogeneity a systematic review without meta-analysis was performed.

For continuous outcomes (duration of surgery, length of hospital stay and direct cost of surgical procedures) we used mean and standard deviations to derive a weighted mean difference (WMD) with 95% confidence intervals using the RevMan software. Difficulties were found with the reporting of continuous outcomes (for example duration of surgery), where the data were skewed and the authors correctly presented them as medians with their range. Whenever possible original data were obtained from the authors although post-treatment means and standard deviations were not always available or calculable. Where only medians and ranges were available, the median was regarded as being identical to the mean and a crude estimate of the standard deviation was calculated from the range (range X 0.95)/4). This method is not ideal for skewed data and is likely to result in an over-estimation of the SD. Therefore, a sensitivity analysis (planned a priori) was performed, with inclusion and exclusion of trials with skewed data in meta-analysis. The distribution of data on duration of surgery is highly likely to be skewed and in these cases the ideal and most appropriate statistical analysis is probably nonparametric rather than inclusion in a meta-analysis assessing a weighted mean difference. Where a standard deviation is not reported it can be calculated from either the standard error or the 95% confidence intervals. A standard deviation can be obtained from the standard error of mean by multiplying by the square-root of the sample size: $SD = SEx\sqrt{N}$. When making this transformation, standard errors must be of means calculated from within an intervention group and not standard errors of the difference in means computed between intervention groups.

Confidence intervals for means can also be used to calculate standard deviations. Again, the following applies to confidence intervals for mean values calculated within an intervention group and not for estimates of differences between interventions . Most confidence intervals are 95% confidence intervals. If the sample size is large (say bigger than 100 in each group), the 95% confidence interval is 3.92 standard errors wide (3.92 = 2 × 1.96). The standard deviation for each group is obtained by dividing the length of the confidence interval by 3.92, and then multiplying by the square root of the sample size: $SD = \sqrt{N} \times (\text{upper limit-lower limit})/3.92$ (section 7.7.3.2 (Higgins 2008).

We pooled the effect measure within a random-effects model, because these outcomes are heavily influenced by the context of care. Sensitivity analysis was planned a priori to compare the study results for type of intervention (ovarian cystectomy or oophorectomy), histological types (any type of benign ovarian tumour, dermoid cysts and ovarian endometriomata) and study design and reporting (adequate vs unclear allocation concealment). Both fixed and random effects meta-analyses were undertaken to assess the robustness of the results.

R E S U L T S

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies.

Initially thirty two studies were identified which compared laparoscopy and laparotomy for benign ovarian tumours (Figure 1) (. Twenty of these studies were excluded, because they were not randomised (Albini 1994; Bateman 1994; Bulletti 1996; Chapron 1997; Darwisch 2001; Deckardt 1994; Hidlebaugh 1994; Hidlebaugh 1997; Howard 1995; Laberge 2006;Lin 1995;

Marana 2004; Mettler 2001a; Papasakelariou 1995; Paredes 1997; Pittaway 1994; Quinlan 1997; Thomas 2006; Zanetta 1999; Yuen 1995). Please see the Characteristics of excluded studies table.

Twelve randomised controlled trials published between 1995 and 2007 met the inclusion criteria for this review (Badawy 2002; Buchweitz 2005; Damiani 1998; Fanfani 2004; Mais 1995; Mais 1996; Mais 2003; Morgante 1998; Nitke 1996; Panici 2007, Panici 2007a; Yuen 1997) (Figure 1).

The six additional primary studies in this update are RCT. Badawy 2002 ; Buchweitz 2005; Fanfani 2004; Mais 2003; Panici 2007; Panici 2007a.

Description of Studies

1. Settings

Ten studies were of single-centre design and two trials were conducted between 2 centres. Eight trials included were conducted in Italy (Damiani 1998;Fanfani 2004; Mais 1995; Mais 1996; Mais 2003;Morgante 1998, Panici 2007; Panici 2007a). The other four studies were from Israel (Nitke 1996), Hongkong (Yuen 1997), Germany (Buchweitz 2005) and Egypt (Badawy 2002).

2. Designs

Nine studies were randomised comparisons of laparoscopy versus laparotomy for benign ovarian tumours (Badawy 2002; Buchweitz 2005; Damiani 1998; Mais 1995; Mais 1996; Mais 2003;Morgante 1998; Nitke 1996; Yuen 1997). Two studies compared laparoscopy with minilaparotomy (Fanfani 2004; Panici 2007a) and a further study compared laparoscopy with laparoscopic guided minilaparotomy Panici 2007).

3. Participants

All women included in the trials had ovarian tumours and underwent a preliminary workup, including transvaginal or transabdominal ultrasonography or both. In all trials, the type of surgeon (gynaecologists and/or general surgeon) was not defined. Only one trial reported that surgeons were undergoing training under supervision of an experienced surgeon (Yuen 1997). Eight studies mentioned that all surgical procedures were performed by the same investigators (Badawy 2002; Buchweitz 2005; Damiani 1998;Fanfani 2004, Mais 1995, Mais 1996, Mais 2003; Panici 2007). Six studies had recorded body mass index of the patients (Badawy 2002;Buchweitz 2005; Fanfani 2004; Mais 1995;Panici 2007; Panici 2007a). Eight studies included women with all histopathological types of benign ovarian tumours (Badawy 2002; Buchweitz 2005; Damiani 1998; Fanfani 2004; Mais 1995; Panici 2007; Panici 2007a; Yuen 1997). Three studies defined a subgroup of dermoid cysts (Morgante 1998; Nitke 1996, Mais 2003). Only one randomised trial considered a subgroup of patients with endometriomata ovarian cysts (Mais 1996).

4. Interventions

Ovarian cystectomy was performed by laparoscopy or laparotomy in 100% of the cases in five studies (Damiani 1998; Mais 1995; Mais 1996; Morgante 1998;Nitke 1996). Ovarian cystectomy was reported bilateral in around 20% of cases in two trials either by laparoscopy or laparotomy (Morgante 1998; Nitke 1996).

Oophorectomy was performed by laparoscopy or laparotomy in around 30% of the cases (Yuen 1997) in each group and 100% of the cases in one trial (Buchweitz 2005). Ovarian cystectomy was reported in 87% of cases in laparoscopy and 70% of laparotomies (Badawy 2002).

In five studies there were no co-interventions in either group (laparoscopy and laparotomy) (Damiani 1998; Mais 1995; Mais 1996; Morgante 1998; Yuen 1997), but in one trial concomitant procedures were made (Nitke 1996).

No trials compared a surgical approach performed by one surgeon with another surgical approach performed by a second surgeon. Seven trials (Damiani 1998; Mais 1995; Fanfani 2004; Mais 1996; Mais 2003, Panici 2007) reported that a team experienced in laparoscopic surgery performed the procedures. Frozen section was mentioned in three trials (Buchweitz 2005; Fanfani 2004; Panici 2007).

5. Outcomes

For each outcome we considered three groups in this analysis according to the ovarian tumour histopathology: all histological types of benign ovarian tumour, dermoid ovarian cysts and ovarian endometriomata. The four major outcome measures were

(1) Surgical
- The mean duration of surgery was reported by ten studies (Badawy 2002; Buchweitz 2005; Damiani 1998;; Fanfani 2004; Mais 1995; Mais 1996; Mais 2003; Morgante 1998; Nitke 1996; Yuen 1997). Both studies by Panici reported median operating time together with interquartile range (Panici 2007;Panici 2007a).

(2) Adverse effects of surgery:
- Surgical injury, post operative complications and any other adverse events of surgery were described in most studies but four studies stated that no postoperative complications occurred (Mais 1995; Mais 1995; Mais 2003;Nitke 1996) described in all twelve studies.
- In our up date three trials described incidence of a suspected malignant ovarian tumour during the procedure by frozen section analysis (Buchweitz 2005; Fanfani 2004; Panici 2007).

(3)Short-term recovery :
- Pain (VAS scores) was reported in four studies (Mais 1995; Morgante 1998;Panici 2007a; Yuen 1997)
- Pain free at 24-48 hours after surgery was reported in six studies (Badawy 2002; Mais 1995; Mais 2003; Morgante 1998; Panici 2007a; Yuen 1997)
- Requirement for analgesia was reported in four studies (Badawy 2002; Buchweitz 2005; Fanfani 2004, Yuen 1997).
- Mean length of hospital stay was reported in nine studies, median length of stay with interquartile range was reported in two studies (Panici 2007 ; Panici 2007a) and Mais 2003 described numbers discharged within three days of surgery.
- Recurrence rates at 6-12 months were reported in four studies (Damiani 1998; Mais 1995; Mais 1996;Mais 2003

• Blood loss by decrease in mean haemoglobin level in each group was described in Buchweitz 2005 and Panici 2007 reported the median pre and post operative haemoglobin level in each group together with 25-75 percentile range.

(4) Economic measure:
• Direct cost of surgical procedures were described in only one study from Italy (Damiani 1998).

Risk of bias in included studies

See Figure 1; Figure 2 Seven trials had score A based on adequate concealment prior to randomisation, used in conjunction with numbered sealed envelopes where the seal was broken in the anaesthetic room prior to surgery (Badawy 2002; Fanfani 2004; Mais 1995; Mais 1996; Mais 2003; Panici 2007; Yuen 1995). The remaining five trials received an allocation score B since the method of randomisation was not reported in the publication (Buchweitz 2005; Damiani 1998; Morgante 1998; Nitke 1996, Panici 2007a)Table 1.

Figure 1.   Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all included studies.
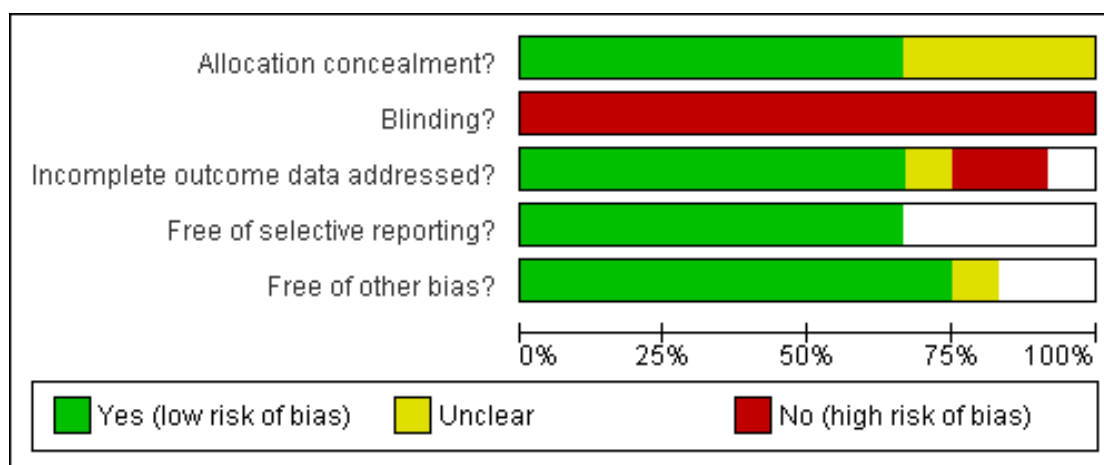
Figure 2.   Methodological quality summary: review authors' judgements about each methodological quality item for each included study.

Five trials showed a power calculation for the sample size (Buchweitz 2005; Fanfani 2004, Mais 1995, Mais 1996, Yuen 1997), and only one trial stated that they performed an intention-to treat analysis (Panici 2007a). One study, (Badawy 2002) did not mention randomisation, but personal communication with Dr. Badawy resulted in confirmation that participants were in fact randomly allocated to treatment groups by the principal investigator using computerized random tables at the time of admission of the patients to the hospital.

Numbers of women included in the trials were generally small ranging from 10 to 64 per treatment arm.

Two studies reported no loss from follow up six months after surgery (Mais 1995; Mais 1996) and another study reported no losses after 2 weeks follow up (Morgante 1998). In Nitke 1996, follow up was only until discharge from hospital after surgery (maximum 4.3 days), and no losses were reported. Damiani *et al.* and Badawy et al., conducted a follow up assessment at 12 months after surgery, but did not mention any patients lost to follow up (Badawy 2002; Damiani 1998). One study (Yuen 1997) stated that four of the original 110 patients recruited into the study refused randomisation and another four were lost from follow up, resulting in a total of eight of the original 110 (7.3%) patients recruited, who were not assessed at the end of follow up, six weeks after surgery. Mais *et al.*, reported 5 years of follow up (Mais 2003). Panici 2007 stated that follow up was for three months and three studies did not specifically state the duration of follow up but it is likely to have been less than 3 months (Buchweitz 2005;Fanfani 2004;Panici 2007a).

Inter-rater agreement for quality assessment by individual reviewers was good (Cohen's kappa=0.79). Disagreements were resolved through discussion in all cases (MCB, ATS, JF).

Sensitivity analysis including and excluding the studies of lower quality assessment was performed based on the quality of allocation concealment (A,B,C).

Effects of interventions

Included studies

Twelve studies and 769 patients were included in this review. Nine studies compared laparoscopy and laparotomy (Badawy 2002; Buchweitz 2005; Damiani 1998; Mais 1995; Mais 1996; Mais 2003; Morgante 1998; Nitke 1996; Yuen 1997). Three studies compared laparoscopy and minilaparotomy (Fanfani 2004; Panici 2007; Panici 2007a).

1 Laparoscopy versus laparotomy
1.1 SURGICAL OUTCOMES

(a) *Duration of surgery*

(i) In the studies of any type of benign ovarian tumour (Badawy 2002; Buchweitz 2005; Damiani 1998;Mais 1995; Yuen 1997). There was considerable heterogeneity in these estimates and it was inappropriate to pool the data. (Figure 3).

Figure 3. Forest plot of comparison: 1 Laparoscopy versus laparotomy, outcome: 1.1 Surgery - Duration of surgery (min).
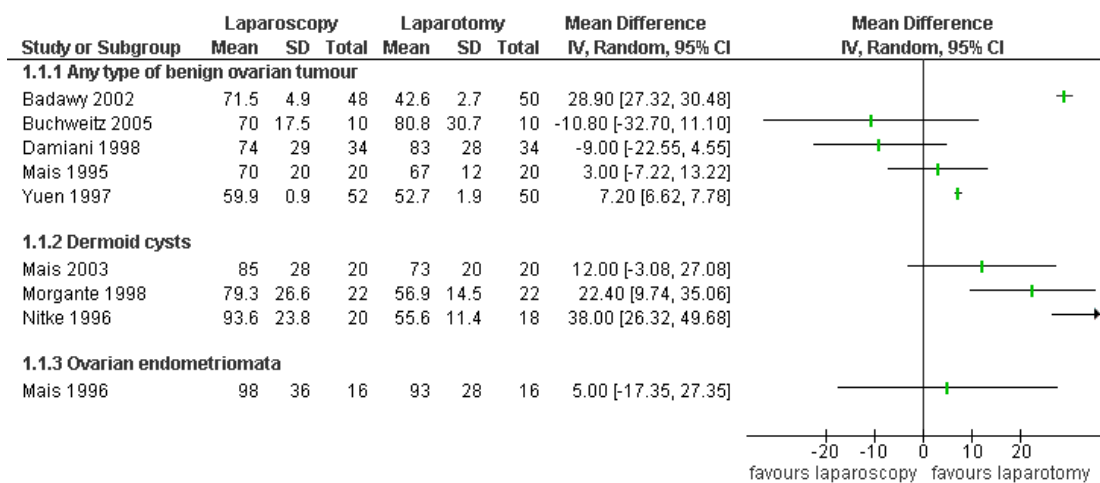
(ii) In the subgroup of dermoid cysts (Mais 2003; Morgante 1998; Nitke 1996) there was substantial inconsistency making it inappropriate to pool these data (chi -squared=7.67, p=0.02, with I^2=74%) (Figure 2).

