

# Cost-Effectiveness Analysis Comparing the Essure Tubal Sterilization Procedure and Laparoscopic Tubal Sterilization

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## Abstract

**Objective:** To analyze the financial implications of establishing a hysteroscopic sterilization program using the Essure micro-insert tubal sterilization system in an ambulatory clinic.

**Methods:** A retrospective cohort study (Canadian Task Force classification Type II-2), in an ambulatory women's health clinic in a tertiary hospital, of 108 women undergoing Essure coil insertion between 2005 and 2006, and 104 women undergoing laparoscopic tubal sterilization for permanent sterilization between 2001 and 2004. The Essure procedures used a 4 mm single channel operative hysteroscope and conscious sedation (fentanyl and midazolam); the laparoscopic tubal sterilizations were completed under general anaesthesia with a 7 mm laparoscope and either bipolar cautery or Filshie clips. Costs associated with the procedure, follow-up, and management of any complications (including nursing, hospital charges, equipment, and disposables) were tabulated.

**Results:** The Essure coils were successfully placed on the first attempt in 103 of 108 women (95%). Three patients required a second attempt to complete placement and two patients required laparoscopic tubal sterilization after an unsuccessful Essure. All 104 laparoscopic tubals were completed on the first attempt with no complications reported. The total cost for the 108 Essure procedures, including follow-up evaluation, was \$138 996 or \$1287 per case. The total cost associated with the 104 laparoscopic tubal sterilization procedures was \$148 227 or \$1398 per case. The incremental cost-effectiveness ratio was \$111.

**Conclusions:** The Essure procedure in an ambulatory setting resulted in a statistically significant cost saving of \$111 per sterilization procedure. Carrying out the Essure procedure in an ambulatory setting frees space in the operating room for other types of cases, improving access to care for more patients.

## Résumé

**Objectif :** Analyser les implications financières de la mise sur pied d'un programme de stérilisation hystérosopique faisant appel au système de stérilisation tubaire *Essure micro-insert* dans le cadre d'une clinique pour femmes offrant des soins ambulatoires.

**Méthodes :** Une étude de cohorte rétrospective (classification du Groupe de travail canadien : Type II-2) menée, au sein d'une

clinique de santé des femmes offrant des soins ambulatoires dans un hôpital tertiaire, auprès de 108 femmes ayant subi l'insertion d'un serpent *Essure* entre 2005 et 2006, et auprès de 104 femmes ayant subi une stérilisation tubaire laparoscopique aux fins de l'obtention d'une stérilisation permanente entre 2001 et 2004. Les interventions *Essure* faisaient appel un hystéroscope opératoire à canal unique de 4 mm et à une sédation consciente (fentanyl et midazolam); les stérilisations tubaires laparoscopiques ont été exécutées sous anesthésie générale au moyen d'un laparoscope de 7 mm et d'une cautérisation bipolaire ou de clips Filshie. Les coûts associés à l'intervention, au suivi et à la prise en charge de toute complication (y compris les soins infirmiers, les frais hospitaliers, le matériel et les articles jetables) ont été compilés.

**Résultats :** Les serpentins *Essure* ont été mis en place avec succès dès la première tentative chez 103 des 108 femmes (95 %). Trois patientes ont nécessité l'exécution d'une deuxième tentative pour achever la mise en place et deux patientes ont nécessité une stérilisation tubaire laparoscopique à la suite de l'échec d'une intervention *Essure*. Les 104 stérilisations tubaires laparoscopiques ont été effectuées avec succès dès la première tentative, sans qu'aucune complication ne soit signalée. Le coût total des 108 interventions *Essure*, y compris l'évaluation de suivi, a été de 138 996 \$, soit 1 287 \$ par cas. Le coût total des 104 stérilisations tubaires laparoscopiques a été de 148 227 \$, soit 1 398 \$ par cas. Le rapport coût-efficacité marginal était de 111 \$.

**Conclusions :** L'intervention *Essure* menée en milieu ambulatoire a permis la réalisation d'une économie significative sur le plan statistique de 111 \$ par intervention de stérilisation. Puisqu'elle est menée en milieu ambulatoire, l'intervention *Essure* permet également de rediriger le temps de SO vers d'autres types de cas, améliorant ainsi l'accès aux soins pour un plus grand nombre de patientes.

