
Authors' objectives
To assess the benefits and risks of the management of symptomatic and asymptomatic uterine fibroids.

Searching
MEDLINE, CINAHL, Cancerlit, EMBASE and HealthSTAR were searched from 1975 (or inception if later) to 2000; the search terms were given. The Cochrane Library (Issue 3, 1999) was also searched. The reference lists of included reports and reviews were checked and e-mail subscriptions were used to identify newly published studies. Reviewers suggested additional articles. Only studies published in English were eligible for inclusion.

Study selection
Study designs of evaluations included in the review
Controlled trials, prospective trials with historical controls, prospective and retrospective cohort studies, and case series of at least 20 patients, were eligible for inclusion. Case series with fewer than 20 patients and case histories were excluded from the review.

Specific interventions included in the review
The following interventions were eligible for inclusion: watchful waiting; medical therapies including non-steroidal anti-inflammatory drugs, oral contraceptive pills, gestational agents, other oral agents (e.g. mifepristone, tibolone and herbal preparations), and gonadotrophin-releasing hormone (GnRH) agonists as either primary or adjuvant therapy; invasive therapies including uterine artery embolisation, coagulation using cautery or laser, myomectomy and hysterectomy. For the management of asymptomatic fibroids, strategies of no intervention, prophylactic myomectomy and prophylactic hysterectomy were eligible for inclusion.

Participants included in the review
Women aged between 20 and 55 years with asymptomatic or symptomatic uterine fibroids were eligible for inclusion in the review.

Outcomes assessed in the review
The following outcomes were eligible for inclusion: anatomical and physiological changes such as change in uterine size, fibroid size, haemoglobin or haemocrit; symptomatic outcomes, including changes in symptoms of bleeding, cyclic pain or noncyclic pain; pregnancy-related outcomes such as pregnancy rates, live birth rates or pregnancy complications; quality of life measures; adverse outcomes such as side effects, complications of treatment and development of new symptoms; need for additional treatment after uterus-conserving therapy; and resource use, including length of stay, medical costs and time lost from work or usual activities.

How were decisions on the relevance of primary studies made?
Four reviewers independently assessed an initial set of studies and inter-rater agreement was assessed using the kappa statistic. Thereafter, two reviewers independently assessed both abstracts and full papers for inclusion in the review. Any disagreements on full papers were resolved through discussion.

Assessment of study quality
Studies were evaluated for internal validity using the following criteria: randomisation, appropriateness of randomisation, adequacy of information on the participants, length of follow-up, losses to follow-up and withdrawals, and appropriate treatment of relevant statistical issues.

External validity was evaluated using the following criteria: patient age, ethnicity, pregnancy and surgical history;
uterine or fibroid size, fibroid number and location; baseline symptoms; timing of the outcome assessment; validity and reliability of the outcomes measures; clinical care provided; and the use of standard validated measures. One reviewer assessed validity and another reviewer checked the assessment.

Data extraction
One reviewer extracted the data and another reviewer checked the accuracy of the extraction.

Methods of synthesis
How were the studies combined?
The studies were combined in an extensive narrative and presented in detailed evidence tables.

How were differences between studies investigated?
The studies were grouped according to the treatments or treatment comparisons examined. Clinical and methodological differences between the studies were discussed.

Results of the review
Two hundred studies were included in the review. Of these, 31 were randomised controlled trials (RCTs).

The majority of studies provided insufficient information for the assessment of internal or external validity.

There were no direct comparisons of the risks and benefits of myomectomy and hysterectomy. The long-term benefits of myomectomy were also unclear. Hysterectomy appeared to result in a majority of favourable outcomes for up to 2 years following surgery.

The review identified either no evidence or insufficient evidence on the following issues: the most appropriate therapy for a given symptomatic patient; morbidity associated with treatment for recurrent or persistent symptoms; medical therapies except for GnRH agonists an adjunct to surgery for women with symptomatic fibroids; the rate of recurrence of fibroids after conservative management.

There were no data to support prophylactic hysterectomy or myomectomy in women with asymptomatic fibroids, but there was clear evidence that both are associated with the risk of complications. There appeared to be a relationship between the number of fibroids removed during myomectomy and the risk of complications, but the nature of the relationship was unclear.

GnRH agonists given prior to surgery (either myomectomy or hysterectomy) reduce estimated blood loss and may facilitate the use of less invasive surgical approaches.

Uterus-conserving measures such as GnRH agonists, uterine artery embolisation and myomectomy may be more effective in perimenopausal than premenopausal women, but further studies are needed.

Hysterectomy may result in changes in ovarian steroid levels even where bilateral preservation of ovaries is possible.

Hysterectomy does not appear to adversely affect sexual function in most women. Where there was significant symptomatology prior to surgery there may be an improvement in function.

Cost information
The authors found no data on the non-medical costs associated with symptomatic fibroids. The only data found on outpatient management concerned drug costs; these were lowest for non-steroidals (less than $60 for 3 months’ therapy), intermediate for progestins and oral contraceptives ($90 to $120 for 3 months’ therapy), and highest for GnRH agonists ($1,500 for 3 months’ therapy). The mean hospital costs for myomectomy were approximately $800 less than those for hysterectomy for fibroids.
Authors' conclusions
There is currently insufficient good-quality evidence for patients, clinicians and policy-makers to make informed
decisions about the appropriate treatment for uterine fibroids.

CRD commentary
The review question and inclusion criteria were clear but very broad. The search was reasonably extensive, although the
restriction to studies published in English might have led to the introduction of publication bias and language bias. The
authors used appropriate criteria to assess validity and appropriate measures to minimise bias and error in the study
selection, validity assessment and data extraction processes. The decision to adopt a narrative synthesis was appropriate
in view of the methodological and clinical heterogeneity of the included studies. This was a well-conducted systematic
review, and the authors’ conclusions are a reliable reflection of the paucity of high-quality evidence available.

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

Research: The authors stated that methodologically rigorous studies of the effectiveness of nonsurgical treatments and
the development of standard measures of disease severity should be a priority for further research.

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Bibliographic details

Original Paper URL
http://www.ahrq.gov/clinic/epcsums/utersumm.htm

Other publications of related interest
Myers ER, Barber MD, Gustilo-Ashby T, Couchman G, Matchar DB, McCrory DC. Management of uterine
leiomyomata: what do we really know? Obstet Gynecol 2002;100:8-17.

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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.