

Hysteroscopic Tubal Sterilization: A Health Economic Literature Review

Toronto Health Economic and Technology Assessment
(THETA) Collaborative

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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 completion of the review. This report is current to the date of the literature review specified in the methods section, if available. This analysis may be superseded by an updated publication on the same topic.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-ohtac-recommendations>.

Abstract

Background

Hysteroscopic sterilization is a minimally invasive alternative to laparoscopic tubal ligation for women who want permanent contraception. In contrast to the laparoscopic technique, a hysteroscope is used to pass permanent microinserts through the cervix and place them in the fallopian tubes. This procedure does not require local or general anesthesia and can be performed in an office setting.

Objectives

The objective of this analysis was to determine, based on published literature, the cost-effectiveness of hysteroscopic tubal sterilization (HS) compared with laparoscopic tubal ligation (LS) for permanent female sterilization.

Data Sources

A systematic literature search was conducted for studies published between January 1, 2008, and December 11, 2012.

Review Methods

Potentially relevant studies were identified based on the title and abstract. Cost-utility analyses (studies that report outcomes in terms of costs and quality-adjusted life-years) were prioritized for inclusion. When not available, cost-effectiveness, cost-benefit, and cost-consequence analyses were considered. Costing studies were considered in the absence of all other analyses.

Results

A total of 33 abstracts were identified. Three cost analyses were included. A retrospective chart review from Canada found that HS was \$111 less costly than LS; a prospective activity-based cost management study from Italy reported that it was €337 less costly than LS; and the results of an American decision model showed that HS was \$1,178 less costly than LS.

Limitations

All studies had limited applicability to the Ontario health care system due to differences in setting, resource use, and costs.

Conclusions

Three cost analyses found that, although the HS procedure was more expensive due to the cost of the microinserts, HS was less costly than LS overall due to the shorter recovery time required.

Plain Language Summary

Hysteroscopic sterilization is a minimally invasive alternative to conventional tubal ligation for women who want a permanent method of contraception. Both approaches involve closing off the fallopian tubes, preventing the egg from moving down the tube and the sperm from reaching the egg. Tubal ligation is a surgical procedure to tie or seal the fallopian tubes, and it usually requires general anesthesia. In contrast, hysteroscopic tubal sterilization can be performed in 10 minutes in an office setting without general or even local anesthesia. A tiny device called a microinsert is inserted into each fallopian tube through the vagina, cervix, and uterus without surgery. An instrument called a hysteroscope allows the doctor to see inside the body for the procedure. Once the microinserts are in place, scar tissue forms around them and blocks the fallopian tubes.

Health Quality Ontario commissioned a systematic review of published economic literature to determine whether hysteroscopic sterilization is cost-effective compared to tubal ligation. This review did not find any studies that reported results in terms of both costs and effectiveness or costs and quality-adjusted life-years. We did find 3 costing studies and included them in our review. All of these studies found that when hysteroscopic sterilization was performed as an outpatient procedure, it was less expensive than tubal ligation due to a shorter recovery time. However, none of the studies apply directly to Ontario because of differences in our health care system compared to those in the studies.

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List of Abbreviations

HQO	Health Quality Ontario
HS	Hysteroscopic tubal occlusion/sterilization
LS	Laparoscopic tubal ligation
OHTAC	Ontario Health Technology Advisory Committee
QALY	Quality-adjusted life-year

Background

The Toronto Health Economics and Technology Assessment (THETA) Collaborative was commissioned by HQO to evaluate the cost-effectiveness of hysteroscopic and laparoscopic strategies for permanent sterilization in women. This report summarizes the results of the systematic literature review conducted to address this question. Original economic analyses were not conducted due to a lack of comparative clinical evidence. A budget impact analysis was developed to explore the expected cost associated with implementation of the OHTAC recommendation supporting the provision of hysteroscopic tubal sterilization as an alternative to tubal ligation.

Health Quality Ontario conducts full evidence-based analyses, including economic analyses, of health technologies being considered for use in Ontario. These analyses are then presented to the Ontario Health Technology Advisory Committee, whose mandate it is to examine proposed health technologies in the context of available evidence and existing clinical practice, and to provide advice and recommendations to Ontario health care practitioners, the broader health care system, and the Ontario Ministry of Health and Long-Term Care.