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## INTRODUCTION

The development of new medical technology invariably leads to an increase in the demand for these technologies by patients and physicians. Ideally, a new technology should be safer than existing methods, have better clinical outcomes, be less expensive, and improve access for patients. Improved access can include both access to the enhanced procedure and access to other services if the new technology frees resources for alternative uses. Accessibility for minor procedures such as tubal sterilization may

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become an issue as the initiatives to address long wait lists in Canada for joint replacement and cataract surgery will require increased operating room time.<sup>1</sup> In the health care system, unlike in a traditional market economy, patient demand is often unchecked and resources may be scarce relative to the demand.<sup>2</sup> One method of assessing the effect of the introduction of new technology is to compare the productive efficiency of the new intervention in monetary, not clinical, terms. The result is a cost-effectiveness analysis, which compares the relative value of an intervention, and from this analysis one can also determine the incremental cost-effectiveness ratio, which assesses the cost incurred to achieve a certain effect or benefit.<sup>3</sup>

The predominant method of permanent contraception in Canada remains vasectomy, with the prevalence of female sterilization decreasing from 16% in 1993 to 7% in 2002.<sup>4</sup> Until the introduction of the Essure hysteroscopic tubal sterilization system, the last advance in tubal ligation was the use of the laparoscope.<sup>5</sup> The Essure tubal sterilization system consists of a micro-insert nickel-titanium (Nitinol) coil surrounding a flexible stainless steel core housing polyethylene terephthalate fibres (Dacron), designed to induce a localized tissue ingrowth and subsequent tubal occlusion. The device is placed in the proximal fallopian tube via a hysteroscope in women who wish to undergo permanent sterilization. The procedure can be done using moderate sedation or oral analgesia in an ambulatory setting, with very few complications and a quick post-procedure recovery time. The Essure device is a safe, reliable form of permanent contraception. In the Phase II trial, 99% of women reported good to excellent results at all visits up to 60 months.<sup>6</sup> Persistent pain and bleeding were not reported by any women.

The purpose of this study was to complete an incremental cost-effectiveness analysis of the Essure micro-coil hysteroscopic sterilization technique in an ambulatory setting and to compare it with the traditional laparoscopic tubal sterilization performed in the operating room.

## **METHODS**

We retrospectively reviewed the charts of 108 women who underwent the Essure hysteroscopic sterilization procedure from March 2005 to November 2006 and of 104 women who underwent laparoscopic tubal sterilization from April 2001 to February 2004. Because the number of laparoscopic tubal sterilization procedures has so markedly decreased since the adoption of the Essure method in the Regina Qu'Appelle Health Region, the control group for this study was selected from a time frame immediately preceding the study period. Ethics approval for the study design was obtained from the Regina Qu'Appelle Health

Region Ethics Review Board. Placement of the Essure micro-insert coils was completed in an ambulatory setting using the technique described by Kerin et al.<sup>6</sup> Patients received indomethacin 100 mg per rectum one hour before the procedure, and intravenous moderate sedation was administered with fentanyl 2 µg /kg body weight and diazepam 2.5 mg.

Direct visualization of the tubal ostium was accomplished using a 2.7 mm 12° diagnostic telescope in a 5.5 mm single channel operative hysteroscope (ACMI, Toronto ON) with normal saline as the distending medium. Confirmation of coil position at three months after insertion was carried out using three-dimensional ultrasonography as previously described.<sup>7,8</sup> Patients were instructed to use alternative contraception until the coil position was confirmed. If the ultrasound did not satisfactorily confirm the coil position, hysterosalpingography was performed to assess tubal occlusion. When one or both coils could not be placed at the initial procedure, a second attempt was scheduled within one month. If the second attempt was not successful, hysterosalpingography was performed to determine whether the tubes were patent. If dye spill was noted on one or both sides on the hysterosalpingogram, the patient was offered laparoscopic tubal sterilization.