(iii) In the subgroup of ovarian endometriomata (Mais 1996): there were no statistically significant difference between treatments arms for duration of surgery (Figure 2).

(b) *Diagnosis of malignant tumour*

In one study ovarian tumours in four women were found to be ma-

lignant after frozen section was performed during laparoscopy with subsequent conversion to laparotomy (Buchweitz 2005). Badawy 2002 excluded from the analysis one patient in the laparoscopy group who had significant intracystic lesions which were identified during endocystic evaluation. Biopsy later showed serous cystadenoma with proliferation activity of the epithelial cells and nuclear abnormalities but with no infiltrative destructive growth (low malignant potential) (Badawy 2002) (Figure 4).

Figure 4.   Forest plot of comparison: 1 Laparoscopy versus laparotomy, outcome: 1.2 Surgery - Change of diagnosis to malignant tumour.
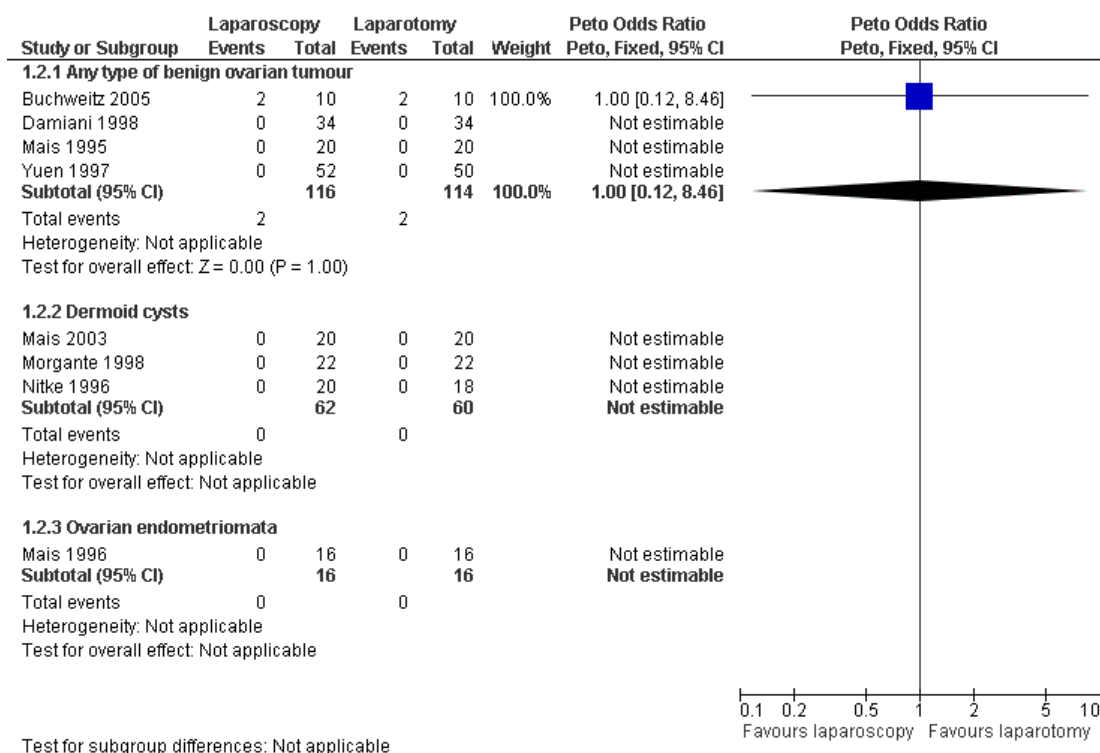
1.2 ADVERSE EVENTS

(a) Surgical injury

Nine studies provided data for analysis of surgical injuries (Badawy 2002; Buchweitz 2005; Damiani 1998; Mais 1995; Mais 1996; Mais 2003; Morgante 1998; Nitke 1996;Yuen 1997).

(i) In the subgroup of any type of benign ovarian tumours (Badawy 2002; Buchweitz 2005; Damiani 1998; Mais 1995;Yuen 1997) no injuries to the ureter, small bowel or colon were reported. One study (Yuen 1997) reported a single case of bladder injury in the laparotomy group and two studies (Badawy 2002; Yuen 1997)

each reported a single case of vascular injury in the laparoscopy group.

(ii) In the subgroup of dermoid cysts (Morgante 1998; Nitke 1996): no surgical injuries were reported.

(iii) In the subgroup for ovarian endometriomata (Mais 1996): no surgical injuries were reported.

(b) *Postoperative complications*

Postoperative complications were infrequent in all of the included studies. Haematoma, chemical peritonitis, requirement for blood

transfusion, or perioperative mortality were not reported in any of the nine included studies.

However febrile morbidity, incision infection, urinary tract infection, urinary retention, thromboembolism, intestinal obstruction were reported as uncommon post operative complications.

(i) In the subgroup of any type of benign ovarian tumour there was a decreased risk of fever in the laparoscopy group (Peto OR 0.37, 95% CI 0.18 to 0.76) without heterogeneity and with I^2 = 0%, in four studies (Buchweitz 2005; Damiani 1998; Mais 1995; Yuen 1997) (Figure 5).

Figure 5. Forest plot of comparison: 1 Laparoscopy versus laparotomy, outcome: 1.10 Post operative complications - Febrile morbidity.
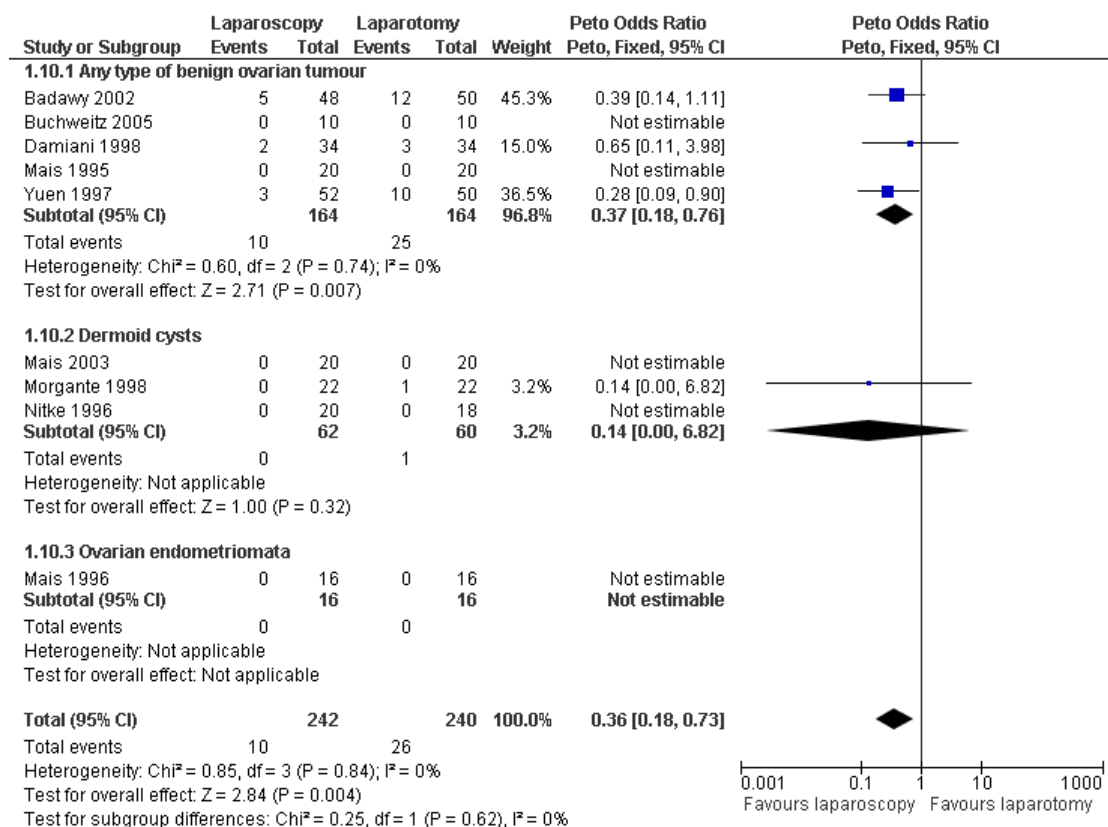
There was a non statistically significant difference between laparoscopy and laparotomy regarding the risk of incision infection (Peto OR 0.18, 95% CI 0.05 to 0.67) and urinary tract infection(Peto OR 0.3, 95% CI 0.08 to 1.16)(Badawy 2002;Yuen 1997) (Figure 6;Figure 7).

Figure 6. Forest plot of comparison: 1 Laparoscopy versus laparotomy, outcome: 1.11 Post operative complications - Incision infection.

Study or Subgroup	Laparoscopy Events	Total	Laparotomy Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
1.11.1 Any type of benign ovarian tumour						
Badawy 2002	1	48	5	50	85.1%	0.26 [0.05, 1.32]
Buchweitz 2005	0	10	0	10		Not estimable
Damiani 1998	0	34	0	34		Not estimable
Mais 1995	0	20	0	20		Not estimable
Yuen 1997	0	52	1	50	14.9%	0.13 [0.00, 6.56]
Subtotal (95% CI)		**164**		**164**	**100.0%**	**0.23 [0.05, 1.05]**
Total events	1		6			
Heterogeneity: Chi² = 0.10, df = 1 (P = 0.76); I² = 0%						
Test for overall effect: Z = 1.89 (P = 0.06)						
1.11.2 Dermoid cysts						
Mais 2003	0	20	0	20		Not estimable
Morgante 1998	0	22	0	22		Not estimable
Nitke 1996	0	20	0	18		Not estimable
Subtotal (95% CI)		**62**		**60**		**Not estimable**
Total events	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
1.11.3 Ovarian endometriomata						
Mais 1996	0	16	0	16		Not estimable
Subtotal (95% CI)		**16**		**16**		**Not estimable**
Total events	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						

Test for subgroup differences: Not applicable

Figure 7.   Forest plot of comparison: 1 Laparoscopy versus laparotomy, outcome: 1.12 Post operative complications - Urinary tract infection.
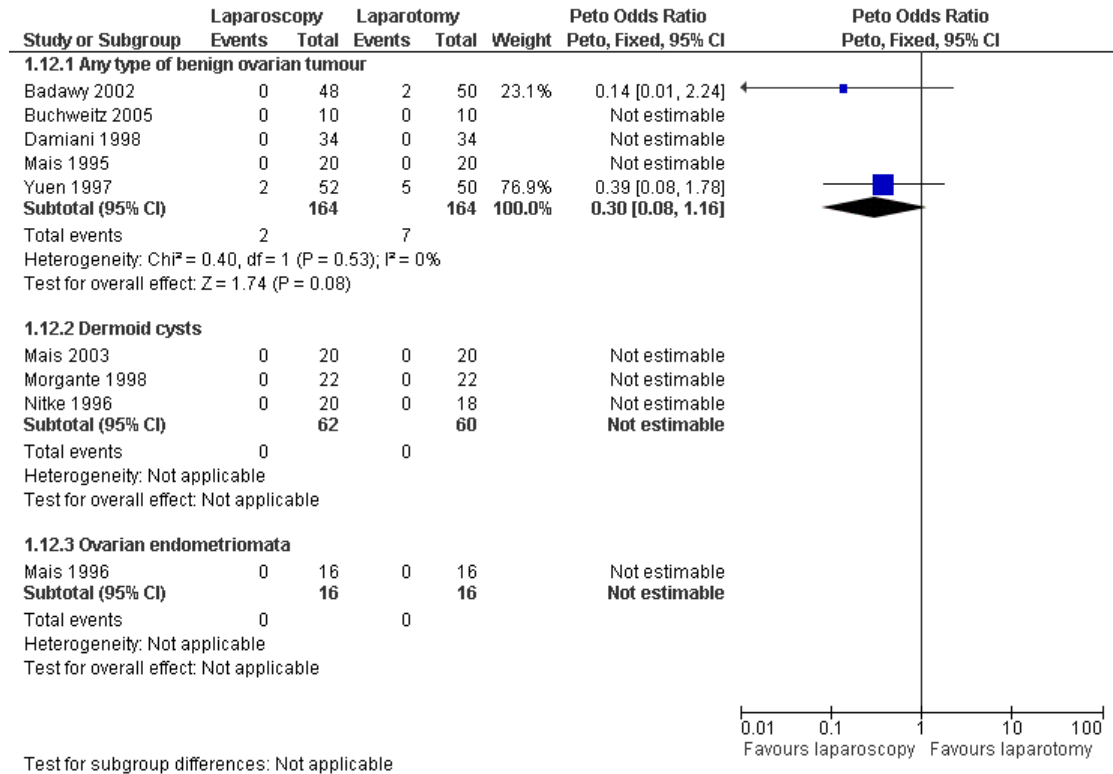
There was also a decreased risk of urinary retention in the laparoscopy group (Peto OR 0.12, 95% CI 0.02 to 0.89) in the one trial that reported this outcome (Yuen 1997) (Figure 8), and blood loss by haemoglobin levels (WMD -0,6, 95% CI -1.39 to 0.19) (Buchweitz 2005) (Figure 9).

Figure 8. Forest plot of comparison: 1 Laparoscopy versus laparotomy, outcome: 1.15 Urinary retention.

Study or Subgroup	Laparoscopy Events	Total	Laparotomy Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI	Peto Odds Ratio Peto, Fixed, 95% CI
1.16.1 Any type of benign ovarian tumour							
Badawy 2002	0	48	0	50		Not estimable	
Buchweitz 2005	0	10	0	10		Not estimable	
Damiani 1998	0	34	0	34		Not estimable	
Mais 1995	0	20	0	20		Not estimable	
Yuen 1997	0	52	4	50	100.0%	0.12 [0.02, 0.89]	
Subtotal (95% CI)		**164**		**164**	**100.0%**	**0.12 [0.02, 0.89]**	
Total events	0		4				
Heterogeneity: Not applicable							
Test for overall effect: Z = 2.07 (P = 0.04)							
1.16.2 Dermoid cysts							
Mais 2003	0	20	0	20		Not estimable	
Morgante 1998	0	22	0	22		Not estimable	
Nitke 1996	0	20	0	18		Not estimable	
Subtotal (95% CI)		**62**		**60**		**Not estimable**	
Total events	0		0				
Heterogeneity: Not applicable							
Test for overall effect: Not applicable							
1.16.3 Ovarian endometriomata							
Mais 1996	0	16	0	16		Not estimable	
Subtotal (95% CI)		**16**		**16**		**Not estimable**	
Total events	0		0				
Heterogeneity: Not applicable							
Test for overall effect: Not applicable							

0.001　0.1　1　10　1000
Favours laparoscopy　Favours laparotomy

Test for subgroup differences: Not applicable

Figure 9. Forest plot of comparison: 1 Laparoscopy versus laparotomy, outcome: 1.18 Blood loss by haemoglobin levels.