DISCLAIMER: Health Quality Ontario uses a standardized costing method for its economic analyses. The main cost categories and associated methods of retrieval from the province's perspective are described below.

Hospital costs: Ontario Case Costing Initiative cost data are used for in-hospital stay, emergency department visit, and day procedure costs for the designated International Classification of Diseases diagnosis codes and Canadian Classification of Health Interventions procedure codes. Adjustments may be required to reflect accuracy in the estimated costs of the diagnoses and procedures under consideration. Due to difficulties in estimating indirect costs in hospitals associated with a particular diagnosis or procedure, Health Quality Ontario normally defaults to a consideration of direct treatment costs only.

Non-hospital costs: These include physician services costs obtained from the Ontario Schedule of Physician Benefits, laboratory fees from the Ontario Schedule of Laboratory Fees, drug costs from the Ontario Drug Benefit Formulary, and device costs from the perspective of local health care institutions whenever possible, or from the device manufacturer.

Discounting: For cost-effectiveness analyses, a discount rate of 5% is applied (to both costs and effects/QALYs), as recommended by economic guidelines.

Downstream costs: All reported downstream costs are based on assumptions of population trends (i.e., incidence, prevalence, and mortality rates), time horizon, resource utilization, patient compliance, health care patterns, market trends (i.e., rates of intervention uptake or trends in current programs in place in the province), and estimates of funding and prices. These may or may not be realized by the Ontario health care system or individual institutions and are often based on evidence from the medical literature, standard listing references, and educated hypotheses from expert panels. In cases where a deviation from this standard is used, an explanation is offered as to the reasons, the assumptions, and the revised approach.

The economic analysis represents *an estimate only*, based on the assumptions and costing methods explicitly stated above. These estimates will change if different assumptions and costing methods are applied to the analysis.

NOTE: Numbers may be rounded to the nearest decimal point, as they may be reported from an Excel spreadsheet.

Objective of Analysis

The objective of this analysis was to determine the cost-effectiveness of hysteroscopic tubal sterilization compared with laparoscopic tubal sterilization for permanent female sterilization.

Clinical Need and Target Population

Hysteroscopic tubal sterilization is a minimally invasive alternative to laparoscopic tubal ligation for women wishing to achieve permanent sterilization. Both procedures aim to prevent conception by closing (occluding) the fallopian tubes. In contrast to the surgery required in the laparoscopic technique, hysteroscopic sterilization uses a hysteroscope to pass permanent microinserts through the cervix and place them in the fallopian tubes. This procedure does not require local or general anesthesia and can be performed in an office setting. Although the cost of the coil insert is greater than that of the laparoscopic procedure, recovery time after the hysteroscopic procedure is significantly reduced and patients report less pain and faster return to work. There is an interest in exploring the use of hysteroscopic sterilization as a more effective and less expensive alternative to laparoscopic tubal ligation in Ontario.

Economic Analysis

Research Question

What is the cost-effectiveness of hysteroscopic tubal sterilization compared with laparoscopic tubal sterilization for permanent female sterilization?

Economic Literature Review

Methods

We searched Ovid MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, Ovid EMBASE, Wiley Cochrane, CINAHL, Centre for Reviews and Dissemination/International Agency for Health Technology Assessment, and EconLit from January 1, 2008, to December 11, 2012, to identify studies comparing hysteroscopic sterilization to laparoscopic tubal sterilization. Potentially relevant studies were identified based on the title and abstract. Full-text articles were retrieved and evaluated against the following criteria:

- Cost-utility analyses (studies that report outcomes in terms of costs and quality-adjusted life-years [QALYs]) were prioritized for inclusion.
- Where these studies were not available for a particular intervention, cost-effectiveness, cost-benefit, and cost-consequence analyses were considered. We also considered costing studies in the absence of these types of analysis.
- Abstracts, posters, reviews, letters/editorials, foreign language publications, and unpublished studies were excluded.

The literature search strategy is described in Appendix 1.

