

A Comparative Study of Hysteroscopic Sterilization versus Laparoscopic Tubal Sterilization

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Abstract

Study objective: To compare female sterilization procedures performed with hysteroscopy versus laparoscopic tubal sterilization

Materials and Methods:

This study was a literature review using Springer link, Bmj, Journal of MAS and major general search engines like Google, MSN, and Yahoo etc. The following search terms were used: Comparison of Laparoscopic tubal sterilization versus Hysteroscopic sterilization. 532 citations found in total selected papers were screened for further references. Criteria for selection of literature were the number of cases [excluded if less than 20], methods of analysis [statistical or non statistical], operative procedure [only universally accepted procedures were selected] and the institution where the study was done [Specialized institution for Larparoscopic tubal sterilization and Hysteroscopic sterilization.

Measurements and main results:

Procedure time, device placement rates, and incidence of complications and effectiveness rate were compared. We found that laparoscopic tubal sterilization was more expensive compare with hysteroscopic sterilization when performed in the same setting. Total procedure time for laparoscopic sterilization averaged 10-20 minutes, with mean hysteroscopy time of 13 minutes. The effectiveness rate for hysteroscopic sterilization was 100% but laparoscopic failure rate has a 0.45% -2.27% failure rates. The overall standard complication rate for laparoscopic sterilization 0.9 complications per 100 procedures and major complication rate for hysteroscopic sterilization was 3.2%

Conclusion:

There was no significant difference between Hysteroscopic sterilization and Laparoscopic tubal sterilization in the total time operative procedure. Hysteroscopic sterilization was less expensive, more effective but more complication rate compare with laparoscopic tubal sterilization.

Keywords:

hysteroscopy, laparoscopy, sterilization, cost, operating time, complication

Introduction

Around 153 million women around the world have chosen to be sterilized for contraceptive purposes, of these 138 million are in the developing countries. 1 Approximately fifty percent of all female sterilization is performed during the puerperal period or a cesarean section, and the other fifty percent is called “interval sterilization” when there has been no pregnancy for the previous six weeks. The most common surgical procedure today for sterilization is via minilaparotomy. However, the technique of fallopian tube ligation is still being done today largely by a procedure developed at the beginning of the 20th century. The advent of fiber optic technology led to the introduction of the laparoscope in the 1960’s followed quickly by techniques of electrocoagulation and application of clip/rings

Hysteroscopic Sterilization

The Essure (previously known as the STOP device) micro-insert underwent several design changes during its evolution. In 1995, there were animal studies with the initial product called the Alpha design which was a static design with curled ends. The second product was Beta 1 and 2 which changed from a curve design to a linear static design. The Beta 2 version was introduced with a delivery catheter. Next a Beta 3 design was developed with an increased quantity of PET (polyethylene terephthalate) fibers to induce the tissue response. The Gamma, or Essure, design is the model sold commercially today. It is a dynamic coil design with increased length and increased quantity of PET fiber.

The Essure permanent birth control system consists of the Essure micro-insert, a disposable delivery system, and a disposable split introducer. A standard hysteroscope with a 5 French working channel, a continuous flow, and a 12-30 degree angled lens is used in concert with the system. The 5mm hysteroscopes made by Karl Storz Endoscopy and Richard Wolf Medical Instruments both accommodate the Essure system.

The Micro-insert

This consists of a stainless steel inner coil, a nitinol super elastic outer coil, and PET fibers. PET fibers are used in other medical application such as prosthetic arterial graphs, percutaneous catheters, aneurysm coils and other long term implants. The PET fiber is wound in and around the inner coil. The micro-insert is 4cm long and 0.8mm in diameter in its wound down configuration. When released the outer coil expands to 1.5-2.0mm. This anchors the micro-insert inside the tube.

The Essure micro-insert remains anchored in the fallopian tube resulting in permanent contraception. This greater outer diameter of the expanded coils initially anchors the micro-insert preventing the migration of the device into the peritoneal cavity.

The PET fibers then begin to elicit the fibrotic response. The long term nature of the tissue response is not known. The majority of the clinical data at the end of 5 years of use suggest permanence of fibrotic response.

