

Hysteroscopic Tubal Sterilization: OHTAC Recommendation

Ontario Health Technology Advisory Committee

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Health Quality Ontario (HQO) is an arms-length agency of the Ontario government. It is a partner and leader in transforming Ontario's health care system so that it can deliver a better experience of care, better outcomes for Ontarians, and better value for money.

Health Quality Ontario strives to promote health care that is supported by the best available scientific evidence. The Evidence Development and Standards branch works with advisory panels, clinical experts, developers of health technologies, scientific collaborators, and field evaluation partners to provide evidence about the effectiveness and cost-effectiveness of health interventions in Ontario.

To conduct its systematic reviews of health interventions, the Evidence Development and Standards branch examines the available scientific literature, making every effort to consider all relevant national and international research. If there is insufficient evidence on the safety, effectiveness, and/or cost-effectiveness of a health intervention, HQO may request that its scientific collaborators conduct economic evaluations and field evaluations related to the reviews. Field evaluation partners are research institutes focused on multicentred clinical trials and economic evaluation, as well as institutes engaged in evaluating the safety and usability of health technologies.

About the Ontario Health Technology Advisory Committee

The Ontario Health Technology Advisory Committee (OHTAC) is a standing advisory subcommittee of the Board of Directors of Health Quality Ontario. Based on the evidence provided by Evidence Development and Standards and its partners, OTHAC makes recommendations about the uptake, diffusion, distribution, or removal of health interventions within the provincial health system. When making its recommendations, OHTAC applies a unique decision-determinants framework that takes into account overall clinical benefit, value for money, societal and ethical considerations, and the economic and organizational feasibility of the health care intervention in Ontario.

Publishing Health Quality Ontario Research

When the evidence development process is nearly completed, draft reviews, reports, and OHTAC recommendations are posted on HQO's website for 21 days for public and professional comment. For more information, please visit: <http://www.hqontario.ca/evidence/evidence-process/evidence-review-process/professional-and-public-engagement-and-consultation>.

Once finalized and approved by the Board of Directors of Health Quality Ontario, the research is published as part of the *Ontario Health Technology Assessment Series*, which is indexed in MEDLINE/PubMed, Excerpta Medica/Embase, and the Centre for Reviews and Dissemination database. Corresponding OHTAC recommendations and associated reports are also published on the HQO website. Visit <http://www.hqontario.ca> for more information.

When sufficient data are available, OHTAC tracks the ongoing use of select interventions it has previously reviewed, compiling data by time period and region. The results are published in the Ontario Health Technology Maps Project Report.

Disclaimer

This report was prepared by Health Quality Ontario or one of its research partners for the *Ontario Health Technology Advisory Committee* and was developed from analysis, interpretation, and comparison of scientific research. It also incorporates, when available, Ontario data and information provided by experts and applicants to Health Quality Ontario. It is possible that relevant scientific findings may have been reported since the development of this recommendation. This report may be superseded by an updated publication on the same topic. Please check the Health Quality Ontario website for a list of all publications: <http://www.hqontario.ca/evidence/publications-and-ohdac-recommendations>.

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Background

An evidence-based analysis was conducted by Health Quality Ontario to answer the following research question: what is the effectiveness and cost-effectiveness of hysteroscopic tubal sterilization compared with tubal ligation for permanent female sterilization?

Conclusions

Hysteroscopic tubal sterilization is associated with:

- lower pregnancy rates compared to tubal ligation (GRADE very low)
- lower complication rates compared to tubal ligation (GRADE very low)
- no significant improvement in patient satisfaction compared to tubal ligation (GRADE very low)

Decision Determinants

OHTAC has developed a decision-making framework that consists of 7 guiding principles for decision making and a decision determinants tool. When making a decision, OHTAC considers 4 explicit main criteria: overall clinical benefit, consistency with expected societal and ethical values, value for money, and feasibility of adoption into the health system. For more information on the decision-making framework, please refer to the *Decision Determinants Guidance Document* available at: <http://www.hqontario.ca/evidence/evidence-process/evidence-review-process/decision-making-framework>.

Appendix 1 provides a summary of the decision determinants for this recommendation.

OHTAC Recommendation

OHTAC Recommendations on Hysteroscopic Tubal Sterilization

The results of a systematic review conducted by Health Quality Ontario demonstrated that hysteroscopic sterilization is a safe, effective, and less invasive alternative to tubal ligation for female sterilization.

OHTAC recommends that:

- Hysteroscopic sterilization be considered as an alternative to tubal ligation for female sterilization.
- Access issues regarding hysteroscopic sterilization being provided in an outpatient setting be considered as part of the associated implementation strategy.