Results

A total of 33 abstracts were identified in the systematic review. None were cost-utility, cost-effectiveness or cost-benefit analyses. In the absence of these types of economic evaluations, 3 cost analyses were included. Study characteristics are summarized in Table 1 and the results of each study are discussed below, with an emphasis on direct health care costs, consistent with the perspective of the Ontario Ministry of Health and Long-Term Care. Please refer to Appendix 2 for full economic evidence tables for each study. Although HQO is aware of 2 other studies on this topic (1;2), these papers were published before the start date of our search and were therefore excluded.

Table 1. Study Characteristics of Included Cost Analyses and Applicability to Ontario

Author, Year	Perspective	Study Design	Limitations and Applicability
Thiel and Carson, 2008 (3)	Canadian hospital	Retrospective chart review	Effectiveness not taken into account. Coil placement in Saskatchewan is associated with a specific physician cost, which is not directly applicable to the Ontario context.
Franchini et al, 2009 (4)	Italian hospital	Prospective cost analysis	Effectiveness not taken into account. Hysteroscopic sterilization was performed in an operating theatre under general anesthetic. Activity-based cost management from an Italian perspective is likely not directly applicable to an Ontario context.
Kraemer et al, 2009 (5)	United States	Decision model	Effectiveness accounted for but based on noncomparative, short-term clinical data. Side effects and anesthetic costs were not included.

Thiel and Carson (3) conducted a retrospective chart review of women who underwent hysteroscopic sterilization (between 2005 and 2006) and laparoscopic tubal sterilization (between 2001 and 2004) in Saskatchewan. Total case costs associated with each procedure (including pre- and postprocedure nursing, intraoperative nursing, hospital charges, device cost, ultrasound, and anaesthesia) were calculated and divided by the number of patients in each group to obtain the average cost associated with each alternative. The results of this study show that when performed in an ambulatory setting, hysteroscopic sterilization was \$111 (Cdn) less costly than the laparoscopic procedure (Table 2).

In Italy, Franchini et al (4) prospectively evaluated costs of patients who chose to undergo 1 of the 2 sterilization procedures. Costs included both direct health care and indirect costs (e.g., loss of wages resulting from time off work) and were reported separately. The mean time required to perform the hysteroscopic procedure was significantly less than for laparoscopic, as was the stay in the operating theatre and hospital following surgery. In total, when only direct health care costs are considered, the hysteroscopic procedure was €337 less costly than laparoscopic sterilization (Table 2).

Table 2. Results Reported by Included Cost Analyses

Cost Component	Included Resources	Laparoscopic Sterilization (LS)	Hysteroscopic Sterilization (HS)	Difference (HS – LS)
Thiel and Carson, 2008 (3)				
Total OR time	Minutes	44 ± 16	9 ± 5	- 35
Total OR cost	Nursing time, anesthesia, Essure device or Filshie clips, disposables	\$670 ± \$158	\$1,007 ± \$185	- \$337
Total nursing costs	Day surgery and preoperative, operating or procedure room, and recovery room nursing	\$181 ± \$39	\$12 ± \$6	\$169
Ancillary costs	Day surgery or recovery room nursing, hospital charges, ultrasound, hysterosalpingography	\$714 ± \$152	\$266 ± \$39	\$448
Total cost (Cdn)		\$1,287 ± \$2,450	\$1,398 ± \$36	- \$111
Franchini et al, 2009 (4)				
OR material	Anesthesia, dressing, nontraceable and traceable items	€576 ± 210	€1,276 ± 31	- €700
OR staff	Surgeons, anesthetists, nurses, ward assistant, indirect costs	€271	€106	€165
Total OR cost		€894 ± 214	€1,412 ± 37	- €518
Recovery unit material	Pharmacy stock, miscellaneous	€41 ± 8	€16 ± 5	€25
Recovery unit staff	Physician, nurses, ward assistant	€557 ± 99	€115 ± 43	€442
Indirect costs	Lab, physician on duty	€244 ± 63	€47 ± 28	€197
Total recovery unit costs		€850 ± 117	€180 ± 52	€670
Total cost (Italy)		€1,829	€1,492	- €337

Abbreviations: HS, hysteroscopic sterilization; LS, laparoscopic sterilization; OR, operating room.