Study or Subgroup	laparoscopy Mean	SD	Total	laparotomy Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI	Mean Difference IV, Random, 95% CI
1.14.1 Any type of benign ovarian tumour									
Buchweitz 2005	1.4	1.2	10	1.7	1.1	10	100.0%	-0.30 [-1.31, 0.71]	
Subtotal (95% CI)			**10**			**10**	**100.0%**	**-0.30 [-1.31, 0.71]**	
Heterogeneity: Not applicable									
Test for overall effect: Z = 0.58 (P = 0.56)									
1.14.2 Dermoid cysts									
Subtotal (95% CI)			**0**			**0**		**Not estimable**	
Heterogeneity: Not applicable									
Test for overall effect: Not applicable									
1.14.3 Ovarian endometriomata									
Subtotal (95% CI)			**0**			**0**		**Not estimable**	
Heterogeneity: Not applicable									
Test for overall effect: Not applicable									
Total (95% CI)			**10**			**10**	**100.0%**	**-0.30 [-1.31, 0.71]**	
Heterogeneity: Not applicable									
Test for overall effect: Z = 0.58 (P = 0.56)									

-10　-5　0　5　10
Favours laparoscopy　Favours laparotomy

(ii) In the dermoid cyst subgroup only one study reported a single case of fever in the laparotomy group (Morgante 1998) (Peto OR 0.14, 95% CI 0.00 to 6.82). There were no reported cases of incision infection or urinary tract infection in this study, but this may be because all patients received prophylactic antibiotics.

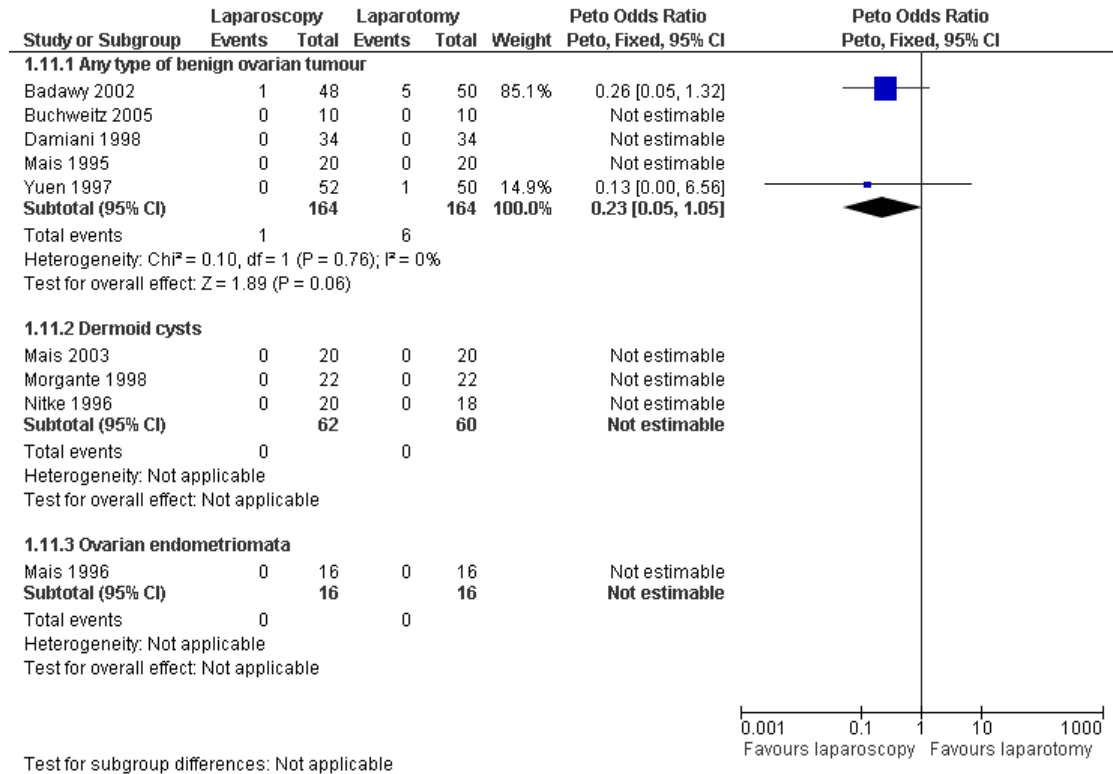(iii) In the subgroup of ovarian endometriomata (Mais 1996): no postoperative complications were reported.

(iv) The pooled estimate for fever including the subgroups of any type of benign ovarian tumour and dermoid cysts showed a reduced odds of febrile morbidity associated with laparoscopy (Peto OR 0.31, 95% CI 0.13 to 0.76) with no heterogeneity detected (Figure 5).

Blood loss assessed by haemoglobin levels

Blood loss was described in two studies (Badawy 2002;Buchweitz 2005). In one study (Buchweitz 2005) there was no statistically significant difference between laparoscopy and laparotomy in mean blood loss as measured by change in haemoglobin levels. In the other study (Badawy 2002) one woman in each group had a blood loss greater than 300 ml.

(c) Any adverse events of surgery (surgical injury, post-operative complications and/or any other adverse events of surgery)

(i) In the subgroup for any type of benign ovarian tumour (Badawy 2002; Buchweitz 2005;Damiani 1998; Mais 1995; Yuen 1997): laparoscopic surgery was associated with an overall reduction in odds of any adverse events (Peto OR 0.3, 95% CI 0.18 to 0.52), without heterogeneity and with I^2=0% (Figure 10).

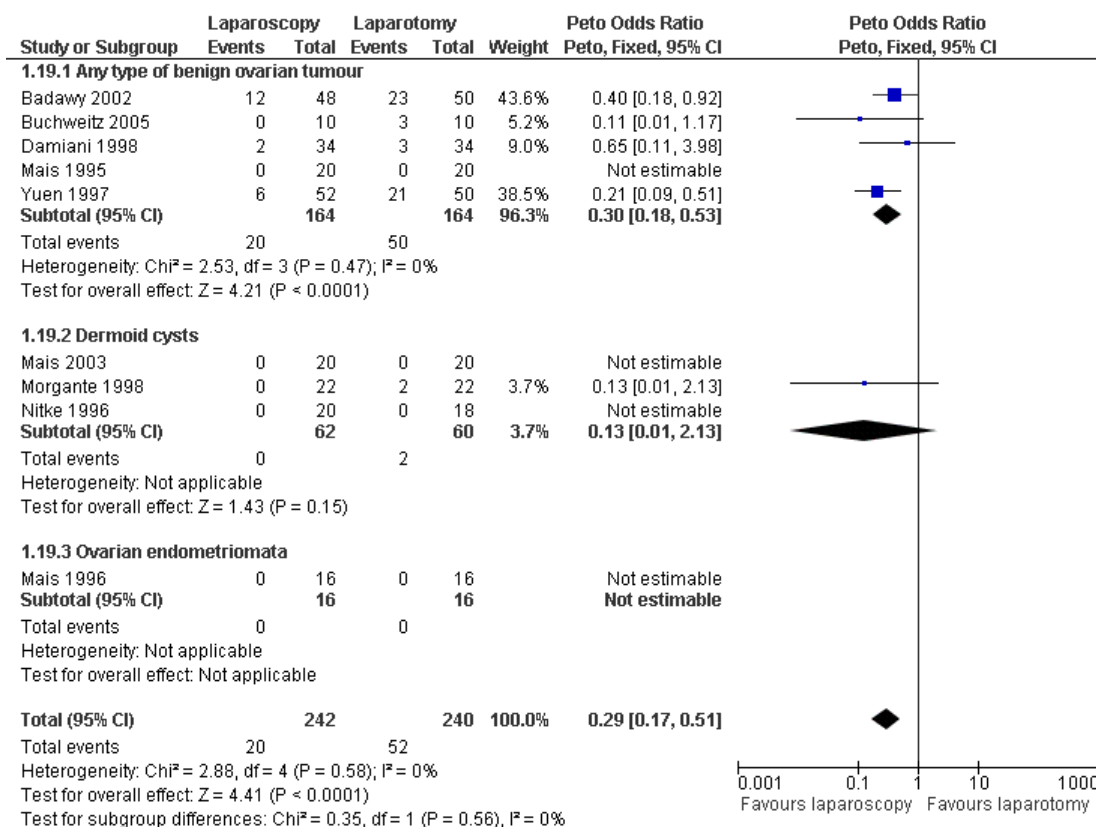**Figure 10. Forest plot of comparison: 1 Laparoscopy versus laparotomy, outcome: 1.19 Any adverse effect of surgery (incl surgical injury or post surgery complication or other).**

(ii) In the subgroup of dermoid cysts (Morgante 1998; Nitke 1996): there were no statistically significant difference between the two treatments arms regarding the total number of adverse events of surgery (Peto OR 0.14, 95% CI 0.00 to 6.82). Only one case

with an adverse events was reported in one trial (Morgante 1998).

(iii) In the subgroup of ovarian endometriomata (Mais 1996): no surgical injuries and no postoperative complications in the only

study analysing this subgroup.

(iv) Pooled estimate for total number of adverse events including the subgroups of any type of benign ovarian tumour or dermoid cysts showed a lower odds for any adverse events for laparoscopy when compared to laparotomy (Peto OR 0.29, 95% CI 0.17 to 0.51), and no heterogeneity was detected (Figure 10).

1.3 *SHORT-TERM OUTCOMES*

(a) *Postoperative pain (VAS scores, free of pain at 24-48 hrs aft her surgery, requirement for analgesia)*
The intensity of postoperative pain was assessed in three ways; visual analogue scores (VAS), the proportion of each group who were pain free 24-48 hours after surgery, and the overall requirement for post operative analgesia in each group.

(i) In the group with any type of ovarian tumour (Mais 1995, Yuen 1997), VAS scores for pain favoured laparoscopy (WMD -2.25, 95% CI -2.94 to -1.56) and in the subgroup of dermoid cysts laparoscopy was also associated with lower pain scores (WMD -2.40; 95% CI -2.79 to -2.01) (Morgante 1998).

The pooled estimate for VAS scores including these two groups favoured laparoscopy (WMD -2.36; 95% CI -2.7 to -2.03) and no heterogeneity was detected (chi-squared=1.78, p=0.41, with I^2=0%) (Figure 11).

Figure 11. Forest plot of comparison: 1 Laparoscopy versus laparotomy, outcome: 1.20 Short term recovery - pain (VAS).
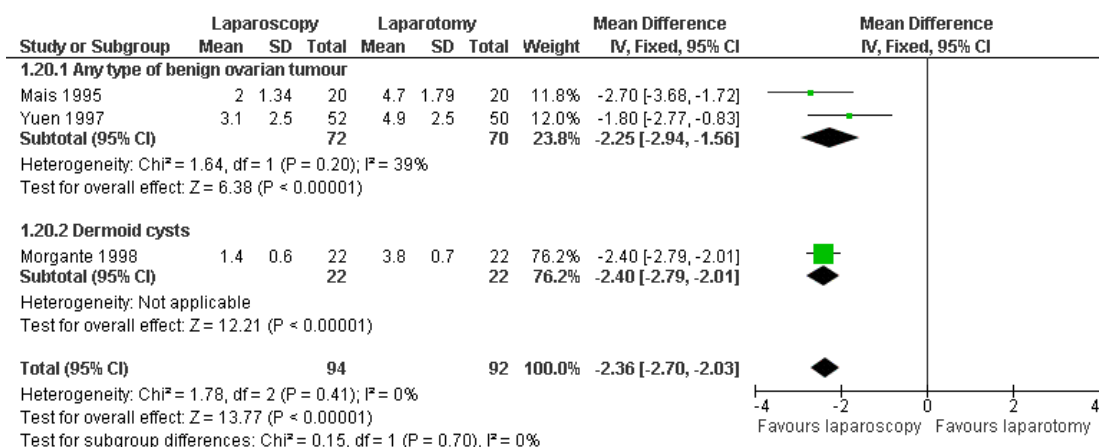
(ii) The odds for being pain free of pain were significantly greater for laparoscopy in each of the three subgroups; any type of benign ovarian tumour (Peto OR 5.87, 95% CI 3.48 to 9.9) (Badawy 2002; Mais 1995; Yuen 1997); dermoid cysts (Peto OR 3.7 CI 1.42 to 9.63) (Mais 2003, Morgante 1998) and ovarian endometriomata (Peto OR 14.51; 95% CI 3.7 to 56.9) (Mais 1996). The pooled estimate for all the subgroups was (Peto OR 7.42, 95% CI 4.86 to 11.33) with no heterogeneity detected among the 356 participants included in these six studies (chi-squared= 4.75 p= 0.45) (Figure 12).

(iii) Two studies reported the mean postoperative consumption of analgesics (Badawy 2002; Buchweitz 2005; Yuen 1997). Only one study (Badawy 2002) found a statistically significant difference between the groups favouring laparoscopy.
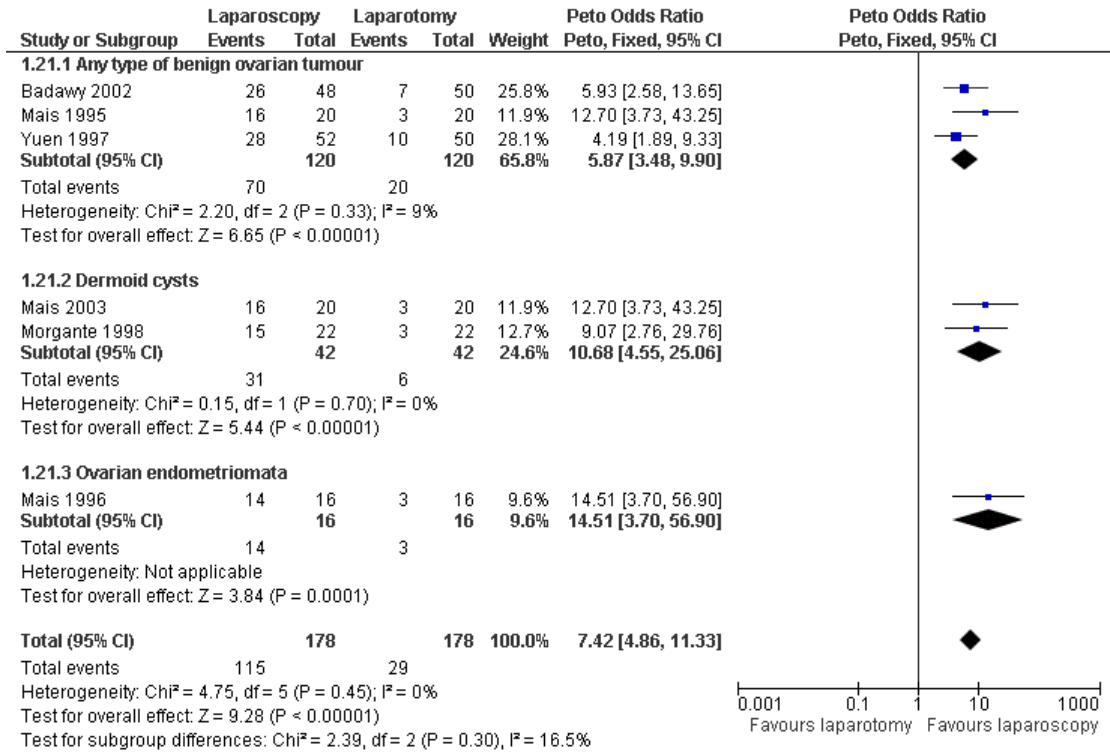
Figure 12. Forest plot of comparison: 1 Laparoscopy versus laparotomy, outcome: 1.21 Short term recovery - pain (pain free 24-48 hours post surgery).

