



Title	EVALUATE Hysterectomy Trial: A Multicentre Randomised Trial Comparing Abdominal, Vaginal and Laparoscopic Methods of Hysterectomy
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Aim

The EVALUATE study was 2 parallel randomized trials, one comparing laparoscopic hysterectomy (LH) with abdominal hysterectomy (AH) and the other comparing LH with vaginal hysterectomy (VH). The trials were designed to: (1) test the null hypothesis of no significant difference between LH and AH; and LH and VH; and (2) appraise the cost and cost effectiveness to health service and patients of AH, VH, and LH.

Conclusions and results

Clinical: Compared with AH, LH showed a higher rate of major complications (11.1% vs 6.2% $p=0.02$), less post-operative pain (visual analogue scale score of 3.51 vs 3.88 $p=0.01$) and shorter hospital stay (3 vs 4 days), but took longer to perform (84 vs 50 minutes). At 6 weeks post-operative, ALH showed a significantly better scores than AH in the physical component of short form 12, Body Image Scale, and frequency of sexual intercourse. These differences were not observed at 4 or 12 months after surgery. No significant differences in outcome were found between LH and VH except that VLH took longer to perform and had a higher rate of detecting unexpected pathology.

Economic: Compared to vaginal hysterectomy, VLH had a higher mean cost per patient of £401 and higher mean QALYs of 0.0015 resulting in an incremental cost per QALY gained of £267,333. The probability that VLH is cost effective was below 50% for a large range of willingness-to-pay values for an additional QALY. Compared to abdominal hysterectomy, ALH had a higher mean cost per patient of £186 and higher mean QALYs of 0.007, resulting in an incremental cost per QALY gained of £26,571. If the NHS is willing to pay £30,000 for additional QALYs, the probability that ALH is cost effective is 56%.

Recommendations

Abdominal trial – LH shows a significantly higher risk of major complications and takes longer to perform

than AH. LH shows less pain, quicker recovery, and better short-term quality of life (QoL) after surgery than AH. The cost effectiveness of LH is finely balanced, depending on the threshold value the NHS attaches to an additional QALY and the balance of reusable equipment versus disposable consumables. The surgeon must determine the optimum balance between patient benefits and the risk of severe complications.

Vaginal trial – Clinical results were not conclusive, as the study was not designed to have sufficient power to detect a statistically significant result. LH was not cost effective relative to VH.

Methods

Please see the full monograph for details of the methods.

Further research/reviews required

Application and relevance of QoL measures following hysterectomy, and long-term followup. Patient preferences – balance between risks and benefits of the various forms of hysterectomy. Reducing complication rates. Improving gynecological surgical training. Surgeon effect in surgery trials. Care pathways for hysterectomy. Additional pathology identification in LH. Meta-analysis / further trial of VH versus LH.