Kraemer and colleagues (5) developed a decision model to compare the cost of laparoscopic and hysteroscopic sterilization. The model assumed that all hysteroscopic procedures took place in an office setting. The study used a 94.6% probability of occlusion following a first procedure and 37.5% for a repeat procedure. A 5-year probability of conception of 0.26% was based on a 2006 news release from the device manufacturer (Conceptus, Inc.; Mountain View, CA). Outcomes following conception included ectopic pregnancy, induced abortion, spontaneous abortion, and live birth. The results of their analysis showed that a total savings of \$1,178 was associated with the use of hysteroscopic sterilization (Table 3).

Table 3. Decision Model Parameters and Results Reported in Kraemer et al, 2009 (5)

Parameter	Laparoscopic Sterilization (base case estimate [range])	Hysteroscopic Sterilization (base case estimate [range])
Health state transitions (%)		
Probability of occlusion following first procedure	100	94.6 (89.4–95.4)
Probability of repeat HS if failure to occlude	Not applicable	33.3 (0.0–100)
Probability of IUD or LS if failure to occlude	Not applicable	50.0 (0.0–100)
Probability of occlusion on second attempt	Not applicable	37.5 (30.0–45.0)
5-year probability of conception	1.2 (1.0–1.5)	0.24 (0.16–0.26)
Probability of ectopic pregnancy	33.0 (29.7–36.3)	11.0 (5.5–33.0)
If not ectopic, probability of live birth	40.0 (32.–48.0)	40.0 (32.0–48.0)
If not ectopic, probability of induced abortion	47.0 (37.6–56.4)	47.0 (37.6–56.4)
Costs (\$)		
Procedure cost	3,467 (2,774–4,160)	2,220 (1,776–2,664)
Ectopic pregnancy	10,518 (8,415–12,622)	10,518 (8,415–12,622)
Live birth	8,797 (7,037–10,556)	8,797 (7,037–10,556)
Induced abortion	853 (682–1,023)	853 (682–1,023)
Spontaneous abortion	853 (682–1,023)	853 (682–1,023)
Results		
Total expected cost (US \$)	3,545	2,367

Abbreviations: HS, hysteroscopic sterilization; IUD, intrauterine device; LS, laparoscopic sterilization.

Original Economic Evaluation

Due to a lack of comparative clinical evidence, an original economic analysis was not developed.

Budget Impact Analysis – Ontario Perspective

Costs

The costs associated with professional fees for each procedure are presented in Table 4. When hysteroscopic sterilization is performed in an endoscopy suite, there is a theoretical savings to the ministry of \$222.75 per procedure. However, in practice this procedure is likely to be cost-neutral once the costs of changes in scheduling and other overheads are taken into account.

Table 4. Professional Fees for Laparoscopic Tubal Ligation and Hysteroscopic Sterilization in Ontario

Resource Item		Unit Cost (\$)	Source
Laparoscopic tubal ligation			
Preprocedure	Obs/gyn specialist physician consultation	101.70	OHIP fee code A205
	Pelvic ultrasound	81.95	OHIP fee code J162 plus Professional 1
Procedure	Physician (plus assistant)	255.70	OHIP fee code S741
	Anesthetist	50.90	OHIP fee code Z735
	Laparoscopic tubal ligation (day surgery)	1,043.00 (direct) 343.00 (indirect)	CCI code 1.RF.51.DA-55
Postprocedure	Specialist physician visit	26.35	OHIP fee code A204
Total cost		1,902.60	
Hysteroscopic sterilization (performed in endoscopy suite)			
Preprocedure	Obs/gyn specialist physician consultation	101.70	OHIP fee code A205
	Pelvic ultrasound	81.95	OHIP fee code J162 plus Professional 1
Procedure	Physician (no assistant)	155.70	OHIP fee code S741
	Hysteroscopic sterilization	1,183.00 (direct) 90.00 (indirect)	CCI code 1.RF.51.FJ-GE
Postprocedure	Specialist physician visit	26.35	OHIP fee code A204
	Hysterosalpingogram	41.15	OHIP fee code X147
Total cost		1,679.85	

Abbreviations: CCI, Canadian classification of interventions; obs/gyn, obstetrician/gynecologist; OHIP, Ontario Health Insurance Plan.

