Laparoscopic surgery is not inherently dangerous for patients presenting with benign gynaecologic pathology: results of a meta-analysis

Authors' objectives
To conduct a meta-analysis of published data on the risks and benefits of laparoscopic surgery versus laparotomy.

Searching
MEDLINE and the Cochrane Controlled Trial Register were searched from 1966 to June 2000, using the search terms 'Randomised Controlled Trial' and 'laparoscopy' crossed with the MeSH terms 'ovarian diseases/surgery', 'ovarian cysts/surgery', 'hysterecotomy', 'urinary incontinence', 'stress/surgery', 'prolapse/surgery', 'gynaecological surgical procedures', 'sterilization, tubal', 'pregnancy, ectopic/surgery', 'uterine neoplasms/surgery', 'leiomyoma/surgery', 'endometriosis/surgery', 'fallopian tube diseases/surgery', 'salpingostomy', 'adhesions/surgery', 'infertility, female/surgery', and 'ovarian neoplasms/surgery'. Reference lists were handsearched. No attempts were made to identify unpublished studies. The authors did not state whether any language restrictions were applied.

Study selection
Study designs of evaluations included in the review
Prospective, randomised equivalence trials were included.

Specific interventions included in the review
Comparisons of laparoscopic surgery and laparotomy were included.

Participants included in the review
Women undergoing operative laparoscopy or laparotomy for gynaecologic surgical procedures were included.

Outcomes assessed in the review
The primary outcome was the existence of any complication related to the procedure. Complications were graded as either major or minor. Major complications included life-threatening peri-operative conditions, risks of major functional sequelae or the inability to return to normal working life for at least 3 months, and major additional surgical procedure during the same or second anaesthesia. Minor complications were those not classed as meeting the above criteria. The secondary outcomes were defined as any need for transfusion, reoperation, or repeat hospitalisation.

How were decisions on the relevance of primary studies made?
The titles and abstracts of retrieved citations were screened to identify those that compared laparoscopic surgery with laparotomy. The authors do not state how many of the reviewers performed the selection, nor whether they were blind to the source or outcomes.

Assessment of study quality
The methodological quality of the trials was rated as very good, moderate or inadequate, using a 22-point score based on published criteria (see Other Publications of Related Interest, nos.1-2). Each trial was independently assessed by two authors. Any disagreements were resolved by discussion with a third epidemiologist.

Data extraction
Two authors independently extracted the data into a computerised form and corroborated their findings. Any disagreements were resolved by discussion with a third epidemiologist. All of the abstracted data were submitted to the original authors of the primary studies, who were also asked for further study details where necessary.
Methods of synthesis
How were the studies combined?
Summary relative risks (RR) and 95% confidence intervals (CIs) were calculated using the Peto fixed-effect model (see Other Publications of Related Interest no.3).

How were differences between studies investigated?
Heterogeneity between the trials was tested using chi-square tests. The random-effects model of DerSimonian and Laird (see Other Publications of Related Interest no.4) was used when heterogeneity arose between the results of the studies. Subgroup analyses were performed for the level of seriousness of the procedure (classed as minor, major or advanced laparoscopic surgery). A sensitivity analysis, which included or excluded studies according to their methodological score, was also performed.

Results of the review
The meta-analysis was based on 27 prospective, randomised controlled trials involving 3,611 women (1,809 treated by operative laparoscopy and 1,802 treated by laparotomy).

The overall risk of complications was significantly lower for patients operated on by laparoscopic surgery (RR 0.59, 95% CI: 0.50, 0.70). Significant heterogeneity between the trials was not found (chi-squared 21.5, d.f.=21). There was no statistically-significant difference in the risk of major complications with respect to the approach used (RR 1.0, 95% CI: 0.60, 1.65).

The risk of minor complications was significantly lower for patients operated on by laparoscopic surgery (RR 0.55, 95% CI: 0.45, 0.66). There was no difference between the two groups in respect of the risks of readmission, second procedure and blood transfusion. Identical results were found after the sensitivity analysis, which included or excluded studies according to their methodological score. A subgroup analysis according to the severity of the surgery (minor, major, advanced) showed a significant increase in the risk of transfusion for advanced procedures performed by laparotomy.

Authors' conclusions
Laparoscopic surgery is not inherently dangerous for patients presenting benign gynaecological pathologies. The potential risk of complications should no longer be offered as an argument against using laparoscopic surgery rather than laparotomy for an operation, when the indication allows the choice.

CRD commentary
The review was based on a clear question. The strategy to identify relevant studies only comprised searches of two databases and citation checking. No attempts were made to identify unpublished studies, and the authors did not state whether language restrictions were applied. Thus, relevant studies might have been missed. The outcome definitions, and data checking, validation and extraction processes were well described, although few details of the included trials were tabulated. The tests of heterogeneity and sensitivity analysis were appropriate. The authors' conclusions are probably well-founded.

Implications of the review for practice and research
Practice: The authors did not make any recommendations.

Research: The authors call for stringent observational studies, based on large series, to provide supplementary information on the risks of laparoscopic surgery.

Bibliographic details
Other publications of related interest

Indexing Status
Subject indexing assigned by NLM

MeSH
Female; Genital Diseases, Female /surgery; Gynecologic Surgical Procedures /adverse effects; Humans; Laparoscopy /adverse effects

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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.