The laparoscopic tubal procedure was performed in the operating room with the patient under general anaesthesia. A 7 mm subumbilical port was used for camera placement, and a single suprapubic secondary port was used for instrumentation. The tubes were ligated using either bipolar cautery or Filshie clips. No test of tubal occlusion was done in follow-up. Patients recovered in the post-anaesthetic unit before transfer to the day surgery unit.

Costs associated with the Essure procedure included pre- and post-procedure nursing, intraoperative nursing, hospital charges, the Essure devices, follow-up ultrasound, and, if necessary, hysterosalpingogram, management of complications and laparoscopic sterilization. Costs incurred with the laparoscopic procedure included day surgery nursing care, operating room and post-anaesthetic nursing care, hospital expenses, anaesthesia, the Filshie clips, and disposables. The 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 anaesthetic time to its completion. Because of the accounting procedures in our Health Region, hospital charges are based on a lump sum for ambulatory and day surgical procedures, rather than individual line cost items. These charges include costs otherwise not specified and recouped, such as clerical costs, instrument sterilization, lights, heat, maintenance, and pharmacy costs.

**Table 1. Patient characteristics**

	Essure (n = 108) Mean ± SD	Lap tubal (n = 104) Mean ± SD	95%CI	P
Age (years)	36.8 ± 5.5	33.4 ± 5.9	1.64–4.73	< 0.01
Gravidity	2.3 ± 1.5	2.5 ± 1.5	–0.63–0.18	0.28
Parity	1.9 ± 1.1	2.0 ± 0.9	–0.43–0.14	0.31
BMI (kg/m <sup>2</sup> )	26.4 ± 7	26.8 ± 6.6	–2.2–1.49	0.70

A comparison of the costs of the two procedures was used to calculate the incremental cost-effectiveness ratio. To compare measures of effectiveness such as failure rate, complications and patient satisfaction meaningfully would require larger sample sizes than those in this study; we therefore used results from previously reported studies for these variables.

## RESULTS

The demographic characteristics of the Essure sterilization and laparoscopic sterilization groups are summarized in Table 1. The mean age of the women in the Essure group (36 years) was significantly greater than that of the women in the laparoscopic sterilization group (33 years) ( $P < 0.01$ ), but the groups were similar in gravidity, parity, and BMI.

Placement of the Essure coils bilaterally on the first attempt was successful in 103 of 108 women (95%). Three patients had a unilateral placement at the first procedure and had the second Essure coil successfully placed at a subsequent procedure. These three repeat cases were included in the total number of 108 cases completed, and the costs for both the first and second Essure placement for each of these three women were included in the total for the Essure group. Two women required laparoscopic tubal sterilization (1%); the costs associated with these two laparoscopic sterilizations were included in the cost of the Essure procedures. Volume contrast ultrasonographic imaging alone was used to identify the proper cornual position of the coils in 80 patients (75%); hysterosalpingography was also required in the remaining 28 women.

A summary of the costs incurred is shown in Table 2. The total cost associated with the 108 Essure procedures was \$138 996, or \$1287 per case. The most expensive single item for the Essure procedure was the coils. Because of the short procedure and recovery times required for the Essure procedure, the total nursing costs were significantly lower than those incurred for laparoscopic tubal sterilization. The total time in the operating room was significantly different from the time required in the ambulatory procedure room ( $P < 0.01$ ). The mean procedure time in the operating room

was 44 minutes; the mean time to complete the Essure was eight minutes.

The total cost associated with the completion of 104 laparoscopic tubal procedures was \$148 227, or \$1398 per case. All of the laparoscopic tubal sterilization procedures were completed on the first attempt, and no complications were noted. Compared with the Essure method, laparoscopic tubal sterilization had significantly ( $P < 0.01$ ) higher total costs, nursing costs, and operating time required ( $P < 0.01$ ). The operating room costs included operating room nursing, anaesthesia charges, disposable items, and either Filshie clips or the Essure micro-insert coil. The operating room costs were lower for the laparoscopic tubal procedure, but when the ancillary costs, such as the higher hospital charges for the day surgery case (\$600 vs. \$160 at the ambulatory centre) and the greater day surgery nursing costs were added, the final cost of the laparoscopic tubal procedure (\$1398 per case) was significantly greater than the cost of the Essure tubal procedure (\$1287 per case) ( $P < 0.01$ ).