Conclusions

There is an absence of evidence regarding the cost-effectiveness of hysteroscopic versus laparoscopic tubal sterilization. Published analyses have not assessed cost per QALY, and we did not conduct original economic analyses due to a lack of comparative clinical literature. Three cost analyses were identified in the health economic literature review. All found that hysteroscopic sterilization procedure was more expensive than laparoscopic due to the cost of the microinserts. However, because procedure and recovery times are significantly shorter for hysteroscopic sterilization, it was found to be less costly overall than laparoscopic, with estimated cost savings of \$111 (Canada), €337 (Italy), and \$1,178 (United States). All studies had limited applicability to the Ontario health care system due to differences in setting, resource use, and unit costs.

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Appendices

Appendix 1: Literature Search Strategies

Search date: February 27, 2013

Databases searched: Ovid MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, EMBASE; Cochrane Library; Centre for Reviews and Dissemination (CRD)

Q: Hysteroscopic tubal sterilization

Limits: 2008-current; English

Filters: None

Database: Ovid MEDLINE(R) <1946 to February Week 2 2013>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <February 26, 2013>, EMBASE <1980 to 2013 Week 08>

Search Strategy:

#	Searches	Results
1	exp *Sterilization, Reproductive/ use mesz	8661
2	exp *female sterilization/ use emez	10036
3	exp Hysteroscopy/	10172
4	exp Hysteroscope/ use emez	390
5	1 or 2	18697
6	3 or 4	10328
7	5 and 6	340
8	(essure or microinsert* or transcervical tubal occlusion).ti,ab.	576
9	(hysteroscop* adj2 sterili?ation).ti,ab.	414
10	7 or 8 or 9	820
11	exp Economics/ use mesz or exp Models, Economic/ use mesz or exp Resource Allocation/ use mesz or exp "Value of Life"/ use mesz or exp "Quality of Life"/ use mesz	565122
12	exp "Health Care Cost"/ use emez or exp Health Economics/ use emez or exp Resource Management/ use emez or exp Economic Aspect/ use emez or exp Economics/ use emez or exp Quality Adjusted Life Year/ use emez or exp Socioeconomics/ use emez or exp Statistical Model/ use emez or exp "Quality of Life"/ use emez	1297215
13	(econom* or cost* or budget* or pharmaco-economic* or pharmaco-economic* or valu*).ti. ((cost\$ adj benefit\$) or costbenefit\$ or (cost adj effective\$) or costeffective\$ or econometric\$ or life value or quality-adjusted life year\$ or quality adjusted life year\$ or quality-adjusted life expectanc\$ or quality adjusted life expectanc\$ or sensitivity analys\$ or "value of life" or "willingness to pay").ti,ab.	493030
14	ec.fs.	198422
15	or/11-15	3485337
16	10 and 16	5413656
17	limit 17 to english language	82
18	limit 18 to yr="2008 -Current"	68
19	remove duplicates from 19	38
20		33

Cochrane

ID	Search	Hits
#1	MeSH descriptor: [Sterilization, Reproductive] explode all trees	318
#2	MeSH descriptor: [Hysteroscopy] explode all trees	283
#3	#1 and #2	10
#4	(essure or microinsert* or transcervical tubal occlusion*):ti,ab,kw (Word variations have been searched)	13
#5	(hysteroscop* near/2 sterili?ation*):ti,ab,kw (Word variations have been searched)	11
#6	#3 or #4 or #5	21
#7	MeSH descriptor: [Economics] explode all trees	20383
#8	MeSH descriptor: [Models, Economic] explode all trees	1505
#9	MeSH descriptor: [Resource Allocation] explode all trees	124
#10	MeSH descriptor: [Value of Life] explode all trees	142
#11	MeSH descriptor: [Quality of Life] explode all trees	12209
#12	(econom* or cost* or budget* or pharmacoeconomic* or pharmaco-economic* or valu*):ti (Word variations have been searched)	21015
#13	((cost* near benefit*) or costbenefit* or (cost near effective*) or costeffective* or econometric* or life value or quality-adjusted life year* or quality adjusted life year* or quality-adjusted life expectanc* or quality adjusted life expectanc* or sensitivity analys* or "value of life" or "willingness to pay"):ti,ab,kw (Word variations have been searched)	32095
#14	#7 or #8 or #9 or #10 or #11 or #12 or #13	52438
#15	#6 and #14 from 2008 to 2013	1