Study or Subgroup	Laparoscopy Events	Total	Laparotomy Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
1.21.1 Any type of benign ovarian tumour						
Badawy 2002	26	48	7	50	25.8%	5.93 [2.58, 13.65]
Mais 1995	16	20	3	20	11.9%	12.70 [3.73, 43.25]
Yuen 1997	28	52	10	50	28.1%	4.19 [1.89, 9.33]
Subtotal (95% CI)		120		120	65.8%	5.87 [3.48, 9.90]
Total events	70		20			
Heterogeneity: Chi² = 2.20, df = 2 (P = 0.33); I² = 9%						
Test for overall effect: Z = 6.65 (P < 0.00001)						
1.21.2 Dermoid cysts						
Mais 2003	16	20	3	20	11.9%	12.70 [3.73, 43.25]
Morgante 1998	15	22	3	22	12.7%	9.07 [2.76, 29.76]
Subtotal (95% CI)		42		42	24.6%	10.68 [4.55, 25.06]
Total events	31		6			
Heterogeneity: Chi² = 0.15, df = 1 (P = 0.70); I² = 0%						
Test for overall effect: Z = 5.44 (P < 0.00001)						
1.21.3 Ovarian endometriomata						
Mais 1996	14	16	3	16	9.6%	14.51 [3.70, 56.90]
Subtotal (95% CI)		16		16	9.6%	14.51 [3.70, 56.90]
Total events	14		3			
Heterogeneity: Not applicable						
Test for overall effect: Z = 3.84 (P = 0.0001)						
Total (95% CI)		178		178	100.0%	7.42 [4.86, 11.33]
Total events	115		29			
Heterogeneity: Chi² = 4.75, df = 5 (P = 0.45); I² = 0%						
Test for overall effect: Z = 9.28 (P < 0.00001)						
Test for subgroup differences: Chi² = 2.39, df = 2 (P = 0.30), I² = 16.5%						

0.001 0.1 1 10 1000
Favours laparotomy   Favours laparoscopy

(b) *Recurrence of ovarian tumours six to twelve months after surgery*
Recurrence was mentioned in only two studies, with a combined total of 108 participants (Damiani 1998; Mais 1995) with 2 cases of recurrence (one in each group) occurring in the group with any type of benign ovarian tumour (Damiani 1998) (Figure 13).

Figure 13.   Forest plot of comparison: 1 Laparoscopy versus laparotomy, outcome: 1.23 Recurrence at 6-12 months.
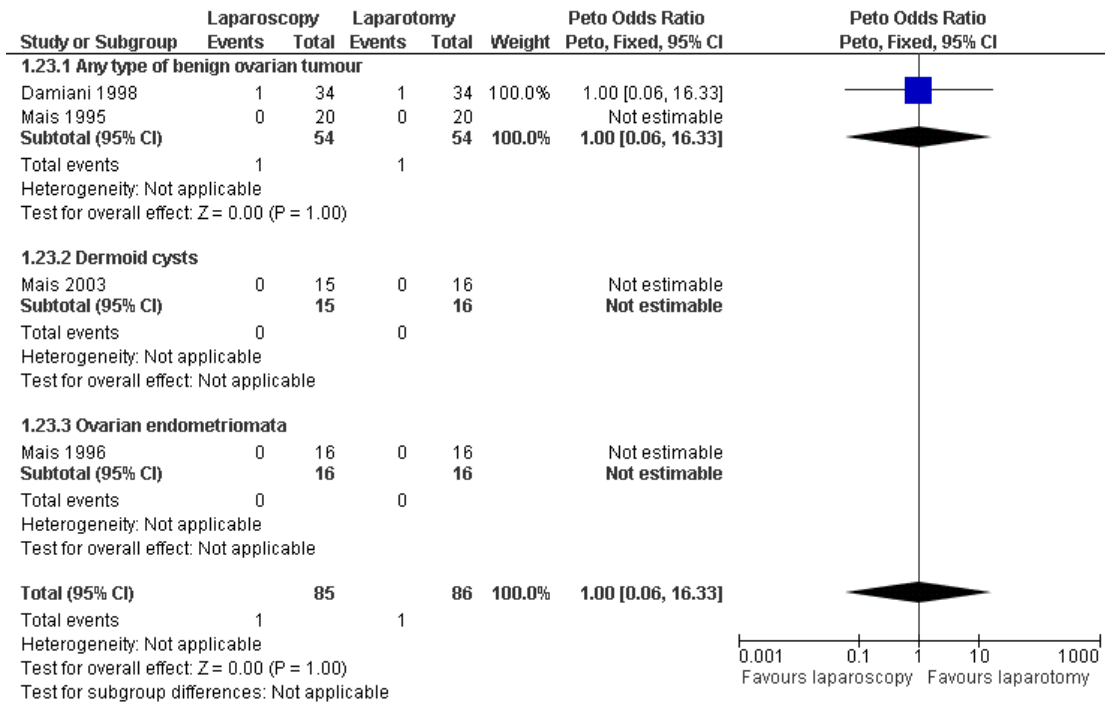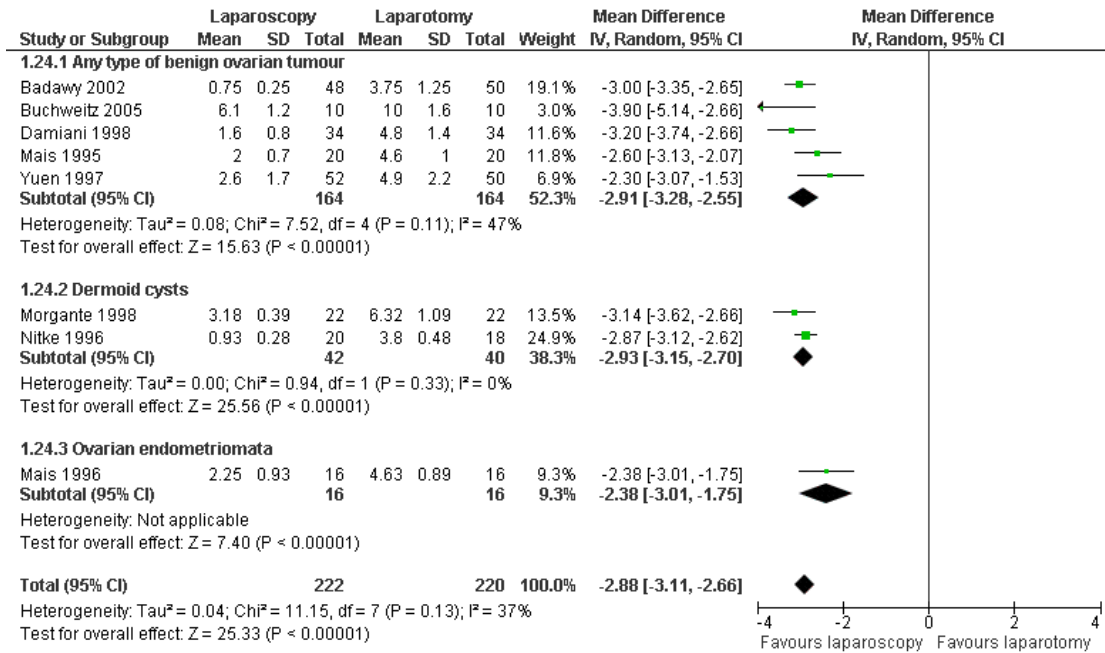

(c) *Length of hospital stay*

A reduced number of days in the hospital was associated with laparoscopy in all the subgroups.

Any type of benign ovarian tumours (Buchweitz 2005;Damiani 1998; Mais 1995; Yuen 1997) (WMD -2.90, 95% CI -3.28 to -2.52), dermoid cysts (Morgante 1998; Nitke 1996) (WMD -2.93, 95% CI -3.15 to -2.70) , and endometriomata (WMD -2.38, 95% CI -3.01 to -1.75).

The pooled estimate for these three subgroups favoured laparoscopy (WMD -2.88, 95% CI -3.10 to -2.65) with heterogeneity (chi-squared=11.63 p=0.11) and inconsistency detected (I^2 =40%) (Figure 14).

Figure 14. Forest plot of comparison: 1 Laparoscopy versus laparotomy, outcome: 1.24 Length of hospital stay (days).

Study or Subgroup	Laparoscopy Mean	SD	Total	Laparotomy Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
1.24.1 Any type of benign ovarian tumour								
Badawy 2002	0.75	0.25	48	3.75	1.25	50	19.1%	-3.00 [-3.35, -2.65]
Buchweitz 2005	6.1	1.2	10	10	1.6	10	3.0%	-3.90 [-5.14, -2.66]
Damiani 1998	1.6	0.8	34	4.8	1.4	34	11.6%	-3.20 [-3.74, -2.66]
Mais 1995	2	0.7	20	4.6	1	20	11.8%	-2.60 [-3.13, -2.07]
Yuen 1997	2.6	1.7	52	4.9	2.2	50	6.9%	-2.30 [-3.07, -1.53]
Subtotal (95% CI)			164			164	52.3%	-2.91 [-3.28, -2.55]

Heterogeneity: Tau² = 0.08; Chi² = 7.52, df = 4 (P = 0.11); I² = 47%
Test for overall effect: Z = 15.63 (P < 0.00001)

Study or Subgroup	Laparoscopy Mean	SD	Total	Laparotomy Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
1.24.2 Dermoid cysts								
Morgante 1998	3.18	0.39	22	6.32	1.09	22	13.5%	-3.14 [-3.62, -2.66]
Nitke 1996	0.93	0.28	20	3.8	0.48	18	24.9%	-2.87 [-3.12, -2.62]
Subtotal (95% CI)			42			40	38.3%	-2.93 [-3.15, -2.70]

Heterogeneity: Tau² = 0.00; Chi² = 0.94, df = 1 (P = 0.33); I² = 0%
Test for overall effect: Z = 25.56 (P < 0.00001)

Study or Subgroup	Laparoscopy Mean	SD	Total	Laparotomy Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
1.24.3 Ovarian endometriomata								
Mais 1996	2.25	0.93	16	4.63	0.89	16	9.3%	-2.38 [-3.01, -1.75]
Subtotal (95% CI)			16			16	9.3%	-2.38 [-3.01, -1.75]

Heterogeneity: Not applicable
Test for overall effect: Z = 7.40 (P < 0.0001)

Study or Subgroup			Total			Total	Weight	Mean Difference IV, Random, 95% CI
Total (95% CI)			222			220	100.0%	-2.88 [-3.11, -2.66]

Heterogeneity: Tau² = 0.04; Chi² = 11.15, df = 7 (P = 0.13); I² = 37%
Test for overall effect: Z = 25.33 (P < 0.00001)
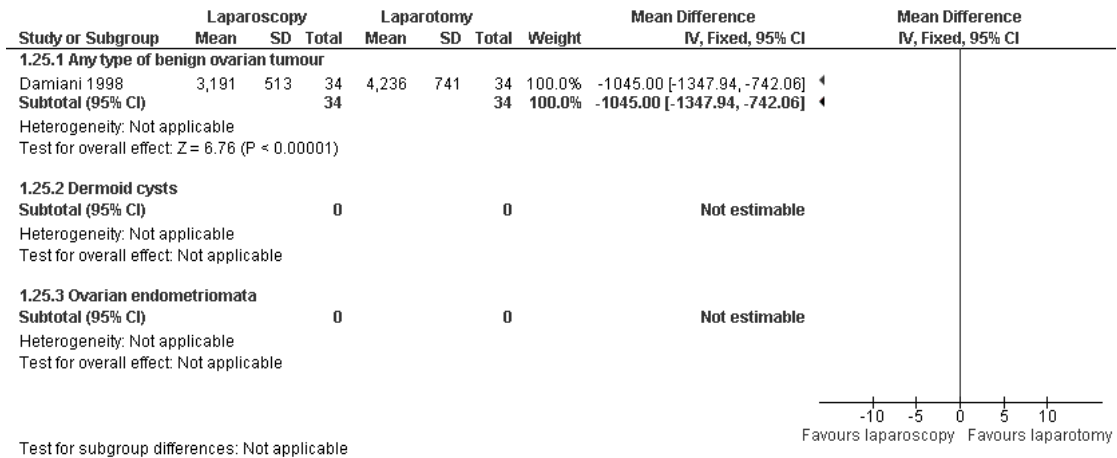
(d) *Readmission rates*

No case of readmission was reported in any of the nine included studies.

1.4. ECONOMIC MEASURE

(a) Direct cost of surgical procedures

Only one study, undertaken in Rome, Italy, described the cost of interventions (Damiani 1998). Using a cost analysis from a social perspective, the total cost of laparoscopy, measured in 1993 US dollars were significantly lower for laparoscopy when compared to laparotomy WMD US$1045 (95% CI -1348 to -742) in this study of 68 women (Figure 15).

Figure 15. Forest plot of comparison: 1 Laparoscopy versus laparotomy, outcome: 1.25 Economic outcomes - total cost (US$1000 1993).
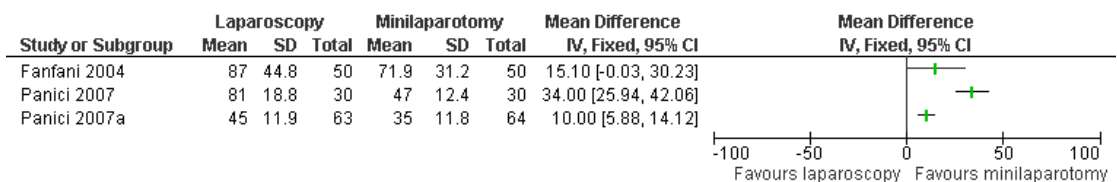
Study or Subgroup	Laparoscopy Mean	SD	Total	Laparotomy Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI	Mean Difference IV, Fixed, 95% CI
1.25.1 Any type of benign ovarian tumour									
Damiani 1998	3,191	513	34	4,236	741	34	100.0%	-1045.00 [-1347.94, -742.06]	◄
Subtotal (95% CI)			34			34	100.0%	-1045.00 [-1347.94, -742.06]	◄
Heterogeneity: Not applicable									
Test for overall effect: Z = 6.76 (P < 0.00001)									
1.25.2 Dermoid cysts									
Subtotal (95% CI)			0			0		Not estimable	
Heterogeneity: Not applicable									
Test for overall effect: Not applicable									
1.25.3 Ovarian endometriomata									
Subtotal (95% CI)			0			0		Not estimable	
Heterogeneity: Not applicable									
Test for overall effect: Not applicable									

-10 -5 0 5 10
Favours laparoscopy Favours laparotomy

Test for subgroup differences: Not applicable

2 Laparoscopy versus minilaparotomy
2.1 SURGICAL OUTCOMES

(a) Duration of surgery

Three trials (Fanfani 2004; Panici 2007; Panici 2007a) reported the outcome of operative time but both the studies by Panici reported medians as the data were skewed. The substantial heterogeneity and inconsistency in these results made it inappropriate to pool these data (chi -squared=55.56, p<0.001) with substantial inconsistency (I^2 =96.4%) (Figure 16).