The incremental cost-effectiveness ratio can be calculated using the total costs summarized in Table 2. The cost per Essure sterilization was \$1287, and the cost per laparoscopic tubal sterilization was \$1398, resulting in an incremental cost-effectiveness ratio of \$111 ( $P < 0.01$ ).

## DISCUSSION

The current standard treatment for women seeking permanent contraception in Canada is tubal sterilization.<sup>4</sup> Some sterilization procedures are performed by mini-laparotomy, but these are most commonly done in the immediate postpartum period. The common denominator for tubal sterilization procedures is that they disrupt the tubal lumen, by excision, destruction with cautery, or occlusion with bands or clips. Approximately 11 million sterilizations are done worldwide every year,<sup>9</sup> although the prevalence of tubal sterilization in Canada declined by 50% between 1993 and 2002.<sup>4</sup> The decreasing prevalence of female sterilization may be related to the relative complexity and risks associated with the procedure.

Laparoscopic procedures require the use of general anaesthesia, which is administered in an operating theatre by an

**Table 2. Costs associated with the Essure hysteroscopic tubal sterilization and laparoscopic tubal sterilization procedures**

	Essure (n = 108) Mean ± SD	Lap tubal (n = 104) Mean ± SD	95%CI	P
Total OR time (minutes)	8.9 ± 4.7	44.0 ± 16.2	-37.5-(-33.1)	< 0.01
Nursing costs* (\$)	12.0 ± 5.8	181.6 ± 39.0	-177-(-162)	< 0.01
OR Cost† (\$)	1007.4 ± 185	670.9 ± 158	289-383	< 0.01
Ancillary Cost‡ (\$)	266 ± 39	714 ± 152		
Total Cost (\$)	1287.7 ± 2450	1398 ± 36	-175-(-162)	< 0.01

\*Total nursing costs, including day surgery or preoperative, operating or procedure room, and recovery room nursing.

†Cost for operating room nursing, anaesthesia, Essure micro-insert coils or Filshie clips, and disposables.

‡Cost for day surgery or recovery room nursing, hospital charges, ultrasound, and hysterosalpingography (when necessary).

anaesthetist. The use of general anaesthesia increases the overall risk of the procedure, and the use of operating rooms and operating room personnel restricts their availability for other procedures. Laparoscopic tubal sterilization can be associated with significant postoperative pain, resulting in nausea, vomiting, and possibly hospital admission.<sup>6</sup> In addition, using the laparoscopic approach requires access to the abdominal cavity. This procedure is generally safe, although the risk of injury to the bowel at entry and during laparoscopic surgery ranges from 0.7 to 3.0 per 1000 laparoscopies.<sup>10-13</sup> Of these injuries, 50% to 60% will not be recognized at the time they occur<sup>14</sup>; the average delay in diagnosis is 1.5 days.<sup>11</sup> The mortality from an unrecognized injury to the bowel can be as high as 20%.<sup>15-17</sup> There is also risk of injury to retroperitoneal structures, which can result in significant hemorrhage.

If the decrease in prevalence of female sterilization in Canada is a result of the complexity and risk of the procedure, the answer would be to provide a method of permanent contraception that bypasses both. The Essure tubal occlusion procedure provides a number of advantages over traditional methods of female sterilization. The five-year follow-up data on Essure placement showed only 64 pregnancies in approximately 50 000 women who had the Essure devices placed.<sup>18</sup> The majority of the failures were associated with noncompliant follow-up by the patient or the physician. The devices are easily placed with very few complications, and the procedure can be completed in an ambulatory setting. In this analysis, this relocation of the procedure not only reduced equipment cost but also significantly reduced nursing costs, from \$181 per case in the OR to \$12 in the ambulatory clinic.