CRD

SearchHits		
1	MeSH DESCRIPTOR sterilization, reproductive EXPLODE ALL TREES	43
2	MeSH DESCRIPTOR Hysteroscopy EXPLODE ALL TREES	43
3	#1 AND #2	7
4	(essure or microinsert* or transcervical tubal occlusion*)	6
5	(hysteroscop* adj2 sterili?ation*)	7
6	#3 OR #4 OR #5	10
7	MeSH DESCRIPTOR Economics EXPLODE ALL TREES	13237
8	MeSH DESCRIPTOR Models, Economic EXPLODE ALL TREES	1417
9	MeSH DESCRIPTOR Resource Allocation EXPLODE ALL TREES	75
10	MeSH DESCRIPTOR Value of Life EXPLODE ALL TREES	116
11	MeSH DESCRIPTOR Quality of Life EXPLODE ALL TREES	1744
12	(econom* or cost* or budget* or pharmacoeconomic* or pharmaco-economic* or valu*):TI	12230
13	((cost* adj benefit*) or costbenefit* or (cost adj effective*) or costeffective* or econometric* or life value or quality-adjusted life year* or quality adjusted life year* or quality-adjusted life expectanc* or quality adjusted life expectanc* or sensitivity analys* or "value of life" or "willingness to pay")	19160
14	#7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13	21382
15	#6 AND #14	2
16	(#15) FROM 2008 TO 2013	1

Appendix 2: Economic Evidence Tables

Table A1. Thiel et al, 2012 (3)

Methods		
Study details	Population:	Interventions:
Type of economic analysis: Costing study	Women who wish to undergo permanent sterilization	Intvn 1: Laparoscopic tubal sterilization (LS) Intvn 2: Hysteroscopic sterilization (HS) performed in an ambulatory setting
Study design: Retrospective chart review	N: 212	
Perspective: Canadian (Saskatchewan) health care system	Mean age: 35 years	
Time horizon: Approximately 3 months		
Approach to analysis:		
Medical charts of women who underwent hysteroscopic sterilization from 2005 to 2006 and laparoscopic tubal sterilization from 2001 to 2004 were retrospectively reviewed. Placement of microinsert coils was conducted in an ambulatory setting. Bilateral placement was successful in 95% of patients (103 of 108). Three had subsequent procedures. Two required laparoscopic tubal sterilization; these costs were included in the cost of the HS procedure. Volume contrast ultrasound imaging was used to identify proper placement of the coils in 80 (75%) patients. Hysterosalpingography was required in the remaining 28 women. All LS procedures were completed on first attempt and no complications were noted.		
Results		
Costs	Health outcomes	Cost-effectiveness
Currency and cost year: Canadian dollars; year NR	Primary outcome: NA	Primary ICER: NA
Total costs (mean per person): Intvn 1: \$1,398 Intvn 2: \$1,287 Incremental (2-1): - \$111	Total QALYs (mean per person): Intvn 1: NA Intvn 2: NA Incremental (2-1): NA	Other: Hysteroscopic sterilization was \$111 less expensive than laparoscopic tubal ligation.
Discount rate: NA	Discount rate: NA	
Interpretation		
Sensitivity analyses	Limitations and applicability	
None conducted	Saskatchewan has a separate fee for HS (not reported in study; \$239 according to current sources), which is not applicable to the Ontario context. Study funding source not reported.	
Data sources		
Clinical effectiveness: Based on chart review conducted for the current study.		
Costs: Costs associated with hysteroscopic sterilization included pre- and postprocedure nursing, intraoperative nursing, hospital charges, the Essure device, follow-up ultrasound, and if necessary hysterosalpingogram, management of complications, and laparoscopic sterilization. Costs included in the laparoscopic procedure included day surgery nursing care, operating room and postanesthetic nursing care, hospital expenses, anesthesia, Filchie clips, and disposables. Operating time in the ambulatory centre was calculated from the start of procedure to the time the patient left the procedure room; in the operating room, it was calculated from the start of the anesthetic time to its completion. Total cost associated with 108 HS procedures was \$138,996, or \$1,287 per case. Total cost for 104 LS procedures was \$148,227, or \$1,398 per case.		
Quality of life: Not included		
Funding:		
Not reported		