The Procedure

The patient is placed in the lithotomy position and is draped per standard protocol, and an under buttocks drape with a pouch for fluid collection is recommended. Ski boot style stirrups are

recommended. If the fallopian tubes are laterally situated the patient's legs may need to be widened to allow hysteroscopic access. Next the speculum is introduced into the vagina to expose the cervix. The cervix is prepped with betadine then a local anesthetic is given as a paracervical block. A bi-valve open-sided speculum is recommended so that it can be readily removed once the hysteroscope is in place. It is important to inform the patient before administering the local anesthetic injection to reduce pain and discomfort. Soothing words may help to minimize the discomfort. The circulating nurse is an important adjunct to this process. The paracervical block takes about 3-4 minutes. This time may be utilized to connect the camera, light source, sealing cap, fluid in flow and out flow to the hysteroscope. The hysteroscope may be balanced and focused, and in-flow may be checked. Then tenaculum is placed on the anterior lip of the cervix. The hysteroscope is introduced without dilation of the cervix through the external os, here the patient may be invited to view the procedure on the monitor while the anatomy is being described. The irrigation is turned on using normal saline through a fluid management system which may be in use in the hospital setting or the fluid may be introduced by gravity. If excessive force is required to enter the cervix it is better to terminate the procedure then run the risk of uterine perforation. Other measures pre-operatively may be utilized in the future to achieve cervical dilation of a stenotic cervix (ie. laminaria, misoprostol, or vaginal suppository).

It is important to maintain visual and verbal contact with the patient during the potentially uncomfortable segment. If cervical dilation is required, dilate only sufficiently to insert a 5mm hysteroscope. After the hysteroscope negotiates the cervix remove the speculum. Uterine cavity distention is achieved with 0.9% saline infusion. It is strongly recommended to pre-warm the infusion fluid to prevent tubal spasm. Adequate uterine distention must be achieved and maintained throughout the procedure to allow the identification and access of the tubal ostia. Fluid intake and out-flow must be accounted for per standard protocol. If the fluid deficit exceeds 1500cc the procedure must be terminated to avoid hypervolemia.

Both tubal ostia must be identified and assessed hysteroscopically prior to proceeding with Essure micro-insert placement. No attempt should be made to place a micro-insert in one tubal ostium unless there is a reasonable expectation that the opposite tubal ostium is accessible and patent. If there is a doubt about successful bilateral placement then the procedure should be terminated. Either tubal or uterine anomalies may make it impossible to place the Essure micro-insert. It is recommended that the system remain within the sterile packaging until both ostia are visualized. It is important to assess the actual system for any damage. Next, insert the split introducer with the opening face up through the sealing cap of the working channel of the hysteroscope. Insert the Essure delivery catheter through the introducer after removing the stylet of the split introducer. Now the Essure delivery catheter is advanced half way down the hysteroscope working channel when the split introducer is removed. The hysteroscope is rotated as required to access the ostium using the light cable attachment while the camera head is kept steady. Angling the lens 12-30 degrees will aid in aligning the hysteroscope with the tubal ostia. Now the catheter is advanced into the fallopian tube until the black positioning marker can be visualized as having reached the ostium.

This visual marker indicates that the micro-insert is spanning the intramural and proximal isthmic segments of the fallopian tube with the outercoil spanning the uterotubal junction. This positioning is for the placement of the micro-insert. Occasionally, it is necessary to exert gentle forward pressure to advance the catheter into the tube to overcome tubal resistance. Resistance to advancement is usually apparent if 1) the black positioning marker on the outside surface of the

catheter does not advance forward to the tubal ostia and/or 2) the delivery catheter bends or flexes excessively preventing the application of forward pressure on the catheter. When such resistance is observed further attempts for advancement must be terminated to avoid uterine or tubal perforation. A follow-up HSG may be undertaken to determine tubal patency. If tubal or uterine perforation occurs or is suspected, immediately discontinue the Essure procedure. If tubal obstruction is encountered or if the delivery catheter cannot be advanced to the black positioning marker then the case should be terminated.