With the introduction of new technologies, initial evaluation of the cost of the technology alone may result in an assumed total that precludes its introduction. The \$1000 cost of the Essure coils has resulted in many Canadian

centres deciding not to adopt the procedure. Although there was a significant increase in the equipment cost alone with the use of the Essure procedure, the change in cost to the Regina Qu'Appelle Health Region was not actually an increase of \$1000. In fact, the introduction of this new technology resulted in a reduction in the cost of tubal sterilization by \$111 per case. A similar increase in equipment cost was noted by Hopkins et al.<sup>19</sup>; however, as with our centre, they also noted an overall reduction in cost of the Essure procedure of US \$181. The cost of completing the ambulatory procedure was similar to that reported by Levie and Chudnoff<sup>5</sup>; however, their laparoscopic tubal cost was almost four times our calculated OR cost. In the US system, this resulted in a much larger cost saving of US \$2075 per Essure completed. Hopkins et al. demonstrated a cost savings of US \$180 when the Essure procedure was compared with laparoscopic tubal coagulation, including the cost of the follow-up hysterosalpingography and the additional costs incurred when the Essure device could not be placed and laparoscopic tubal sterilization was necessary.<sup>19</sup>

Operator experience reduces both the time needed to complete the Essure procedure and patient discomfort. This means that more patients are able to have the procedure completed using only oral analgesia, which in turn shortens post-procedure nursing requirements. These factors have all helped to further limit the costs associated with the Essure procedure and, in addition to the other benefits, make it increasingly affordable for the majority of health regions.

In addition to the cost saving of \$111 per Essure procedure, a number of additional benefits were noted. Most important, we were able to offer a safer, more reliable method of permanent contraception for women. It is estimated that the cost of the 700 000 tubal sterilization procedures completed annually in the USA is increased by US \$50 million dollars because of failures and procedural complications.<sup>5</sup>

Because the time needed to complete the Essure case is about 20% of the time needed in the OR for laparoscopic tubal sterilization, the number of cases completed per unit of time in the ambulatory clinic is greater than in the operating room. Wait times for the Essure procedure are considerably shorter than for operating room procedures. The shorter wait time should translate into fewer pregnancies resulting from contraceptive failures while awaiting permanent contraception.

Because there is no laparoscopic entry with the Essure procedure, there are no significant complications related to injuries to bowel or major vessels. The Essure procedure is not made more difficult or risky by multiple previous abdominal surgeries and can therefore be safely offered to a wider range of patients, including the morbidly obese. The reduced risk in complications will further reduce the overall costs associated with tubal sterilization.

The Essure procedure is very well tolerated when completed in an ambulatory setting, with a high rate of patient satisfaction. Duffy et al. reported 100% of the women undergoing the Essure procedure were satisfied with the length of recovery compared with only 80% for women having laparoscopic tubal sterilization.<sup>20</sup> Over 80% of the women in this study rated their tolerance of the procedure as good to excellent, with only 40% of those having laparoscopic tubal giving a similar rating.<sup>20</sup> Only 30% of women undergoing the Essure procedure reported moderate to severe pain, compared with over 60% of women having laparoscopic tubal sterilization.

In addition to the safety of the Essure procedure and its high patient satisfaction rate, the relocation of the sterilization procedure from the operating theatre to an ambulatory clinic results in an increase in available operating room space. In the Regina Qu'Appelle Health Region, each tubal sterilization in the operating room requires 45 minutes of booked time to complete. Relocating these sterilization procedures to the ambulatory clinic resulted in 77 hours of OR time becoming available for other surgical procedures. As access to care and surgical wait lists become more of a problem in Canada, this benefit alone would justify even an increase in cost. The 77 hours would provide increased total system capacity within the system and make it possible to have other non-ambulatory cases completed at an earlier date. This enhances access to care for all patients contacting the system.

## CONCLUSIONS

The incremental cost-effectiveness ratio for the Essure tubal sterilization procedure when compared with traditional laparoscopic sterilization is \$111. This significant reduction in the cost of the sterilization procedure is

associated with improved reliability, fewer significant complications, improved patient satisfaction, and improved accessibility, which has a positive effect on wait times for sterilization as well as other surgical procedures.

Provision of a safer, more reliable and cost effective method of permanent contraception for women may result in an increase in the prevalence of women choosing sterilization as a contraceptive method.