Abbreviations: HS, hysteroscopic sterilization; ICER, incremental cost-effectiveness ratio; LS, laparoscopic tubal sterilization; NA, not applicable; NR, not reported.

Table A2. Franchini et al, 2009 (4)

Methods		
Study details	Population	Interventions
<p>Type of economic analysis: Costing study</p> <p>Study design: Activity-based cost management nonrandomized study</p> <p>Perspective: Italian hospital</p> <p>Time horizon: From presurgery to recovery follow-up (time NR)</p>	<p>Women seeking tubal sterilization; excluded were those with positive pregnancy tests, unsure about ending their fertility, and with uterine, cervical, or adenexal pathologies, uterine or cervical neoplasia, chronic pelvic pain, or pelvic inflammatory disease.</p> <p>N: 49</p> <p>Mean age: NR</p>	<p>Intvn 1: Laparoscopic tubal sterilization (LS)</p> <p>Intvn 2: Hysteroscopic sterilization (HS) performed in an operating room</p>
Approach to analysis		
<p>The authors prospectively evaluated costs of patients who chose to undergo 1 of the 2 procedures. Costs were calculated using an activity-based cost management system and included both direct health care and indirect costs (e.g., loss of wages resulting from time off work), and these were reported separately. Patients who underwent HS were admitted as a day case and received nonsteroidal anti-inflammatory drugs before the procedure, which took place under general anesthesia in an operating theatre. Women receiving LS were admitted on the evening of the day before surgery and underwent tubal coagulation under general anesthesia. All patients recovered sufficiently after the procedure to be discharged home on the day of surgery or the day after. Comparison of costs between groups was performed by unpaired t test and comparison between proportions was performed using Fisher exact test. Results were reported in means and SD.</p>		
Results		
Costs	Health outcomes	Cost-effectiveness
<p>Currency and cost year: 2005 Euros</p> <p>Total costs (mean per person): Intvn 1: €1,829 Intvn 2: €1,492 Incremental (2-1): - €337</p> <p>Discount rate: NA</p>	<p>Primary outcome: None</p> <p>Total QALYs (mean per person): Intvn 1: NA Intvn 2: NA Incremental (2-1): NA</p> <p>Discount rate: NA</p>	<p>Primary ICER: NA</p> <p>Other: Although the cost of the Essure device was high, operating costs, anesthesia costs, and nontraceable costs (such as disposable items and dressings) were lower for HS, and recovery costs were lower due to shorter length of stay.</p>
Interpretation		
Sensitivity analyses:	Limitations and applicability:	
<p>HS resulted in fewer days missed from work due to shorter hospital stay and shorter recovery after discharge. As a result, indirect costs were much lower in this group (€339) compared to LS (€876).</p>	<p>Hysteroscopic coil placement took place in an operating theatre under general anesthetic. Microcosting from an Italian perspective was designed to provide insight into hospital cost structure and health system and is likely not directly applicable to an Ontario context.</p>	
Data sources		
<p>Clinical effectiveness: NA</p> <p>Costs: Costs were calculated using an activity-based cost management system, “an accounting technique that allows organizations not only to determine the actual costs associated with their services based on the resources they consume, but also to detect when, where and why the money is spent.” This included all equipment, materials, staff costs for presurgical, surgical, and recovery times.</p> <p>Quality of life: NA</p>		
Funding		
NR		

Abbreviations: HS, hysteroscopic sterilization; ICER, incremental cost-effectiveness ratio; LS, laparoscopic tubal sterilization; NA, not applicable; NR, not reported; SD, standard deviation.

