

Title:	Uterine artery embolisation for the treatment of symptomatic uterine fibroids
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Aim

To assess the safety, effectiveness and cost-effectiveness of uterine artery embolisation (UAE) for the treatment of symptomatic uterine fibroids relative to other uterine conserving treatments (eg myomectomy) and hysterectomy.

Conclusions and Results

Safety

On the basis of one randomised and three non-randomised studies, UAE appeared to be as safe as, or safer than, abdominal hysterectomy. Major complications of haemorrhage, deep vein thrombosis and organ damage were more prevalent after hysterectomy compared to UAE. Conversely, UAE was associated with higher rates of minor complications such as vaginal discharge, thigh paraesthesia, renouretal colic and vulvovaginitis. The two procedures were equivalent for reoperation or rehospitalisation as a consequence of complications, and for the preservation of ovarian function. UAE case reports highlight the potential for rare infective complications associated with tissue necrosis *in situ*.

On the basis of limited evidence, UAE appears to be as safe as, or safer than, abdominal myomectomy. Comparative safety data on UAE and myomectomy were primarily based on one medium quality non-randomised study, with one additional poor quality non-randomised study contributing to the evidence base for some outcomes. Comparative studies reported no serious complications, although overall abdominal myomectomy was associated with a higher rate of safety complications compared to UAE.

Effectiveness

Evidence from randomised and non-randomised studies indicates that UAE is less effective for controlling menorrhagia, pain and the pressure symptoms associated with uterine fibroids than hysterectomy. UAE patients are also more likely to undergo further intervention to resolve their symptoms than hysterectomy patients. Nevertheless, improvements in quality of life after the two procedures have been shown to be equivalent and convalescence time after UAE is approximately one-third that of hysterectomy. In terms of primary clinical outcomes, UAE is less effective than hysterectomy, although this conclusion needs to be considered in the context of patient preference for an intact uterus.

Based primarily on one medium quality non-randomised study, UAE appears to be as, or more, effective than abdominal myomectomy. Menorrhagia and pain symptoms are more likely to be resolved or significantly improved after UAE compared to myomectomy, whereas the converse applies for pressure symptoms. Convalescence time is significantly shorter after UAE; and the

rehospitalisation or reoperation rate, due to failure of the procedure to resolve symptoms, is equivalent to abdominal myomectomy.

Cost-effectiveness

As there was limited evidence to assess the trade-off (ie net benefits or harms) of potentially improved safety over reduced effectiveness for UAE compared to hysterectomy, a cost-effectiveness analysis was not undertaken. Although UAE was found to be as safe as, or safer than, abdominal myomectomy and just as effective, this conclusion was primarily based on very limited evidence (one small study) and it was thought that a cost-effectiveness analysis was unlikely to provide guidance to policy makers.

A cost-comparison analysis was therefore conducted for UAE and its comparators, abdominal hysterectomy and abdominal myomectomy. The perspective of this analysis was that of the Australian health system overall rather than a societal approach. The costs per patient calculated for UAE (private sector), abdominal hysterectomy for non-malignancy (public sector) and uterine myomectomy (public sector) were \$5,731, \$6,195 and \$6,331, respectively. However, because of the inability to estimate the cost per patient for all three procedures within either one or other of the private or public health sectors specifically, it was not possible to determine if there were substantial differences between hysterectomy, myomectomy and UAE in the cost per patient to the Australian health system overall.

The maximum additional federal government expenditure, assuming that all private sector uterine-conserving and removal procedures subsidised in 2002–03 (n = 19,036) are replaced by UAE, was estimated at \$24.0 million. An alternative estimate, assuming that only the uterine-conserving treatments in the private sector that were subsidised by the federal government in 2002–03 (n = 2,424) are replaced by UAE, resulted in a substantially lower estimate of additional federal government expenditure of \$3.1 million.

Recommendations

“The evidence suggests that UAE is safe, clinically effective and potentially cost-effective for the treatment of symptomatic uterine fibroids. It appears to be more effective than myomectomy for the control of menorrhagia and pain but less effective in controlling pressure symptoms. It is safer but less effective in controlling symptoms compared with hysterectomy.

The MSAC recommends that UAE be funded on an interim basis for the treatment of women with symptomatic uterine fibroids with a review within 5 years. The MSAC recommends that patients be referred by a specialist gynaecologist.”

The Minister for Health and Ageing accepted this recommendation on 28th of March 2006.

Method

A protocol for this assessment was written and peer-reviewed by various stakeholders. Medline, Embase, The Cochrane Library, and several other biomedical databases, HTA and other internet sites were searched (1990- March 2005). Specific journals were handsearched and reference lists perused. Studies were included in the review using pre-determined PICO selection criteria and reasons for exclusion were documented. Study quality was appraised and data extracted in a standardised manner. Synthesis was qualitative.