

Title:	Hysteroscopic Sterilisation by Tubal Cannulation and Placement of Intrafallopian Implant, August 2003
Agency:	Medical Services Advisory Committee (MSAC) Mail Drop Point 107 Commonwealth Department of Health and Ageing GPO Box 9848 Canberra ACT 2601 Australia.
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Aim

To assess the safety, effectiveness and cost-effectiveness of hysteroscopic sterilisation by tubal cannulation and placement of intrafallopian implant (HSTCPII) using the Essure® device.

Conclusions and results

Safety HSTCPII appears to be a relatively safe procedure and has not been associated with any major safety concerns to date. However, this conclusion is based on relatively short-term data and it is only with extensive use that the true safety profile will be elucidated.

Effectiveness HSTCPII appears to be a relatively effective procedure and has not been associated with any pregnancies to date. However, as with safety, further follow-up data is required to ascertain the full effectiveness of HSTCPII.

Cost-effectiveness There is no evidence concerning the rate of substitution of HSTCPII for laparoscopic tubal ligation (LTL), its major comparator. In addition there is no evidence in terms of economic outcomes i.e. pregnancies avoided for HSTCPII.

Recommendations

The MSAC recommended that on the strength of evidence pertaining to hysteroscopic sterilisation by tubal cannulation and placement of intrafallopian implant that public funding should not be supported.

Method

MSAC conducted a systematic review of the medical literature using the Cochrane Library, Medline, PreMedline, Current Contents, CINAHL and EMBASE databases from 1966 – November 2002. In addition the application contained four study reports®. Assessment of clinical effectiveness relied on two primary studies (a Phase II and a Pivotal study) provided with the application one of which was also published, while assessment of cost-effectiveness was based on a review of the current literature.

Further research

Current follow-up from the primary studies is relatively short. As of May 2003 only 50% of patients in the Phase II study and 5% of patients in the Pivotal study had been followed-up for three-years. However, five-year follow-up of patients is intended.