Figure 16. Forest plot of comparison: 2 Laparoscopy versus minilaparotomy, outcome: 2.1 Surgery - duration of surgery.

Study or Subgroup	Laparoscopy Mean	SD	Total	Minilaparotomy Mean	SD	Total	Mean Difference IV, Fixed, 95% CI	Mean Difference IV, Fixed, 95% CI
Fanfani 2004	87	44.8	50	71.9	31.2	50	15.10 [-0.03, 30.23]	
Panici 2007	81	18.8	30	47	12.4	30	34.00 [25.94, 42.06]	
Panici 2007a	45	11.9	63	35	11.8	64	10.00 [5.88, 14.12]	

-100 -50 0 50 100
Favours laparoscopy Favours minilaparotomy

(b) Diagnosis of malignant tumour

One study reported inadvertent treatment by endoscopic surgery for tumours found to be malignant on frozen section analysis during the surgery (Panici 2007). Conversion was carried out through an increase of the transverse cutaneous incision. Fanfani et al., had three cases of unexpected borderline ovarian tumour after intensive surgical staging by laparoscopy (Fanfani 2004).

These studies did not report a complete five-year follow-up. We found no statistically significant difference between two groups (Peto OR 0.95, 95% CI 0.19 to 4.7), and no heterogeneity was detected (Figure 17).

Figure 17.   Forest plot of comparison: 2 Laparoscopy versus minilaparotomy, outcome: 2.2 Surgery - change of diagnosis to malignant tumour.
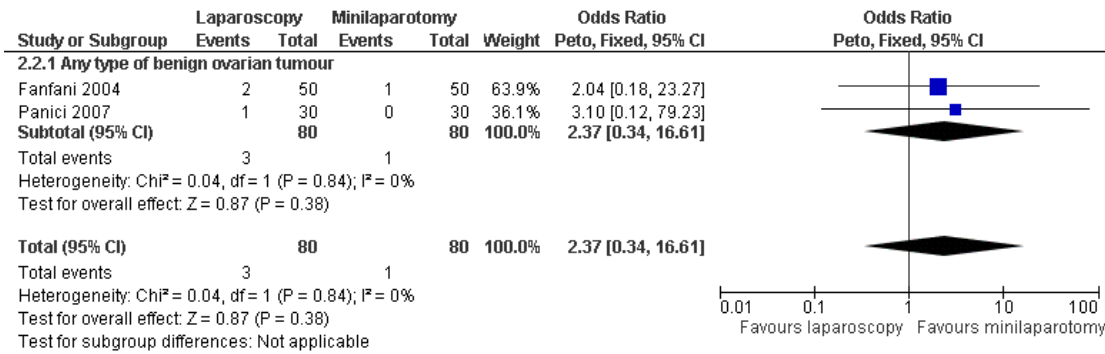
2. 2 ADVERSE EVENTS

(a) Surgical injury

In the three studies no injuries to the ureter, small bowel, colon, bladder or vascular tissue were reported (Fanfani 2004; Panici 2007, Panici 2007a).

(b) Postoperative complications

Blood transfusion, haematoma, thromboembolism, chemical peritonitis, intestinal obstruction or perioperative mortality were not reported in any of the three included studies (Fanfani 2004; Panici 2007, Panici 2007a).

One trial (Panici 2007) reported median pre and post operative heamoglobin levels in each group and stated the the difference between groups was not statitically significant.

There was no statistically significant difference between laparoscopy and laparotomy for febrile morbidity in two studies (Fanfani 2004;Panici 2007a) (Peto OR 0.16, 95% CI 0.02 to 1.38) (Figure 18) or for risk of incision infection (Peto OR 0.14, 95% CI 0.01 to 2.73) in the one trial that reported this outcome (Panici 2007a) (Figure 19).

Figure 18. Forest plot of comparison: 2 Laparoscopy versus minilaparotomy, outcome: 2.10 Post operative complications - Febrile morbidity.
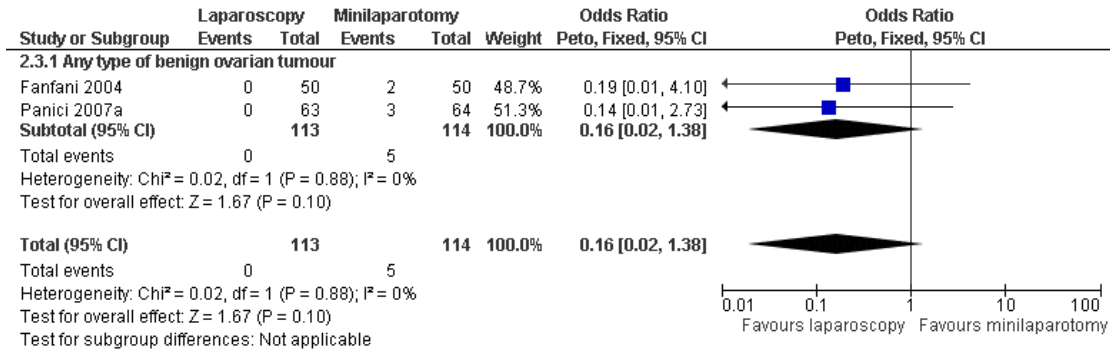
Figure 19. Forest plot of comparison: 2 Laparoscopy versus minilaparotomy, outcome: 2.11 Post operative complications - Incison infection.
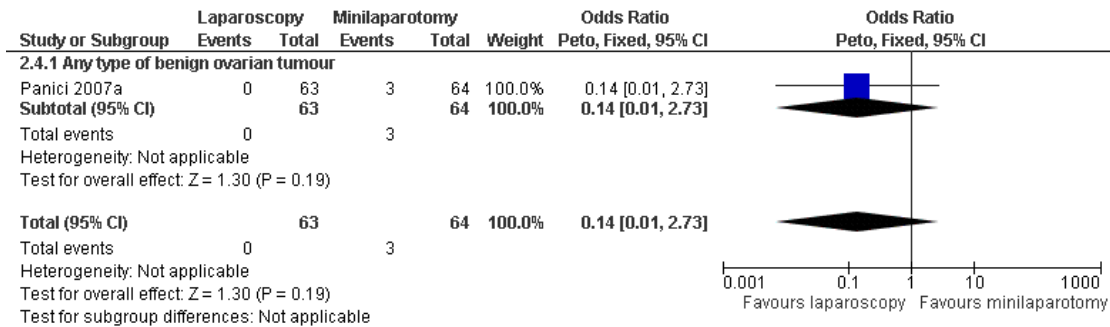
(c) *Any adverse events of surgery (surgical injury, post-operative complications and/or any other adverse events of surgery).*

The pooled estimate for odds of any adverse event favoured laparoscopy (Peto OR 0.10, 95% CI 0.01 to 0.77) with no heterogeneity detected(Fanfani 2004; Panici 2007a) (Figure 20).

Figure 20. Forest plot of comparison: 2 Laparoscopy versus minilaparotomy, outcome: 2.19 Any adverse effect of surgery (incl surgical injury or post surgery complication or other).
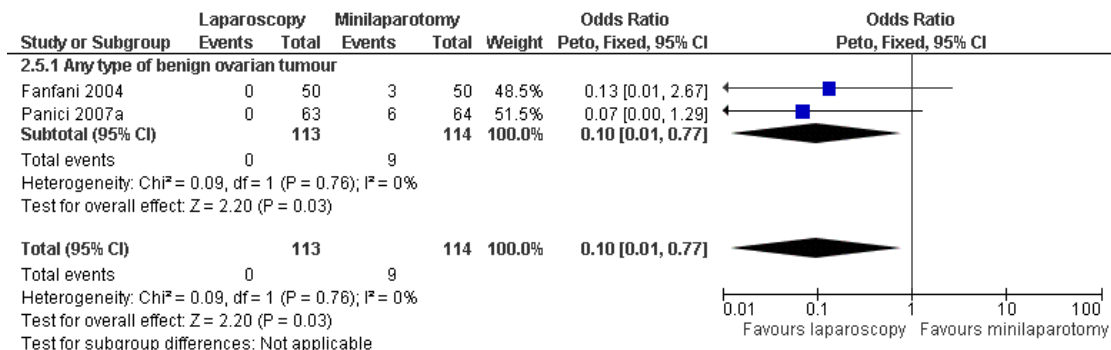
2.3 SHORT-TERM OUTCOMES

(a) Postoperative pain (VAS scores, free of pain at 24-48 hrs after surgery, requirement for analgesia)

(i) VAS scores for pain were reported in one study (Panici 2007a) which found no statistically significant difference between laparoscopy and minilaparotomy. (WMD -1.00, 95% CI -1.55 to -0.45). (Figure 21).

Figure 21. Forest plot of comparison: 2 Laparoscopy versus minilaparotomy, outcome: 2.20 Short term recovery - pain (VAS).
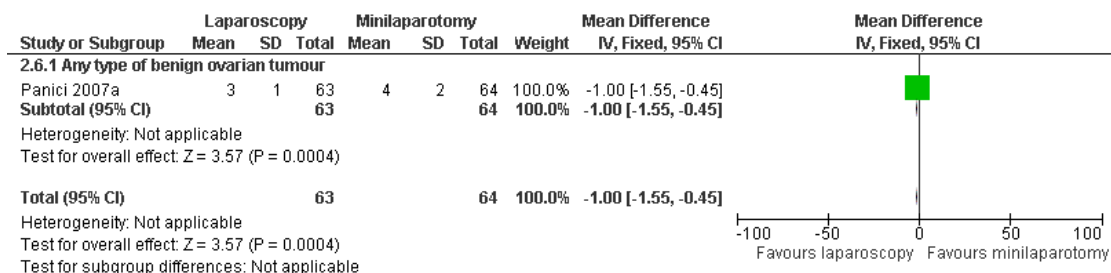
The odds for being free of pain were significantly greater for laparoscopy group (Peto OR 10.85, 95% CI 4.62 to 25.49) in the one trial that reported this outcome (Panici 2007a) (Figure 22).

Figure 22.   Forest plot of comparison: 2 Laparoscopy versus minilaparotomy, outcome: 2.21 Short term recovery - pain (pain free 24-48 hours post surgery).
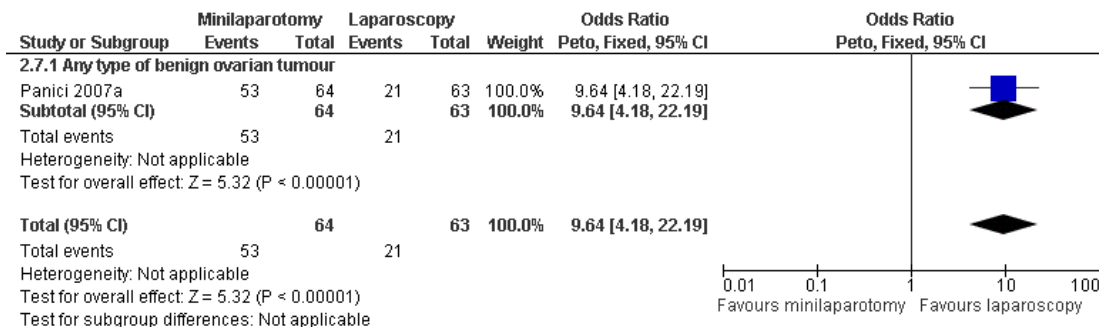
Only one study reported requirement for analgesia (Fanfani 2004) and found no difference between laparoscopy and laparotomy
(b) Length of hospital stay
(i) Mean length of stay in hospital ranged between 1 and 2.2 days in the three studies. There was a very high level of heterogenieity and inconsistency (I^2 =94%) which made it inappropriate to pool these data. (Figure 23).

Figure 23.   Forest plot of comparison: 2 Laparoscopy versus minilaparotomy, outcome: 2.24 Lenght of hospital stay (days).
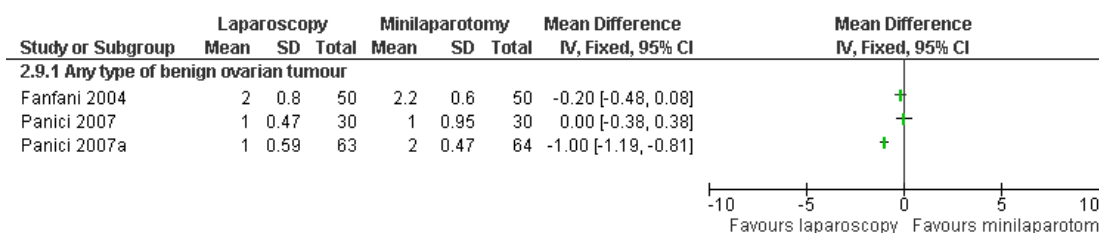
SENSITIVITY ANALYSES
Sensitivity analysis was performed to test the robustness of the findings (Egger 2001) in the comparison between laparoscopy and laparotomy. We found that the pooled estimate treatment effect was similar for studies with adequate and with unclear allocation concealment for the following outcomes: length of hospital stay, postoperative pain and total number of complications.
In the comparison between laparoscopy and minilaparotomy no sensitivity analysis was undertaken due to the small number of studies (Fanfani 2004; Panici 2007; Panici 2007a).

DISCUSSION

This systematic review update has evaluated the benefits, harms and costs of laparoscopy versus laparotomy for the treatment of benign ovarian tumours. The results of twelve randomised controlled trials (n=769 women) showed that laparoscopic surgery was associated with significantly less post operative pain, fewer adverse events of surgery (surgical injury or post operative complications) and a shorter length of stay in hospital.

The results of this review give no clear information about the operating time for the two procedures compared. Operating time was very variable, and this was likely due to clinical heterogeneity

in the populations included in the trials. Variations in the age and BMI of the women, the number, size and location (unilateral or bilateral) of the ovarian tumours and the presence of adhesions due to previous abdominal surgery are all factors likely to influence the duration of surgery. Furthermore the experience of the surgeon, the requirement to wait for the results of an intraoperative frozen section, and the need to perform concomitant procedures such as oophorectomy would also influence the operating time. For example, in one study (Badawy 2002) only 12 % of the laparoscopy group underwent oophorectomy, whereas 30% in the laparotomy group had this procedure. Many of the studies did not clearly describe the factors which may have accounted for differences in the duration of surgery.