## REFERENCES

1. Noseworthy, TW, McGurran JJ, Hadorn DC. Waiting for scheduled services in Canada: development of priority-setting scoring systems. *J Eval Clin Pract* 2003;9:23.
2. Inadomi JM. Decision analysis and economic modeling: a primer. *Eur J Gastroenterol Hepatol* 2004;16:535-42.
3. Bambha K, Kim WR. Cost-effectiveness analysis and incremental cost-effectiveness ratios: uses and pitfalls. *Eur J Gastroenterol Hepatol* 2004;16:519-26.
4. Fisher W, Boroditsky R, Morris B. The 2002 Canadian Contraception Study: part 1. *J Obstet Gynaecol Can* 2004;26:580.
5. Levie MD, Chudnoff SG. Office hysteroscopic sterilization compared with laparoscopic sterilization: a critical cost analysis. *J Minim Invasive Gynecol* 2005;12:318-22.
6. Kerin JF, Cooper JM, Price T, van Herendaal BJ, Cayuela-Font E, Cher D, et al. Hysteroscopic sterilization using a micro-insert device: results of a multicenter Phase II study. *Hum Reprod* 2003;18:1223-30.
7. Thiel JA, Suchet IB, Lortie K. Confirmation of Essure microinsert tubal coil placement with conventional and volume-contrast imaging three-dimensional ultrasound. *Fertil Steril* 2005;84:504-8.
8. Veersema S, Vleugels MP, Timmermans A, Brolmann HA. Follow-up of successful bilateral placement of Essure microinserts with ultrasound. *Fertil Steril* 2005;84(6):1733-6.
9. Ross JA. Sterilization: past, present, future. *Stud Fam Plann* 1992;23:187-98.
10. Krebs HB. Intestinal injury in gynaecologic surgery: a ten year experience. *Am J Obstet Gynecol* 1986;155:509-14. [Erratum in: *Am J Obstet Gynecol* 1987;156:264.]
11. Molloy D, Kaloo PD, Cooper M, Nguyen TV. Laparoscopic entry: a literature review and analysis of techniques and complications of primary port entry. *Aust N Z J Obstet Gynaecol* 2002;42:246-54.
12. Shen CC, Lu HM, Chang SY. Characteristics and management of large bowel injury in laparoscopic-assisted vaginal hysterectomy. *J Am Assoc Gynecol Laparosc* 2002;9:35-9.
13. Wang P, Wen-Ling L, Yuan C, Chao HT, Liu WM, Yu KJ, et al. Major complications of operative and diagnostic laparoscopy for gynaecologic disease. *J Am Assoc Gynecol Laparosc* 2001;8:68-73.
14. Vilos GA. Laparoscopic bowel injuries: forty litigated gynaecological cases in Canada. *J Obstet Gynaecol Can* 2002;24:224-30.
15. Schäfer M, Lauper M, Krähenühl L. Trocar and Veress needle injuries during laparoscopy. *Surg Endosc* 2001;15:275-80.
16. Dubuisson JB, Chapron C, Decuyper F, De Spirlet M. 'Classic' laparoscopic entry in a university hospital: a series of 8324 cases. *Gynaecol Endosc* 1999;8:349-52.
17. Brosens I, Gordon A, Campo R, Gordts S. Bowel injury in gynecologic laparoscopy. *J Am Assoc Gynecol Laparosc* 2003;10:9-13.
18. Levy B, Levie MD, Childers ME. A summary of reported pregnancies after hysteroscopic sterilization. *J Minim Invasive Gynecol* 2007;14:271-4.
19. Hopkins MR, Creedon DJ, Wagie AE, Williams AR, Famuyide AO. Retrospective cost analysis comparing Essure hysteroscopic sterilization and laparoscopic bilateral tubal coagulation. *J Minim Invasive Gynecol* 2007;14:97-102.
20. Duffy S, Marsh F, Rogerson L, Hudson H, Cooper K, Jack S, et al. Female sterilisation: a cohort controlled comparative study of ESSURE versus laparoscopic sterilisation. *BJOG* 2005;112:1522-8.