After confirming proper positioning of the black marker the micro-insert can be deployed. To do so, stabilize the handle of the Essure micro-insert against the hysteroscope or the camera to prevent inadvertent forward movement of the micro-insert during the retraction of the delivery catheter. Care must be taken at all times to not to bend the delivery catheter outside of the hysteroscope which may result in the unwanted movement of the distal tip of the catheter. Now the thumb wheel on the ergonomic handle is rotated toward the physician to withdraw the delivery catheter. The thumb wheel rotation should be performed at the rate of one click per second until the wheel stops. The black positioning marker will move away from the tubal ostium towards the hysteroscope and will disappear in the hysteroscope operating channel. Withdrawal of the delivery catheter exposes the wound down Essure micro-insert attached to the orange release catheter. Approximately one centimeter of the micro-insert wound down coils should appear trailing into the uterus when the delivery catheter is withdrawn.

A small notch identifies this aspect of the micro-insert – the notch appears where there is a slight increase in the diameter of the coils. The visualization outside the notch just outside the ostium, as well as, the visualization of the distal tip of the orange release catheter will confirm proper positioning. Forward and backward movements of the entire system may be gently performed to achieve perfect placement. After retracting the delivery catheter and confirming the proper positioning the deployment button on the ergonomic handle is depressed to enable the thumb wheel to be further rotated. Now rotate the thumb wheel backwards towards the physician to withdraw the orange release catheter while continuing to stabilize the handle. When the thumb wheel cannot be rotated any further then the withdrawal of the orange release catheter is complete. This enables the outer coil of the Essure micro-insert to expand which is easily visible to the operator. Allow ten seconds for the outer coil expansion while aligning the hysteroscope and the delivery system to minimize the bending of the catheter. The entire delivery system should be carefully straightened out prior to the next step which is the counter clockwise rotation of the ergonomic handle. This rotation allows the delivery wire to become visibly disengaged from the Essure micro-insert. Ten such rotations are usually required to allow disengagement. While continuing the rotation to remove the delivery wire, the delivery system may be gently drawn from the micro-insert by pulling the handle backwards. If there is difficulty in separation of the micro-insert from the delivery wire then the hysteroscope tip may be used to accomplish this step as a last resort. In a majority of instances counter-clockwise rotation and application of gentle backward tension on the handle is able to achieve successful detachment of the delivery wire from the micro-insert. To verify the separation, obtain a panoramic view by sliding the hysteroscope backwards over the delivery wire. For trouble shooting Essure system retraction appropriate training with a clinical specialist is recommended. It is encouraging that the learning curve is very short for these procedures. If none of these techniques are successful the deployed micro-insert can be pulled out of the fallopian tube by continuous backward movement of the delivery system and removing the hysteroscope and the Essure system out of the patient as a unit. If the micro-insert is partly broken, the patient must be instructed not to rely on this for

contraception and if the broken micro-insert is causing an adverse event an attempt must be made to remove it.

The ideal number of expanded outer coils trailing within the uterine cavity is 3-8 coils. If the number of outer coils is less than eighteen the micro-insert should be left in place and evaluated with an HSG three months post device placement. Removal may be attempted if eighteen or more coils are trailing into the uterine cavity. The physician must refer to company sponsored instructions on how to attempt removal of micro-insert. There is a likelihood of fallopian tube perforation or other patient injury if such instructions are not adhered to. If the micro-insert is inadvertently deployed into the uterine cavity it should be removed from the uterus and another attempt should be made at tubal placement. Repeat the Essure micro-insert placement procedure in the contralateral fallopian tube. Do not place more than one micro-insert in a single fallopian tube.

Complications

Possible side effects: post-procedure pain, bleeding: nausea/ vomiting, pregnancy and ectopic pregnancy and changes in menstrual cycle. There were rare episodes of pelvic, back, and abdominal pain following the Essure procedure, but very few women reported persistent pain.

Laparoscopic Sterilization

Laparoscopic sterilization was the first popular minimal access surgical procedure ever performed. Laparoscopic sterilization is straightforward procedure. Worldwide laparoscopic sterilization is now the most commonly method used for family planning.