Appendix 1 – Decision Determinants

Table A1: Decision Determinants for Hysteroscopic Tubal Sterilization

Decision Criteria	Subcriteria	Decision Determinants Considerations
Overall clinical benefit How likely is the health technology/intervention to result in high, moderate, or low overall benefit?	Effectiveness How effective is the health technology/intervention likely to be (taking into account any variability)?	Hysteroscopic sterilization is associated with: <ul style="list-style-type: none"> • lower pregnancy rates compared to tubal ligation (GRADE very low) • improvement in patient satisfaction compared to tubal ligation (GRADE very low) Limitations to the studies include a lack of long-term follow-up, lack of comparable follow-up durations, and a paucity of studies that directly compare hysteroscopic tubal sterilization to tubal ligation. The CREST trial, which reported results of tubal ligation, was a large, multicentre, prospective, noncomparative observational study.
	Safety How safe is the health technology/intervention likely to be?	Hysteroscopic sterilization is associated with: <ul style="list-style-type: none"> • lower complication rates compared to tubal ligation (GRADE very low) <ul style="list-style-type: none"> ○ lack of long-term follow-up for hysteroscopic sterilization and a paucity of studies that directly compare tubal ligation to hysteroscopic sterilization ○ no mortalities reported for hysteroscopic sterilization to date ○ early versions of device occasionally expelled <ul style="list-style-type: none"> ▪ changing device design allowed more distal and successful placement in tube ○ most instances of perforation associated with early use of additional support catheter <ul style="list-style-type: none"> ▪ use of catheter subsequently discontinued
	Burden of illness What is the likely size of the burden of illness pertaining to this health technology/intervention?	Fiscal year 2008/2009: <ul style="list-style-type: none"> • 8,923 women in Ontario underwent tubal occlusion procedures for the purpose of sterilization
	Need How large is the need for this health technology/intervention?	Conventionally, laparoscopic tubal sterilization: <ul style="list-style-type: none"> • interrupts tubal patency by using rings, clips, electrocoagulation or excision • requires general anesthesia • requires gas insufflation to distend the peritoneal cavity • is associated with a mortality rate of 1 to 2 per 100,000 procedures No mortalities have been associated with hysteroscopic sterilization to date in the literature.

Decision Criteria	Subcriteria	Decision Determinants Considerations
Consistency with expected societal and ethical values^a How likely is adoption of the health technology/intervention to be congruent with societal and ethical values?	Societal values How likely is the adoption of the health technology/intervention to be congruent with expected societal values? Ethical values How likely is the adoption of the health technology/intervention to be congruent with expected ethical values?	Patients and their families may prefer an outpatient/office procedure compared to surgery requiring general anesthetic.
Value for money How efficient is the health technology likely to be?	Economic evaluation How efficient is the health technology/intervention likely to be?	Three cost analyses were identified in the systematic literature review: <ul style="list-style-type: none"> • The cost of the hysteroscopic sterilization procedure was associated with higher costs compared to laparoscopic sterilization due to the cost of the Essure device. • However, pre- and post-procedure care was less costly for hysteroscopic compared with laparoscopic sterilization. • Overall, hysteroscopic sterilization was found to be less costly than laparoscopic sterilization, with estimated cost savings of \$111 (Canada), €337 (Italy), and \$1,178 (USA). • None of the studies included quality of life or quality-adjusted life years as an outcome.
Feasibility of adoption into health system How feasible is it to adopt the health technology/intervention into the Ontario health care system?	Economic feasibility How economically feasible is the health technology/intervention? Organizational feasibility How organizationally feasible is it to implement the health technology/intervention?	<ul style="list-style-type: none"> • Hysteroscopic sterilization can be performed without the use of general anesthesia in an office setting. • Hysteroscopic sterilization can be performed in an endoscopy clinic in hospital. • Implementation plan: start in hospital and over time move to independent health facilities. • Currently, Ontario has no specific fee code for hysteroscopic sterilization; it is likely claimed under the general code S741 (Cdn \$255.70). According to the manufacturer: <ul style="list-style-type: none"> • 10 gynecologists in Ontario perform hysteroscopic sterilization. • Fewer than 200 procedures were performed in Ontario in 2012. • Approximately 1,300 procedures were performed in Canada in 2012.

Abbreviations: CREST, Collaborative Review of Sterilization study; GRADE, Grading of Recommendations Assessment, Development and Evaluation.

^aThe anticipated or assumed common ethical and societal values held in regard to the target condition, target population, and/or treatment options. Unless there is evidence from scientific sources to corroborate the true nature of the ethical and societal values, the expected values are considered.

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