Table A3. Kraemer et al, 2009 (5)

Methods		
Study details	Population	Interventions
<p>Type of economic analysis: Cost-consequence analysis</p> <p>Study design: Decision analytic model</p> <p>Perspective: United States health care payer</p> <p>Time horizon: 5 years</p>	<p>Hypothetical population of women undergoing permanent sterilization</p> <p>Mean age: NR</p>	<p>Intvn 1: Laparoscopic bilateral tubal ligation (LS)</p> <p>Intvn 2: Hysteroscopic sterilization (HS)</p>
Approach to analysis:		
<p>A decision model was developed to compare the costs and consequences of HS versus LS. All HS procedures were assumed to take place in a clinic office setting. All patients were assumed to undergo a follow-up hystero-graphy exam for occlusion. If the tubes are not occluded, an additional procedure (repeat Essure, LS, IUD or IUS) is performed. A second hystero-graphy was performed in about 3.5% of patients.</p>		
Results		
Costs	Health outcomes	Cost effectiveness:
<p>Currency and cost year: 2008 US dollars</p> <p>Total costs (mean per person):</p> <p>Intvn 1: \$3,545</p> <p>Intvn 2: \$2,367</p> <p>Incremental (2-1): -\$1,178</p> <p>Discount rate: 3%</p>	<p>Primary outcome: None reported</p> <p>Total QALYs (mean per person):</p> <p>Intvn 1: NA</p> <p>Intvn 2: NA</p> <p>Incremental (2-1): NA</p> <p>Discount rate: NA</p>	<p>Primary ICER: NA</p> <p>Other: HS was estimated to result in a savings of \$1,178 compared to LS.</p>
Interpretation		
Sensitivity analyses:	Limitations and applicability:	
<p>A series of 1-way sensitivity analyses were used to assess the impact of different model inputs on the overall cost of HS. The expected cost of HS was most sensitive to the cost of the Essure device (range, \$1,776–\$2,664).</p> <p>The results of the model were relatively insensitive to factors such as the probability of LS versus IUD (range, 0–1), probability of occlusion after first procedure (range, 0.918–0.967), probability of repeat HS procedure (range, 0.0–1.0), HS conception probability (range, 0.002–0.0094), and LS procedure costs (range, \$2,774–\$4,160).</p>	<p>There is a lack of comparative, long-term data of conception rates and ectopic pregnancy. This is acknowledged by the authors, who use base case values based on short-term follow-up studies and broad ranges to reflect uncertainty.</p> <p>The costs used in this study are not applicable to the Ontario context. Ontario does not currently have a separate reimbursement fee for HS, as modelled by the study.</p> <p>The authors state that values were chosen to minimize the difference in costs between strategies. To achieve this aim, the evaluation does not capture the cost of side effects or adverse events related to either intervention. The cost of anesthesia is not included in the cost of LS, and the cost of side effects is not included in either arm. The reason for this is unclear.</p>	
Data sources		
<p>Clinical effectiveness: The 5-year probability of conception was based on an Essure news release, which stated that at 5 years, 99.74% of patients did not conceive (0.26% probability of conception). Outcomes following conception (including ectopic pregnancy, induced abortion, spontaneous abortion, live birth) were taken from Chiou et al (6) for LS, IUD, and IUS. Because no ectopic pregnancies are reported on the company website, a conservative base case estimate of 11% (equal to one-third that of LS) was used in the base case with a 50% upper and lower limit. The rate of other types of pregnancy for patients treated with Essure were based on Chiou et al. (6)</p> <p>Costs: Current Procedural Terminology codes were used to estimate the resource-based relative value units (RVUs) for each procedure (including physician work RVUs, nonfacility RVUs for Essure, IUD, and IUS, and malpractice RVUs). Costs of conception were based on those reported by Chiou et al (6) and inflated to 2008 \$ (US) using a multiplier of 140%.</p>		

Quality of life: NR.

Funding:

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Abbreviations: HS, hysteroscopic sterilization; LS, laparoscopic tubal sterilization; IUD, intrauterine device; IUS, intrauterine system; NA, not applicable; NR, not reported.

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