Laparoscopic sterilization Techniques

Electrical methods - Unipolar or Bipolar

- Always use the cutting mode set at 25 to 30 watts. Most bipolar generators only deliver electrical current in the cutting/desiccation mode or waveform.
- Desiccate at least 2.0 cm, preferably 3.0 cm of contiguous tissue. There is no data supporting desiccation followed by transection as any improvement.
- Desiccate the isthmus portion of the fallopian tube; spare the cornua to reduce fistula formation.
- With bipolar instruments, the use of an ammeter until current flow reaches zero reassures the surgeon that complete desiccation has occurred.

Clip methods

Place a clip 3 cm from the cornua at a 90 degree angle.

- With the Hulka ClipT, check for the "envelope" sign (a flattening of the grasp area of tube) after application. If in doubt, apply another clip adjacent to the first.
- With the Filshie ClipT, expose the lower jaw seen through the mesosalpinx before closing the clip on to the tube.

Band method

- Because the silastic rubber band may lose its memory if it is stretched over the applicator beyond 15 minutes, apply the silastic band to the band applicator just before application.
- Grasp the isthmus portion, 3-4 cm from the cornua.
- Squeeze the applicator handle slowly to reduce the risk of tubal transection

Materials and Methods

This study was a literature review using Springer link, Bmj, Journal of MAS and major general search engines like Google, MSN, and Yahoo etc. The following search terms were used: Comparison of Laparoscopic tubal sterilization versus Hysteroscopic sterilization. 532 citations found in total selected papers were screened for further references. Criteria for selection of literature were the number of cases [excluded if less than 20], methods of analysis [statistical or non statistical], operative procedure [only universally accepted procedures were selected] and the institution where the study was done [Specialized institution for Laparoscopic tubal sterilization and Hysteroscopic sterilization].

Measurements and main results

Procedure time, cost, and incidence of complications and effectiveness rate were compared.

Cost

The various costs associated with the two procedures were compiled, and a direct cost comparison was made. We found laparoscopic tubal ligations to cost \$3449 compared with hysteroscopic placement of the Essure device that costs \$1374 yielding a \$2075 difference between the procedures.. The Essure system of hysteroscopic sterilization had a significantly decreased cost compared with laparoscopic tubal sterilization when both procedures were performed in an operating room setting.

Time

Total procedure time compared favorably to reported average length of laparoscopic sterilization procedures, and patient recovery was rapid and uncomplicated. Total procedure time averaged 10-20 minutes, with mean hysteroscopy time of 13 minutes. Women spent an average of 44 minutes in the recovery room. The average time from procedure room entry to discharge from the facility was 80 minutes.

The effectiveness rate

The effectiveness rate effectiveness rate for the hysteroscopic sterilization during the first year of follow-up, based on 5305 women-months of follow-up, was 100% . According to recent studies, unipolar electrocoagulation has a 0.45% failure rate; bipolar electrocoagulation has a lower rate but a higher percentage of ectopic pregnancies. The failure rate of a silicone ring was 0,3%, while the use of the clips was 2.27% failure rate.

Complications

The overall standard complication rate for laparoscopic sterilization with the used advanced laparoscopy equipment, properly trained laparoscopists, and a system of delineated operating privileges was 0.8 - 0.9 complications per 100 procedures. Unipolar electrocoagulation can cause a small percentage of intestinal or parietal burns and bleeding, and so does bipolar electrocoagulation. The silicone ring can cause pain in about 3.9% of cases, and bleeding in 2.5%, while the clip usually causes only pains. Possibility of reversal of sterilization has recently greatly improved thanks to microsurgery; success rate is about 60% with electrocoagulation and with the silicone ring, and can approach 100% with the Hulka clip. Major complication rate for hysteroscopic sterilization was 3.2%. These included uterine perforations 1.8%, bowel damage, peritonitis, ectopic pregnancy, expulsion of Essure device: 2.9%, mis-placed device: 0.6% and altered menstrual flow (5%).

Conclusions

- This study showed that laparoscopic tubal sterilization was more expensive compare with hysteroscopic sterilization when performed in the same setting.
- There was no significant difference in time perform between the laparoscopic tubal sterilization and hysterescopic sterilization.
- Based on this study, we found that hysteroscopic tubal sterilization was more effective compared to laparoscopic tubal sterilization.
- Our results suggest that **laparoscopic tubal sterilization** generally is a safe procedure with rates of intraoperative or postoperative complications compare with hysteroscopic sterilization.

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