In this systematic review, the quality of allocation concealment was graded as adequate (A) in seven studies (Badawy 2002; Mais 1995; Mais 1996; Mais 2003; Panici 2007; Panici 2007a; Yuen 1997) and five studies were graded as unclear (B) (Buchweitz 2005; Damiani 1998; ;Fanfani 2004; Morgante 1998; Nitke 1996). (Table 1) The adequacy of the allocation concealment did not affect the outcomes of duration of surgery, postoperative pain, total number of complications or length of hospital stay.

Although duration of hospital stay was significantly reduced by nearly three days after laparoscopy when compared to laparotomy significant heterogeneity was detected. This was likely to be due to differences in the patient populations in the trials - factors such as age and previous surgery may have an influence on length of stay, and it would appear that there are differences between hospitals in their policy of post operative stay. The data from individual trials reported longer hospital stay after laparotomy than would be expected and this suggests that discharge after laparotomy in some trials may have relied more on tradition than on clinical demands.

Cost is another factor that should be taken into consideration when choosing the surgical approach (Barnes 1982; Krahn 1999). The costs of laparoscopy compared to laparotomy were reported by one trial with limited sample size, with only 34 patients in each group (Damiani 1998). This trial, undertaken in Rome, Italy, performed a simple cost analysis from a social perspective, presented in 1993 US dollars. The findings were that the costs of laparoscopy were one thousand US dollars less per patient when compared to laparotomy, due to the longer hospital stay and the increased requirement for nursing care, medical care, laboratory tests, analgesics, antibiotics and intravenous infusions in the laparotomy group. However these data were published 10 years ago and it is likely that some factors which have an impact on costs of these procedures have changed in the intervening period.

Overall frequency of inadvertent rupture of the cysts during operation was large in the laparoscopy group that in the minilaparotomy group (Fanfani 2004; Panici 2007). In patients with unrecognised neoplasms, laparoscopy may be associated with an increase in the rate of intraperitoneal spillage with consequent dissemination of tumour cells and advance in disease stage (Gal 1995). Minilaparotomy has been proposed for the surgical treatment of apparently benign gynecologic conditions as an alternative minimally invasive procedure in appropriate settings and where patients make an informed choice after careful counselling (Panici 2007).

Since inappropriate treatment of malignant tumours by laparoscopy is associated with risks of tumoral spread in the abdominal cavity, rupture of a malignant ovarian tumour should be avoided during surgery (Volz 1999; Vergote 2004). Only five of the 385 women in this review who were randomised to laparoscopy for treatment of a benign ovarian tumour, were subsequently found to have a malignant tumour. In all cases the procedure was converted to laparotomy and successfully completed. Thus, we would suggest that careful preoperative examination, as undertaken in these studies, decreases the risk of a malignancy being identified during a laparoscopy procedure. The standards for management of benign ovarian tumour by laparoscopy include:

(1) careful examination of the external surface of the tumour and sampling of the peritoneal cavity;

(2) avoidance of any tumoral rupture;

(3) protection of the ovarian tumour with an endoscopic bag before removal;

(4) avoidance of any contact between the tumour and the abdominal wall;

(5) frozen-section intraoperative histologic examination; and

(6) conversion to laparotomy when there is a suspicion that the ovarian tumour could be borderline or malignant (Guglielmina 1997; Nissole 1994; Canis 2000;Mettler 2001a).

The diagnostic accuracy of frozen section analysis is high for malignant and benign ovarian tumours, but accuracy is poor in the case of borderline ovarian tumours (Medeiros 2005). However, the incidence of borderline ovarian tumours is relatively low, around 6% compared with benign (71%) and malignant (23%) ovarian tumours (Medeiros 2005).

It should be noted that the follow up periods in the trials included in this review are generally short. Seven studies had follow periods of 3 months or less (Buchweitz 2005; Fanfani 2004; Morgante 1998; Nitke 1996; Panici 2007; Panici 2007a;Yuen 1997) two studies followed women for 6 months (Mais 1995;, Mais 1996), two for twelve months (Badawy 2002; Damiani 1998), and only one trial (Mais 2003) followed 31 of the 40 women randomised, for 5 years. Consequently we are unable to comment on the long term benefits or harms of laparoscopy compared to laparotomy for benign ovarian tumours.

This review is limited in its ability to guide surgical practice because of the small number of women randomised in twelve studies. The small number of randomised studies may be the result of

surgeons' resistance to accept this type of design, since only 39% of all treatments validated in surgery are from randomised studies (McLeod 1999; Sauerland 1999).

AUTHORS' CONCLUSIONS
Implications for practice

In this update we have found evidence, based on twelve studies with 769 women, that laparoscopic surgery for women with benign ovarian tumours was associated with reduced pain, fewer adverse events and reduced time in hospital. In clinical settings where surgical expertise and equipment are available and affordable, and adequate pre operative evaluation is undertaken to exclude malignant tumours, laparoscopic surgery can be recommended. The decision about which surgical approach to choose should follow careful preoperative evaluation and may take into consideration the setting, experience of the surgeon and the preference of the patient.

Implications for research

There are very few trials in this field. Further trials should carefully address the methods of randomisation as blinding is impractical in surgical studies. Future research should include specific patient subgroups (childbearing and non-child-bearing age ranges) and include additional outcomes such as surgical efficacy, tumour recurrence, patient satisfaction, quality of life and cost, with a longer follow-up period of at least five years. This follow up period may provide more information on recurrence, and the potentially harmful effects of laparoscopy in patients who have an ovarian malignancy diagnosed during the procedure. For evaluation of costs, it would be helpful to report cost separately for the preoperative, intraoperative and postoperative periods. Comparison of cost effectiveness or cost utility of these procedures would provide further useful information.

ACKNOWLEDGEMENTS

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Badawy 2002

Methods	Randomisation: randomly allocated to either treatment group using computerized random tables;(personal communication from author) Number of women randomised: 100 Number of women analysed:98 Number of withdrawals: 2 women in laparoscopic group was excluded after randomisation because one had diagnosis of suspected malignancy and another was excluded from the analysis because patient had thick adhesion Centre: one. The study was carried out between April 1997 and July 2001 in Department of Gynaecology at Mansoura University hospital in Egypt
Participants	Inclusion: Premenopausal women aged <=40 years with ovarian tumour(s), which did not meet sonographic criteria for malignancy. Tumours to be at least 3 cm and less than 15 cm in diameter, and serum CA-125 levels less than 35 U/ml. Colour doppler not mentioned Exclusion: preoperative or interoperative diagnosis of ovarian cancer, and no pathology associated with an indication for hysterectomy Age (years) 32.1 (SD 5.3) in the laparoscopy group, 34.6 (SD 6.2) in the laparotomy group Average cysts dimensions two groups were 12.4 cm (SD 2.3 cm) for laparoscopy and 13. 6 cm (SD 1.8) for laparotomy. The histology of the surgical specimens consisted of 43 endometrioma, 27 dermoid cysts, 24 cystadenoma, 4 paraovarian cysts. 88% (42/48) of the laparoscopy group had cystectomy only and 70% (35/50) of the laparotomy group has cystectomy only, a statistically significant difference
Interventions	Laparoscopy for ovarian cystectomy: 4 trocar technique; enucleation of cysts by traction and countertraction and also fenestration and cyst drainage were performed; the ovary was sutured with Vicryl 4/0 endosuture; bipolar haemostasis; saline solutions were used to lavage the pelvic cavity Laparotomy for ovarian cystectomy: Pfannenstiel incision. A standardised anaesthesia protocol was followed for all the procedures Cystectomy was performed in 87,5% cases in laparoscopy group and 70% in laparotomy group. Frozen section was not mentioned in the trial.
Outcomes	operative time, intraoperative blood loss, complications, conversion to laparotomy, post-operative complications, analgesic requirement, hospital stay
Notes	Follow up: 10, 30, and 365 days after surgery evaluated clinically and asked to complete a standard questionnaire concerning return to their normal lifestyle or any complications and improvement in their symptoms Conversions to laparotomy: 2 cases.

Risk of bias

Badawy 2002 (*Continued*)

Item	Authors' judgement	Description
Allocation concealment?	Yes	A Personal communication from Dr Badawy confirmed that participants in this study were randomly allocated to either treatment group using computerized random tables.Randomization was done on admission of the patients to the hospital by the principal investigator. However, it was not described in the published trial
Blinding? All outcomes	No	
Incomplete outcome data addressed? All outcomes	No	2 women in laparoscopy group were excluded after randomisation because the one had diagnosis of suspected malignancy and another was excluded from the analysis because of a thick adhesion
Free of selective reporting?	Yes	

Buchweitz 2005

Methods	Randomisation: method not stated Blinding: not mentioned. Number of women randomised: 23 Number of women analysed:20 Number of withdrawals: 1 women in each groups was excluded after randomisation because the diagnosis changed to malignancy and another was excluded from the analysis because her IL-6 level on admission was very high (an extreme outlier) Centre: one The study was carried out between January 2001 and August 2002 in Departament of Gynecology at a university hospital in Germany
Participants	Inclusion: Consecutive patients older than 60 years with ovarian tumour(s), which did not meet sonographic criteria for malignancy. Tumours to be at least 3 cm and less than 8 cm in diameter, and serum CA-125 levels less than 35 U/ml. Colour doppler not mentioned Exclusion: preoperative or interoperative diagnosis of ovarian cancer, and treatment with 'high doses' of corticoids Age (years) 66.5 (SD 5.8) in the laparoscopy group, 68.8 (SD 6.9) in the laparotomy group Average cysts dimensions two groups were 4.8 cm (SD 1.3 cm) for laparoscopy and 4.0 cm cm (SD 1.0) for laparotomy. The anatomicopathologic study of surgical specimen consisted of 11 adenofibroma, 4 serous cystadenoma, 1 mucous cystadenoma, and 4 functional cysts, with no differences

Buchweitz 2005 *(Continued)*

	between the 2 groups
Interventions	Laparoscopy for oophorectomy: 3 trocar technique, the ovarian tumours were placed in a disposable plastic bag and removed via the suprapubic port. All adnexal masses were sent for immediate frozen section and If malignancy was detected the procedure was converted to laparotomy Laparotomy for ovarian cystectomy: Pfannenstiel incision. A standardised anaesthesia protocol was followed for all the procedures Bilateral oophorectomy were performed in 50% cases in laparotomy group and 40%in laparoscopy group Frozen section was mentioned in the trial.
Outcomes	Interleukin 6, C reactive protein levels (objective stress response) operative time, estimated blood loss by haemoglobin drop, Postoperative pain duration and requirement for analgesia, hospital stay, convalescence day
Notes	Follow up was mentioned (3 months).

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B
Blinding? All outcomes	No	No
Incomplete outcome data addressed? All outcomes	No	23 women were randomised; 2 women were found to have malignant tumours intraoperatively (1 from each group) and 1 women was found to have a very high IL-6 level (at some point) so 3 women were excluded from the analysis
Free of other bias?	Unclear	3 patients excluded from analysis post randomisation

Damiani 1998

Methods	Randomisation:method not stated Blinding: not mentioned. Centre: one. Number of women randomised:68 Number of women analysed: 68 The study was carried out between January 1992 and November 1994 in the Endocrinological Gynaecology Department of Catholic University S. Cuore in Rome, Italy

Damiani 1998 *(Continued)*

Participants	Inclusion: Women of reproductive age with ovarian cysts which had persisted for at least 3 months or were noted to have increasing volume on consecutive ultrasound. Cyst diameter less than 10cm, liquid content, thin walls without septa, unilocular cysts without irregular solid parts inside the cyst. CA 125 levels and Colour Doppler not mentioned Exclusion: previous pelvic surgical interventions. Age (years) 28.6 (SD 6.2; range 16-38) in the laparoscopy group and 27.3 (SD 6.2; range 18-39) in the laparotomy group Average cysts dimensions were 6.6 cm (SD 1.6; range 3-9 cm) for laparoscopy and 6.6 cm (SD 1.7; range 4-10 cm) for laparotomy. All laparoscopy surgery were performed by a team which had several years' experience. Histological findings in laparoscopy group (number of cases): serosal (3); mucinous (4); endometriotic (8); functional (12); paraovarian (2); dermoid (5). Histological findings in laparotomy group (number of cases): serosal (5); mucinous (2); endometriotic (10); functional (11); paraovarian (3); dermoid (3)
Interventions	Laparoscopy for ovarian cystectomy: 3 trocar technique; enucleation of cysts by traction and countertraction and also fenestration and cyst drainage were performed; excised tissue were placed in a disposable plastic bag, the ovary was not sutured; bipolar haemostasis; saline solutions were used to lavage the pelvic cavity; all patients received intra-operative prophylactic antibiotic therapy. Laparotomy for ovarian cystectomy: Pfannenstiel incision; all cases ovarian was sutured in two layers; use 0 polyglactin to internal layer and 6-0 polyglactin suture for the external surface; all patients received intra-operative prophylactic antibiotic therapy. Anaesthesia protocol not described. Frozen section was not mentioned in the trial.
Outcomes	Cost of interventions in the US dollars (direct, indirect), operative time, length of stay
Notes	Follow up for 12 months, with one recurrence in each group (one endometrioma and one mucinous cystadenoma). Number of women excluded, number of women withdrawn and lost to follow-up, not stated: Conversions to laparotomy: unknown;

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B
Blinding? All outcomes	No	
Incomplete outcome data addressed? All outcomes	Unclear	No information given

Fanfani 2004

Methods	Randomisation: centralised and computer based, performed on the day of surgery Blinding: none Centre:One Number of women randomised:100 Number of women analysed:100 This trial was carried out between January and August 2003 at the Department of Gynecologic Oncology, University of the Sacred Heart, Rome, Italy
Participants	100 consecutive women were randomised Inclusion:Adnexal mass, presumed to be benign, requiring surgical treatment Exclusion: BMI greater than 32 kg/m2, cyst(s) greater than 12 cm in diameter, postmenopausal women with serum CA125 level greater than 35 IU/ml requirement for hysterectomy at same time All women underwent standard preoperative assessment including serum markers, an ultrasound scan with colour Doppler evaluation to assess the size and characteristics of the lesions Age (years) 36.3 (SD 12.1) in the laparoscopy group and 37.5 (SD 13.4) in the minilaparotomy group Histopathological diagnosis: endometriotic cysts (n=33), benign ovarian and parasalpingoserous cysts (n=32) dermoid cysts (n=18) benign mucinous cysts (n=16). Only accounts for 99/100
Interventions	All surgical procedures, both laparoscopy and minilaparotomy were performed by one senior and one fellow. Intraoperative frozen section performed if required Bowel preparation and antithrombotic prophylaxis always performed and second generation cephalosporin administered to all women. General anaesthesia given to all women. Decision on cystectomy vs oophorectomy made based on operative findings and age of patient Laparoscopy; 4 trocar technique, 10 mm transluminal port for the laparoscope and three 5mm ports right, left and sovrapubic. Enucleation by traction and counter traction and fenestration and cyst drainage were performed. The ovary was not sutured Minilaparotomy: A 4-9 cm transverse incision 1-2 cm below the pubic hair line, end of incision sutured to avoid accidental lengthening. Vertical incision used where patient had previous longitudinal scar Local anaesthetic also given if operating time exceeded 2 hours Frozen section was mentioned in the trial.
Outcomes	operative time, intraoperative blood loss, complications, conversion to laparotomy, postoperative complications, change of diagnosis to malignant
Notes	Follow up period of 30 days.

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A
Blinding? All outcomes	No	
Free of other bias?	Yes	consecutive patients

Mais 1995

Methods	Randomisation: using random numbers table, with allocation in sealed envelopes. The envelope seal was broken in the anaesthetic room before surgery Blinding: no Centre: one Number of women randomised: 40 Number of women analysed: 40 The study was carried out between January 1993 to June 1994 in the Department of Obstetrics and Gynecology of the University of Cagliari, Cagliari, Italy
Participants	Inclusion: Premenopausal (18-40 years) women with ovarian tumours, assumed to be benign, which had persisted for more than 6 months, diameter less than 10 cm. All women were submitted a preliminary workup, including ultrasonography. CA 125 levels and Colour Doppler not mentioned Exclusion: women unfit for general anaesthesia, those with systemic infections and those unable to give informed consent Age (years) 30.4 (SD 6.1) in the laparoscopy group and 29.8 (SD 6.4) in the laparotomy group Average cyst dimensions two groups were 6.7 cm (SD 1.6) for laparoscopy and 6.3 cm (SD 1.7) for laparotomy Histological findings in laparoscopy (number of cases): serous paratubal (8); serous ovarian (10); serous cystadenoma (0); mucinous cystadenoma (2) Histological findings in laparotomy (number of cases): serous paratubal (6); serous ovarian (12) serous cystadenoma (1); mucinous cystadenoma (1) All surgical procedures were performed by the same investigators
Interventions	Laparoscopy for ovarian cystectomy: 3 trocar technique; enucleation of cysts by traction and countertraction and also fenestration and cyst drainage were performed; the ovary was not sutured; saline solutions were used to lavage the pelvic cavity. Laparotomy for ovarian cystectomy: Pfannenstiel incision. The procedures were performed under general anaesthesia. Frozen section was not mentioned.
Outcomes	Numbers in each group analgesic free at day 2, discharged from hospital within 3 days and fully recuperated at day 15, difference in mean VAS score for pain, operative time; hospital stay
Notes	Follow up: 15, 30, 90 and 180 days after surgery (clinical examination and ultrasonographic scan); 83 women were screened, underwent ultrasound evaluation and 6 months expectant management. After 6 months 32 women whose cysts resolved spontaneously were excluded from surgery. Of the remainder if cyst was still present (n=38) or if cyst size was increased (n=13) surgery was planned. Of these, 2 women were deemed unfit for anaesthesia, 1 had a systemic infection, and 1 had a psychiatric condition which excluded them from study. A further 7 women refused randomisation Al cysts were found to be benign.

Risk of bias

Item	Authors' judgement	Description

Mais 1995 *(Continued)*

Allocation concealment?	Yes	A
Blinding? All outcomes	No	
Incomplete outcome data addressed? All outcomes	Yes	
Free of selective reporting?	Yes	
Free of other bias?	Yes	

Mais 1996

Methods	Randomisation: table of random digits. Allocation concealed in numbered sealed envelopes and the seal was broken in the anaesthetic room before surgery Centre: one. Number of women randomised:32 Number of women analysed: 32 The study was carried out between January 1993 and June 1994 in the Department of Obstetrics and Gynecology of the University of Cagliari, Cagliari, Italy
Participants	Inclusion: premenopausal (18-40 years) women without acute pelvic symptoms and with hypoechoic, unilateral, unilocular persistent ovarian cysts, 3-10 cm in diameter, suspected to be endometrioma by transvaginal sonography. CA 125 levels and Colour Doppler not mentioned Exclusion: unfit for general anaesthesia, systemic infection or unable to give informed consent Age (years) 30.1 (SD 5.8) in the laparoscopy group, 31.2 (SD 6.3) in the laparotomy group Average cyst dimension were 5.4 cm (SD 2.0) for laparoscopy and 5.5 cm (SD 2.1) for laparotomy Histological findings in laparoscopy and laparotomy group: all cases were endometrioma
Interventions	Laparoscopy for ovarian cystectomy: 3 trocar technique; enucleation of cysts by traction and countertraction and also fenestration and cyst drainage were performed; the ovary was not sutured; saline solutions were used to lavage the pelvic cavity Laparotomy for ovarian cystectomy: Pfannenstiel incision. All procedures were performed by the same investigators and women were given general anaesthesia Frozen section was not mentioned in the trial.
Outcomes	Operative time; analgesic requirement, pain (VAS scale), numbers of women in each group analgesic free at day 2, proportion of women in each group discharged from hospital within day 3

Mais 1996 (*Continued*)

Notes	Follow up: 15, 30, 90 and 180 days after surgery (clinical examination and ultrasono-graphic scan); number of women excluded, number of women withdrawn and lost to follow-up: No details given; Conversions to laparotomy: unknown

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A
Blinding? All outcomes	No	
Incomplete outcome data addressed? All outcomes	Yes	All women randomised are included in the analysis
Free of selective reporting?	Yes	
Free of other bias?	Yes	

Mais 2003

Methods	Randomisation by the use of a random digits. Allocation concealed in sealed envelopes. The envelope seal was broken in the anaesthetic room before surgery Centre: one Number of women randomised: 40 Number of women analysed: 40 for most outcomes, with 5 year follow up on 31 women The study was carried out between December 1992 and January 1996 in the Department of Obstetrics and Gynecology of the University of Cagliari, Cagliari, Italy
Participants	Inclusion: women without symptoms of reproductive age (19-43) with one unilateral persistent ovarian cyst, which was suspected to be a dermoid ovarian cyst (teratoma) by ultrasonography, with diameter less than 10 cm. CA 125 levels and Colour Doppler not mentioned 58 women were screened, and underwent abdominal and transvaginal ultrasonography. One woman was deemed unfit for general anaesthetic, two had systemic infections and one had a psychiatric condition which precluded informed consent, so were excluded. A further 5 women were excluded because their cyst diameter exceeded 10 cms Age (years) 31.4 (SD 6.1) in the laparoscopy group and 30.7 (SD 5.5) in the laparotomy group Average cysts dimensions were 5.8 cm (SD 1.3 cm) for laparoscopy and 6.1 cm (SD 1.5 cm) for laparotomy groups
Interventions	Laparotomy: a Pfannestiel incision was always used for laparotomy. Laparoscopy 10 mm port was inserted through the umbilicus to introduce the laparoscope. Two additional 5 mm ports were inserted in the right and left lower abdominal quadrants for introduction of surgical instruments. A fourth port 10 mm was introduced in the midline 4 cm above

Mais 2003 (*Continued*)

	the symphysis pubis for introduction of endoscopic bag. After the ovary was grasped with atraumatic forceps, a superficial incision of ovarian cortex was made with scissors. The incision was gently enlarge to locate the cleavage plane between the cyst wall and the ovarian cortex. Bipolar coagulation and scissors were used to separate fibrous adhesions. During laparoscopy procedures, the cyst was inserted into an endoscopic bag which was closed by pulling the drawstring. The drawstring and the margins of the bag were removed from the abdominal cavity through the suprapubic port During both laparotomy and laparoscopy careful exploration of the pelvis and the abdomen was performed for evidence of malignancy. During both laparotomy and laparoscopy, the ovary was left open without sutures If unintended spillage of the cysts contents occurred, a copious saline solution was used to irrigate the pelvic cavity. Any particulate material was carefully grasped and removed Minimal or mild spillage occurred in the nine women (seven laparoscopy and two laparotomies) but the post operative course was always uneventful Frozen section was not mentioned in the trial.
Outcomes	operative time, analgesic requirement, hospital stay,(reported in Mais 1995 and Mais 1993) recurrence rate over 5 years follow up
Notes	A 5 year follow up of 31 of the 40 women originally randomised. Reasons for loss of data on 9 women were described

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A
Blinding? All outcomes	No	
Incomplete outcome data addressed? All outcomes	Yes	In the laparoscopy group 2 women were lost to follow up after 2 years, one lost after 2.5 years and a further 2 lost after 3 years (2 of these due to pregnancy). In the laparotomy group 2 women were lost to follow up after 2.5 years and a further 2 were lost after 4 years(1 of these due to pregnancy)
Free of selective reporting?	Yes	
Free of other bias?	Yes	

Morgante 1998

Methods	Randomisation:random number table RCT: method of randomisation unclear. Blinding: not mentioned. Centre: one Number of women randomised:44 Number of women analysed:44 The study was carried out between January 1992 and 31 December 1996 in the Department of Obstetrics and Gynecology of the University of Siena, Siena, Italy
Participants	Inclusion: Women of reproductive age (14-42) with dermoid ovarian cysts, assumed to be benign, with diameter less than 12 cm. CA 125 levels and Colour Doppler not mentioned Age (years) 29.4 (SD 6.8; range 15-40) in the laparoscopy group, 30.3 (SD 8.3; range 14-42) in the laparotomy group The average cysts dimension were 6.7 cm (range 4-12) for laparoscopy and 6.5 cm (range 4-12) for laparotomy Histological findings were dermoid ovarian cyst but in association with other histological types: functional nature (17.2%); endometriotic (4.5%), serous cystadenomas (5.3%), mucinous cystadenoma (1.2%). Dermoid cysts were bilateral in 7.9% of cases
Interventions	With both procedures the pelvic cavity was examined for signs of malignancy, and all women received prophylactic antibiotics to prevent infection 40 of the 44 women underwent transabdominal and transvaginal ultrasound prior to surgery; 4 who did not were young women who had never had sexual intercourse Laparoscopy for ovarian cystectomy: 4 trocar technique; enucleation of cysts by traction and countertraction; aspiration of the cysts and after the capsule was removed in such a way as to avoid spillage of cyst fluid into the abdominal cavity. Bipolar cautery for haemostasis; When spillage occurred (six cases) saline solutions were used to lavage the pelvic cavity. Ovary was not sutured. Laparotomy for ovarian cystectomy: details were not given. No details were given concerning anaesthetic protocol. Frozen section was not mentioned in the trial.
Outcomes	Duration of surgery, mean blood loss, mean length of stay hospital, postoperative complications, pain, requirement for analgesics, return to work
Notes	Follow up 2 weeks: No details given; number of women excluded, number of women withdrawn and lost to follow-up: ;

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B
Blinding? All outcomes	No	

Morgante 1998 (*Continued*)

Incomplete outcome data addressed? All outcomes	Yes	
Free of selective reporting?	Yes	
Free of other bias?	Yes	

Nitke 1996

Methods	Randmisation: method not stated Blinding: not mentioned. Centre: one. Number of women randomised:38 Number of women analysed:38 The study was carried out between 1992 and 1995 in the Department of Obstetrics and Gynecology of the Rabin Medical Center, Tel Aviv, Israel
Participants	Inclusion: Women of reproductive age (16-39) with dermoid ovarian cysts. All women were submitted a preliminary workup, including ultrasonography, CA 125, as well as colour Doppler ultrasonography to exclude malignancy Exclusion: Women with contraindications to laparoscopy - gross obesity, bowel disease, massive adhesions following previous surgery, a large abdominal mass and cardiorespiratory disorders Age (years) 27.7 (SD 6.8; range 16-39) in the laparoscopy group and 24.3 (SD 5.2; range 17-38) in the laparotomy group No information provided on average cyst dimensions in each group. Histological findings in laparoscopy and laparotomy group: all cases were dermoid ovarian cyst
Interventions	The procedures were performed under general anaesthesia, and the pelvic cavity was thoroughly inspected for signs of malignancy. Laparoscopy for ovarian cystectomy: 3 trocar technique; enucleation of cysts by traction and countertraction; the ovary was not sutured; In 10 cases the cyst was removed intact, and in the remainder the cyst was aspirated to remove fluid and the capsule was removed in such a way as to minimise spillage of cyst fluid into the abdominal cavity; electrocoagulation for haemostasis; Ringers solution was used to lavage the pelvic cavity. Laparotomy for ovarian cystectomy: Pfannenstiel incision (minilaparotomy); in all cases ovarian resection by conservative enucleation followed by suture of the ovary in two layers. When spillage occurred the pelvic cavity was lavaged with ringers solution. Frozen section was not mentioned in the trial.
Outcomes	Operative time; length of stay in hospital, complications ;hospital stay
Notes	Follow up:No details given. Number of women excluded, number of women withdrawn and lost to follow-up: No details given; Conversions to laparotomy: unknown. Table 2 gives a list of concomitant procedures performed during laparoscopy which may have influenced duration of operation

Nitke 1996 *(Continued)*

Risk of bias		
Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	B
Blinding? All outcomes	No	
Incomplete outcome data addressed? All outcomes	Yes	
Free of other bias?	Yes	

Panici 2007

Methods	Randomisation: Computerised randomisation list was independently generated and allocation to treatment arms was recorded in sequentially numbered sealed envelopes by a third party. Envelopes were opened in theatre after initial laparoscopy had been performed Blinding: None Centres: Two Number of women randomised: 60 Number of women analysed: 60 (primary endpoint) The study was conducted between January 2005 and September 2006 in the Department of Obstetrics and Gynecology , la Sapienza University, Rome, Italy and Department of Obstetrics and Gynecology, Campus Biomedico University, Rome, Italy
Participants	All patients had a preoperative assessment of transabdominal and transvaginal ultrasound including estimation of cyst size. Colour Doppler not mentioned Inclusion: women aged 18-45 years with large (7-18 cm) apparently benign, non-endometriotic adnexal cysts, serum CA125 in the normal range, BMI less than 29 kg/m2, American Society of Anaesthesiologists physical status classification 0-2, no known acute or chronic pelvic disease, no previous laparotomies, no requirement for other associated surgical procedures, possibility of placing an intrauterine manipulator, and signed informed consent to the procedure and to traditional surgical staging in case of unexpected malignancy Exclusion:identification of peritoneal signs of malignancy during diagnostic laparoscopy, inadequate surgical field for minilaparotomy Median age (years) 31 (range 24-36) in the laparoscopy group and 29 (range 34-35) in the minilaparotomy group Median cyst dimensions were 8.4 (range 8-12.2) in the laparoscopy group and 8.2 (range 7.9-10.4) in the minilaparotomy group
Interventions	No mechanical bowel preparation was performed and all patients had antithrombotic (low molecular weight heparin) and antibiotic (IV cefalotin) prophylaxis. All women underwent diagnostic open laparoscopy and if the inclusion/exclusion criteria were satisfied a sequentially numbered sealed envelope was opened in theatre to determine which

Panici 2007 (*Continued*)

	procedure then followed Laparoscopy - 3 additional ports were inserted. Plane of cleavage was located with the aid of grasping forceps and cyst capsule was separated from the ovarian cortex using diverting traction. ancillary port in the sovrapubic region was enlarged to fir a 10 mm trocar for insertion of an endobag. Wherever possible unruptured cyst was placed in bag to contain spillage, or controlled cyst aspiration was carried out under direct view Haemostasis by bipolar coagulation. Peritoneal cavity was copiously rinsed with Ringers solution, and 1000ml was left in cavity for adhesion prevention Minilaparotomy:3-7 cm transverse incision 1-2 cm below pubic hair line and 2-4 cm above pubic symphysis was made based on the finding of the diagnostic laparoscopy. Where possible the cyst was delivered outside the abdomen through the incision. Alternatively the cyst was aspirated and cyst wall rupture site controlled with a clamp. Excision of the cyst was performed in standard fashion and the ovarian edges approximated with a suture stitch avoiding the ovarian cortex. haemostasis by bipolar coagulation, peritoneal lavage using copious Ringers solution Intraoperative frozen section was routinely performed. Six patients in laparoscopy group were not treated per protocol. Three were converted to laparoscopically guided minilaparotomy, one was converted to a Pfannanstiel incision (diagnosis of malignancy) , and two a low vertical incision Two patients in minilaparotomy group were not treated as per protocol; in both increase in transverse incision was made due to technical difficulties Frozen section was mentioned in the trial.
Outcomes	Primary outcome was uncontrolled cyst spillage and/or rupture rate, secondary outcomes surgical difficulty, operative and postoperative results, short and long-term complications, and short term patient satisfaction
Notes	Relative risk of cyst rupture of laparoscopy group versus laparoscopy guided minilaparotomy was 5.55 (95% CI 1.88 to 16.33). Spillage of cyst contents occurred in 21 and 8 patients respectively. Follow up 3 months

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	
Blinding? All outcomes	No	
Incomplete outcome data addressed? All outcomes	Yes	
Free of selective reporting?	Yes	
Free of other bias?	Yes	

Panici 2007a

Methods	Randomisation: Allocation to treatment arms was recorded in a blind envelope system. Envelopes were opened in theatre after initial laparoscopy had been performed Blinding: None Centres: two Number of women randomised: 127 Number of women analysed: 127 The study was conducted between July 2002 and June 2004 in the Department of Obstetrics and Gynecology , la Sapienza University, Rome, Italy and Department of Obstetrics and Gynecology, Campus Biomedico University, Rome, Italy
Participants	All women underwent preoperative transabdominal and transvaginal ultrasound on the day before surgery. surgery was performed under general endotracheal anaesthesia. In postmenopausal women bilateral salpingo-oophorectomy was performed Inclusion: women aged more than 16 years and less than 70 years with apparently benign adnexal cysts of less than 10 cm diameter, absence of ultrasonographic evidence of malignancy, serum CA125 in the normal range for postmenopausal women, BMI less than 29 kg/m2, American Society of Anaesthesiologists physical status classification 0-2, no known acute or chronic pelvic disease, no previous laparotomies, and signed informed consent Exclusion: 127 women were randomised; 63 to laparoscopy group and 64 to minilaparotomy group Median age (years) 30 (range 17-70) in the laparoscopy group and 32 (range 16-65) in the minilaparotomy group Median cyst dimensions were 5.5 (range 3.5-9.5) in the laparoscopy group and 5.2 (range 3.2-9) in the minilaparotomy group
Interventions	Laparoscopy via 4 ports. Careful exploration of the pelvis and abdomen for visual exclusion of malignancy. Adhesions were lysed and the cyst capsule was separated from the ovarian cortex using diverging tractions. Haemostasis by bipolar coagulation. Ovary left un sutured. Cyst was removed from the abdominal cavity using an endobag. Intraoperative frozen section was always performed Minilaparotomy: 3-7 cm transverse incision, 1-2 cm below pubic hairline and 2-4 cm above the pubic symphysis. laparoscope was introduced through the incision to explore the abdominal cavity. if the size of cyst did not permit its delivery through the incision or if the cyst ruptured during mobilisation, cyst content was aspirated, cyst wall rupture site controlled with clamp and then the cyst was delivered with minimum spillage. Ovaries were left un sutured Intraoperative frozen section was performed.
Outcomes	Operating time, blood loss, pain, time to recovery to regular bowel movements, tolerance of liquid diet, mobility around the ward, duration of postoperative stay. Intraoperative and post operative complications
Notes	Follow up 3 months

Risk of bias

Item	Authors' judgement	Description

Panici 2007a *(Continued)*

Allocation concealment?	Yes	A
Blinding? All outcomes	No	
Incomplete outcome data addressed? All outcomes	Yes	
Free of selective reporting?	Yes	
Free of other bias?	Yes	consecutive patients

Yuen 1997

Methods	Randomisation : computer generated numbers were used to assign the surgical approach and were placed in sealed opaque consecutively numbered envelopes Blinding:not mentioned. Centre:one Number of women randomised:102 Number of women analysed:102 The study was carried out between July 1994 and September 1995 in the Department of Obstetrics and Gynaecology, Prince of Wales Hospital, Hong Kong
Participants	All women had standard preoperative assessment with a ultrasound scan usually transvaginal. Postmenopausal women had serum CA 125 levels measured. Colour Doppler not mentioned Inclusion:women requiring surgical management of benign ovarian tumours Exclusion: women where ultrasonic scan suggested a malignancy, tumour greater than 10 cm diameter, or requirement for concurrent hysterectomy Age (years) 35.1 (SD 10.3) in the laparoscopy group and 34.7 (SD 8.8) in the laparotomy group Average cysts dimension two groups were 5,6cm (SD 1.8 cm) for laparoscopy and 5. 7cm (SD 2.1 cm) for laparotomy
Interventions	All procedures were performed under general anaesthesia. All surgical procedures were performed by physicians undergoing training under the supervision of an experienced surgeon. Frozen section was not mentioned in the trial. Laparoscopy : 3 trocar technique; procedures were cystectomy or oophorectomy ; excised tissue were placed in a disposable plastic bag; bipolar haemostasis; Oophorectomy was performed in 27.6% of cases in the laparoscopy group. Laparotomy : Pfannenstiel incision or subumbilical midline incision; procedures were cystectomy or oophorectomy; not stated whether ovary was sutured. Oophorectomy was performed in 25% of cases in the laparotomy group
Outcomes	Operative time; operative blood loss, postoperative pain, intraoperative complications, post operative complications hospital stay, return to work

Yuen 1997   (*Continued*)

Notes	Follow up : 8 weeks; 4 of women excluded because they refused randomisation and 4 women lost to follow up, no details given. All ovarian tumours benign

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	
Blinding? All outcomes	No	
Incomplete outcome data addressed? All outcomes	Yes	
Free of selective reporting?	Yes	
Free of other bias?	Yes	

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Albini 1994	Not randomised
Bateman 1994	Not randomised
Bulletti 1996	Not randomised
Chapron 1997	Not randomised
Darwisch 2001	Not randomised
Deckardt 1994	Not randomised, even though it claims to be (allocation to different wards by an admitting clerk is NOT a method of randomisation, and it is not likely to result in groups which are equal and balanced with regard to all possible known and unknown confounding factors. This is evidenced by the numerically unbalanced groups which resulted (n=116 vs n=76))
Hidlebaugh 1994	Not randomised
Hidlebaugh 1997	Not randomised
Howard 1995	Not randomised
Laberge 2006	Not randomised

Lin 1995	Not randomised
Marana 2004	Not randomised
Mettler 2001	Not randomised
Papasakelariou 1995	Not randomised
Paredes 1997	Not randomised
Pittaway 1994	Not randomised
Quinlan 1997	Not randomised
Thomas 2006	Not randomised
Yuen 1995	Not randomised
Zanetta 1999	Not randomised

DATA AND ANALYSES

Comparison 1.   Laparoscopy versus laparotomy

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Surgery - Duration of surgery (min)	9		Mean Difference (IV, Random, 95% CI)	Totals not selected
1.1 Any type of benign ovarian tumour	5		Mean Difference (IV, Random, 95% CI)	Not estimable
1.2 Dermoid cysts	3		Mean Difference (IV, Random, 95% CI)	Not estimable
1.3 Ovarian endometriomata	1		Mean Difference (IV, Random, 95% CI)	Not estimable
2 Surgery - Change of diagnosis to malignant tumour	8		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
2.1 Any type of benign ovarian tumour	4	230	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.01 [0.12, 8.46]
2.2 Dermoid cysts	3	122	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
2.3 Ovarian endometriomata	1	32	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
3 Surgical Injury - Bladder	9		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
3.1 Any type of benign ovarian tumour	5	328	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.13 [0.00, 6.56]
3.2 Dermoid cysts	3	122	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
3.3 Ovarian endometriomata	1	32	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
4 Surgical Injury - Ureter	9		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
4.1 Any type of benign ovarian tumour	5	328	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
4.2 Dermoid cysts	3	118	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
4.3 Ovarian endometriomata	1	32	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
5 Surgical Injury - Vascular	9		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
5.1 Any type of benign ovarian tumour	5	328	Peto Odds Ratio (Peto, Fixed, 95% CI)	7.40 [0.46, 118.39]
5.2 Dermoid cysts	3	122	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
5.3 Ovarian endometriomata	1	32	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
6 Surgical Injury - Small bowel	9		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
6.1 Any type of benign ovarian tumour	5	328	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
6.2 Dermoid cysts	3	122	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
6.3 Ovarian endometriomata	1	32	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
7 Surgical Injury - Colon	9		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
7.1 Any type of benign ovarian tumour	5	328	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
7.2 Dermoid cysts	3	122	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
7.3 Ovarian endometriomata	1	32	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
8 Post operative complications - Blood transfusion required	9		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
8.1 Any type of benign ovarian tumour	5	328	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
8.2 Dermoid cysts	3	122	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
8.3 Ovarian endometriomata	1	32	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable

9 Post operative complications - Haematoma	9		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
9.1 Any type of benign ovarian tumour	5	328	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
9.2 Dermoid cysts	3	122	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
9.3 Ovarian endometriomata	1	32	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
10 Post operative complications - Febrile morbidity	9	482	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.36 [0.18, 0.73]
10.1 Any type of benign ovarian tumour	5	328	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.37 [0.18, 0.76]
10.2 Dermoid cysts	3	122	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.14 [0.00, 6.82]
10.3 Ovarian endometriomata	1	32	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
11 Post operative complications - Incision infection	9		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
11.1 Any type of benign ovarian tumour	5	328	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.23 [0.05, 1.05]
11.2 Dermoid cysts	3	122	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
11.3 Ovarian endometriomata	1	32	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
12 Post operative complications - Urinary tract infection	9		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
12.1 Any type of benign ovarian tumour	5	328	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.30 [0.08, 1.16]
12.2 Dermoid cysts	3	122	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
12.3 Ovarian endometriomata	1	32	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
13 Post operative complications - Thromboembolism	9		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
13.1 Any type of benign ovarian tumour	5	328	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.12 [0.01, 2.09]
13.2 Dermoid cysts	3	122	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
13.3 Ovarian endometriomata	1	32	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
14 Blood loss by hemoglobin levels	1	20	Mean Difference (IV, Random, 95% CI)	-0.30 [-1.31, 0.71]
14.1 Any type of benign ovarian tumour	1	20	Mean Difference (IV, Random, 95% CI)	-0.30 [-1.31, 0.71]
14.2 Dermoid cysts	0	0	Mean Difference (IV, Random, 95% CI)	Not estimable
14.3 Ovarian endometriomata	0	0	Mean Difference (IV, Random, 95% CI)	Not estimable
15 Perioperative mortality	9		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
15.1 Any type of benign ovarian tumour	5	328	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
15.2 Dermoid cysts	3	122	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
15.3 Ovarian endometriomata	1	32	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
16 Urinary retention	9		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
16.1 Any type of benign ovarian tumour	5	328	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.12 [0.02, 0.89]
16.2 Dermoid cysts	3	122	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
16.3 Ovarian endometriomata	1	32	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
17 Chemical peritonitis	9		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
17.1 Any type of benign ovarian tumour	5	328	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
17.2 Dermoid cysts	3	122	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
17.3 Ovarian endometriomata	1	32	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
18 Intestinal obstruction	9		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only

18.1 Any type of benign ovarian tumour	5	328	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
18.2 Dermoid cysts	3	122	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.14 [0.00, 6.82]
18.3 Ovarian endometriomata	1	32	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
19 1.18 Any adverse effect of surgery (incl surgical injury or post surgery complication or other)	9	482	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.29 [0.17, 0.51]
19.1 Any type of benign ovarian tumour	5	328	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.30 [0.18, 0.53]
19.2 Dermoid cysts	3	122	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.13 [0.01, 2.13]
19.3 Ovarian endometriomata	1	32	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
20 Short term recovery - pain (VAS)	3	186	Mean Difference (IV, Fixed, 95% CI)	-2.36 [-2.70, -2.03]
20.1 Any type of benign ovarian tumour	2	142	Mean Difference (IV, Fixed, 95% CI)	-2.25 [-2.94, -1.56]
20.2 Dermoid cysts	1	44	Mean Difference (IV, Fixed, 95% CI)	-2.05 [-2.79, -2.01]
21 Short term recovery - pain (painfree 24-48 hours post surgery)	6	356	Peto Odds Ratio (Peto, Fixed, 95% CI)	7.42 [4.86, 11.33]
21.1 Any type of benign ovarian tumour	3	240	Peto Odds Ratio (Peto, Fixed, 95% CI)	5.87 [3.48, 9.90]
21.2 Dermoid cysts	2	84	Peto Odds Ratio (Peto, Fixed, 95% CI)	10.68 [4.55, 25.06]
21.3 Ovarian endometriomata	1	32	Peto Odds Ratio (Peto, Fixed, 95% CI)	14.51 [3.70, 56.90]
22 Short term recovery - Pain (requirement for analgesia)			Other data	No numeric data
22.1 any type of benign ovarian tumour			Other data	No numeric data
23 Recurrence at 6-12 months	4	171	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.01 [0.06, 16.33]
23.1 Any type of benign ovarian tumour	2	108	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.01 [0.06, 16.33]
23.2 Dermoid cysts	1	31	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
23.3 Ovarian endometriomata	1	32	Peto Odds Ratio (Peto, Fixed, 95% CI)	Not estimable
24 Length of hospital stay (days)	8	442	Mean Difference (IV, Random, 95% CI)	-2.88 [-3.11, -2.66]
24.1 Any type of benign ovarian tumour	5	328	Mean Difference (IV, Random, 95% CI)	-2.91 [-3.28, -2.55]
24.2 Dermoid cysts	2	82	Mean Difference (IV, Random, 95% CI)	-2.93 [-3.15, -2.70]
24.3 Ovarian endometriomata	1	32	Mean Difference (IV, Random, 95% CI)	-2.39 [-3.01, -1.75]
25 Economic outcomes - total cost (US$1000 1993)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
25.1 Any type of benign ovarian tumour	1	68	Mean Difference (IV, Fixed, 95% CI)	-1045.01 [-1347.94, -742.06]
25.2 Dermoid cysts	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
25.3 Ovarian endometriomata	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable