Panel Session 3:
Controversies in Sterilization Techniques

PROGRAM CHAIR
Moty Pansky, MD

Samar Nahas, MD, MPH  Andreas L. Thurkow, MD  Megan Wasson, DO
Professional Education Information

Target Audience
This educational activity is developed to meet the needs of residents, fellows and new minimally invasive specialists in the field of gynecology.

Accreditation
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Panel Session 3: Controversies in Sterilization Techniques

Moty Pansky, Chair

Faculty: Samar Nahas, Andreas L. Thurkow and Megan Wasson

This session provides a broad overview of current trends and options for permanent female sterilization. During the session, expert faculty will review the indications, contraindications, patient selection, based upon their experiences with each technique. A wide-ranging discussion is planned regarding the informed consent, success and failure rate of each technique, complications and the medico-legal implication of such complications and or failures. The issue of sterilization reversal will also be discussed.

Learning Objectives: At the conclusion of this course, the clinician will be able to: 1) Differentiate between the most common procedures for permanent female sterilization and consult with their patients on the indications, contraindications, complications, sterilization reversal and failure rate of each technique.

Course Outline

11:00 Welcome, Introductions and Course Overview  M. Pansky
11:05 Bilateral Salpingectomy as a Permanent Contraception Method  S. Nahas
11:15 Essure: Is It Really the Answer for Permanent Female Sterilization?  A.L. Thurkow
11:25 Post-Partum Sterilization: When and How  M. Pansky
11:35 The Good Old Tubal Sterilization: When, How, and Who Is the Best Candidate  M. Wasson
11:45 Questions & Answers  All Faculty
12:00 Adjourn
PLANNER DISCLOSURE
The following members of AAGL have been involved in the educational planning of this workshop and have no conflict of interest to disclose (in alphabetical order by last name).
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Amber Bradshaw
Speakers Bureau: Myriad Genetics Lab
Other: Proctor: Intuitive Surgical
Erica Dun*
Frank D. Loffer, Medical Director, AAGL*
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FACULTY DISCLOSURE
The following have agreed to provide verbal disclosure of their relationships prior to their presentations. They have also agreed to support their presentations and clinical recommendations with the “best available evidence” from medical literature (in alphabetical order by last name).
Samar Nahas*
Moty Pansky*
Andreas L. Thurkow
Consultant: Aegea Medical, Ethicon Endo-Surgery, Gedeon Richter, Hologic, Olympus
Other: Payment for giving training courses: Bayer-Sherring
Contracted Research: Altascience
Megan Wasson*

Asterisk (*) denotes no financial relationships to disclose.
The Good Old Tubal Sterilization: When, How, and Who is the Best Candidate

Megan Wasson, DO
Mayo Clinic Arizona

OBJECTIVES

• Report the risk of pregnancy following sterilization
• Describe the impact of sterilization on ovarian function
• Discuss the impact of sterilization on ovarian cancer risk

Current Opinion

• Preferred method of sterilization
  – Filshie clips 36.5%
  – Bipolar coagulation 32.2%
  – Silicone rubber band 24.0%
  – Bilateral salpingectomy 7.2%

Current Opinion

• 13.5% would NOT consider performing bilateral salpingectomy as a sterilization procedure
  – Increased risk of complications (41.2%)
  – Increased operative time (23.5%)
  – Not superior to other methods (23.5%)
  – Not beneficial (11.8%)

DISCLOSURE

• I have no financial relationships to disclose.

Risk of Pregnancy after Sterilization

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Expected Cumulative Risk of Pregnancy (per 1000 Women)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 year</td>
<td>10 years</td>
</tr>
<tr>
<td>Bipolar Coagulation</td>
<td>2.3 24.8</td>
</tr>
<tr>
<td>Monopolar Coagulation</td>
<td>0.7 7.5</td>
</tr>
<tr>
<td>Silicone Rubber Band Application</td>
<td>5.6 17.7</td>
</tr>
<tr>
<td>Spring Clip Application</td>
<td>18.2 36.5</td>
</tr>
<tr>
<td>Interval Partial Salpingectomy</td>
<td>7.3 20.1</td>
</tr>
<tr>
<td>Postpartum Partial Salpingectomy</td>
<td>0.6 7.5</td>
</tr>
</tbody>
</table>
**Risk of Pregnancy after Sterilization**

- Hysteroscopic Sterilization: 57, 96
- Laparoscopic Silicone Rubber Band Application: 72, 4
- Laparoscopic Bipolar Coagulation: 3, 30

**Ovarian Reserve-Tubal Ligation**

- Bipolar technique may negatively impact
- Not changed during 3-month and 1-year follow-up
  - No significant change in AMH, FSH, LH, E2
  - No significant change in antral follicle count, ovarian volume

**Ovarian Reserve-Salpingectomy**

- Decrease in Proliferating Cell Nuclear Antigen
- Increase in fibrosis, apoptosis, atretic follicles
- Ischemia and reperfusion damage
- Decrease in follicular reserve
- Lower AMH
- Higher FSH

**Tubal Ligation and Ovarian Cancer**

- Average risk women-34% risk reduction
  - Endometrioid cancer RR 0.40
  - Serous cancer RR 0.73
  - No significant reduction for mucinous or borderline tumors
- BRCA1 mutation carrier-57% risk reduction
  - Tubal ligation alone OR 0.39
  - Tubal ligation with OCPs OR 0.28

**Salpingectomy vs. Tubal Ligation**

- No data currently showing reduced risk in average or high risk populations
- Will take decades to demonstrate change in mortality with opportunistic salpingectomy
Salpingectomy vs. Tubal Ligation

- Need 10,000 salpingectomies/year to decrease incidence by 40%
- 336 women (95% CI, 338-379) need salpingectomy to prevent one case
- Cost-effectiveness
  - Assume tubal ligation reduces ovarian cancer risk by 30%
  - Salpingectomy needs to reduce risk by >37.5%

Conclusion

- Tubal ligation
  - Effective means of sterilization
  - Does not adversely impact ovarian reserve
  - Reduces ovarian cancer risk

Postpartum Sterilization

- Salpingectomy vs. tubal ligation
  - Incision size
  - Blood vessel size
  - Operating time
  - Cost

REFERENCES

Bilateral Salpingectomy as a Permanent Contraception Method

SAMAR NAHAS, MD, MPH, FRCSC, FMIGS
Consultant Gynecologic Oncology
Assistant professor University of Toronto
Trillium Health partners, Credit Valley Hospital
Mississauga . ON

OBJECTIVES

- Review the literature for bilateral Salpingectomy as a Permanent Contraception Method
- Review the literature and discuss the causal relationship between the tubes and different pathologies.
- Discuss the risks and complication from F. tubes post hysterectomy and sterilization via tubal ligation.
- Demonstrate the tech.

Traditionally

Post sterilization failure

- PC study, > 10,000 patients, 143 failure, the cumulative 10-year probability of pregnancy 7.5-54/1000.
- One-third of post sterilization failures are ectopic.

Risk of hydrosalpinx

- Significantly higher (odds ratio 6.67, P = .019) in patient after hysterectomy post tubal sterilization compared to hysterectomy alone,

• I have no financial relationships to disclose.
Causal relationship:

- Serous intraepithelial tubal carcinomas (STIC) co-exist with in >50% serous ovarian cancer.
  
- STIC in 47% of women with primary serous peritoneal carcinomas.
  

Causal relationship:

- Borderline serous Tumor, Noninvasive implants, and Endosalpingiosis.
  
- Fallopian tube cancer is the most common occult cancer (2/3) found in Prophylactic BSO in patient with BRCA1/2 mutation.
  
  Yates et al., Cancer prev res. 2011 Mar;6:463–70.

Sterilization by Bilateral Salpingectomy

- The most effective contraception
- Prevents: ectopic pregnancy
- Hydrosalpinx
- TIC, Cancer

Bartz and Greenberg, 2008. Full reference

Why not:

Piacenza and Salsano, 2001; Basu and Ward, 2007; Singla, 2007; Ghose, et al., 2009;
Trisch et al., 2010; Rezvani and Shabani, 2011.
Hysterectomy with bilateral salpingectomy

- Prevents all the risks from retained fallopian tube
- Ovarian blood supply and hormone profile is not affected when hysterectomy is combined with salpingectomy.

Dar et al., 2000; Sezik et al., 2007; Ghezzi et al., 2009.

Conclusion

- Bilateral salpingectomy concomitant with hysterectomy is widely recommended to avoid subsequent tubal pathology.
- Bilateral salpingectomy is the most effective method for tubal sterilization.

REFERENCES

9. Piacenza and Salsano, 2001; Basu and Ward, 2007; Singla, 2007; Ghezzi et al., 2009; Timor-Tritsch et al., 2010; Rezvani and Shaaban, 2011.
10. Dar et al., 2000; Sezik et al., 2007; Ghezzi et al., 2009.

Which surgical technique for tubal sterilization has the lowest failure rate

- Ligation with bipolar cautery.
- Ligation with monopolar cautery.
- Ligation with clips.
- **Bilateral Salpingectomy**.
- Ligation with bilateral Fimbriectomy.
ESSURE: IS IT REALLY THE ANSWER FOR PERMANENT FEMALE STERILIZATION?

Andreas Thurkow MD
St Lucas Andreas Hospital Amsterdam, DC Lairesse Amsterdam, MC Amstelveen Netherlands

DISCLOSURES
- Consultant: Aegea Medical, Ethicon Endo-Surgery, Gedeon Richter, Hologic, Olympus
- Other: Payment for giving training courses: Bayer-Sherring
- Contracted Research: Altascience

OBJECTIVE
At the conclusion of this presentation, participants will be better able to:

- Compare the options for female sterilization
- Assess which topics to discuss with patients during counseling for sterilization
- Prioritize the key points to make an office procedure successful
- Interpret the possible added value of future alternatives

PERMANENT FEMALE STERILIZATION OPTIONS

- (vaginal sterilization)
- laparoscopic sterilization
- hysteroscopic sterilization

LAPAROSCOPIC STERILIZATION

- General anaesthesia, day care, OR
- Incisions (10 mm, 5 - 8 mm) or single port (15 mm)
- Tubal occlusion: clips, rings, coagulation
- 2 - 5 d abdominal pain
- Immediate reliability

RESULTS LAPAROSCOPIC STERILIZATION

PR: 18,5/1000
(n=10685, FU up to 14 yrs)

Petersen et al. '96
(Flow clips: 1.2/1000 Sokal '00)

Complications 45/1000

Jansen et al. '94

Mortality 0.04/1000

Khairullah et al. '92

www.thurkow.com
HYSTEROSCOPIC STERILIZATION
METHODS THAT HAVE EVER MADE IT TO THE MARKET (EC OR FDA)

- Essure (2001)
- Adiana (2009 - 2012)

www.thurkow.com

COMPARISON
“ACTUAL” METHODS

<table>
<thead>
<tr>
<th>Hyt</th>
<th>Successful bilateral placement 1st attempt (%)</th>
<th>Satisfactory confirmation after total bilateral placements (%)</th>
<th>Satisfactory confirmation after successful placement 1st attempt (A x B)</th>
<th>Pregnancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chiaboni</td>
<td>0.80</td>
<td>0.77</td>
<td>12 / 1212</td>
<td>9.9/1000</td>
</tr>
<tr>
<td>Essure</td>
<td>0.98</td>
<td>0.89</td>
<td>6 / 606</td>
<td>1/1000</td>
</tr>
<tr>
<td>Adiana</td>
<td>0.99</td>
<td>0.86</td>
<td>9 / 970</td>
<td>15.7/1000</td>
</tr>
</tbody>
</table>

Feasibility and efficacy of three methods of hysteroscopic sterilization: La Chapelle/Veersema '15

Essure vs lap ster: - both high efficacy
- both low complications, hyst less serious
- cost saving: Connor '09

www.thurkow.com

SETTING

- ambulatory / office
- no anesthesia (NSAIDs)
- vaginoscopy
- < 10 mins

Outpatient: higher successful placement rate: 97.3% vs 92.8%

Savage '09

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VAGINOSCOPIC VS CONVENTIONAL HYSTEROSCOPY

Controversy?

various complaints about Essure (pain, rash, fatigue, hair loss, depression, etc):

Focus on AAGL: Are We Listening to Our Patients? May 2, 2014 By Franklin D. Loffer, MD, FACOG

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CONTROVERSY?

FDA Conclusion (website):
To date, we have found no conclusive evidence in the literature indicating any new or more widespread complications definitely associated with Essure occurring more than five years after Essure placement.

FDA will continue to monitor the safety of Essure to ensure it does not pose an increased risk to public health and that its benefits continue to outweigh the risks.

FUTURE DEVELOPMENTS

• Altaseal®: pivotal trial started Feb 2015: SS, immediate closure
• Ovalastic®: redesigned Ovabloc, CE marked: silicone, inert
• Others?

CONCLUSIONS

Yes, to date Essure still remains the Answer for Permanent Female Sterilization!

Because:
- efficacy (PR)
- safety (complications)
- ease of use
- costs

But:
- perhaps some (2-3%) experience long term side effects
  > counseling
  > lap removal if needed

> Future devices may prove to have added value

REFERENCES


www.thurkow.com
Postpartum sterilization
When and How

Moty Pansky, Prof. M.D
Gyn. Endoscopy Unit
Asaf Harofe Medical center
Zerifin, Israel
Affiliated to Sackler Medical School
Tel Aviv University

Disclosure
• I have no financial relationships to disclose.

Objective
• Discuss postpartum sterilization

Sources

Prevalence of sterilization compared with other methods
(National Survey of Family Growth, 2006-2010)

• In The U.S 38.4 millions women aged 15-44 years used contraception's.
• Within married couples:
  - 47.3% used Permanent sterilization (Tubal=30.2%, Vasectomy 17.1%)
  - 18.6% Used OC
  - 15.3% Used male condoms
  - 7.1% Used IUD’S
  - 3.9% Used Injectables

Female Sterilization- timing

• Female sterilization can be performed at any time before or after pregnancy
• The choice and timing of sterilization are affected by:
  - Individual patient preference
  - Medical assessment of acute risk
  - Access to services
  - Insurance coverage
Female Sterilization - timing

- The timing of the procedure influences both the surgical approach and the method of tubal occlusion
- In the U.S, more than one half of all tubal occlusions are performed in the early postpartum period
- Sterilization procedures performed after 8–9% of all hospital deliveries

No. of female Post partum sterilizations In U.S

- Rates of female sterilization increased dramatically in the 1970s
- Peaking at 702,000 procedures in 1977
- Remained stable in the 1980s and early 1990s
- Decreased slightly to 643,000 procedures in 2006

Postpartum Sterilization

- Performed at the time of cesarean delivery or after a vaginal delivery
- Should not extend the patient’s hospital stay

Post Partum Tubal Sterilization (PPTS) is one of the most effective methods of contraception

Most Women are good candidate for PPTS

One half of women with unfulfilled PPTS requests become pregnant within 1 year

Only 50% of women who request PPTS during prenatal counseling actually undergo the procedure

??????

Young age and concern for patient regret

- The reality:
  - Medicaid, Indian health service and US military health ins. Will cover PPTS above 21 years old
  - Most other insurances will cover PPTS only above 30 years old.
- The Facts:
  - 80% of women younger than 30 do not regret
  - Long term regret is more common among underserved women
- The solution:
  - Thorough presterilization counseling may identify women more likely to experience regret.

??????

- Young age and concern for patient regret
- Consent Documents
- Lack of available OR or Anesthesia
- Receiving care in religiously affiliated hospital
Consent Documents

- **The reality:**
  - Federal regulations require specific sterilization consent:
    * Consent must be signed at least 30 days before the procedure
    * The consent remain valid for 180 days
    - Reimbursement to the hospital for the delivery and postnatal care may be denied due to improperly complete all federal consent forms.
    - Women with other than federal or governmental insurances are not mandate to follow the same consent rules.

- **The Solution:**
  - The regulations must be revised in order to create fair and equitable access for women to PPTS.

Lack of available OR or Anesthesia

- **The Reality:**
  - Inadequate hospital resources can hinder a women from obtaining her desired PPTS, lack of OR space and personal in labor and delivery OR’S, inadequate staff, inability to schedule in advance the procedure Ecc.

- **The Solution:**
  - Considering other OR sites for the procedure.
  - Emphasize on the urgent nature of the procedure.
  - Use of an existing epidural catheter is efficient to provide anesthesia for PPTS.

Receiving care in religiously affiliated hospital

- **The reality:**
  - Policies at some religiously hospitals may pose barrier to PPTS
  - Approximately 10% of US hospitals are Catholic and around 25% are Jewish or Catholic in Israel and may refuse to perform PPTS

- **The Solution:**
  - Women who plan to use maternity care in those institutions should be provided with the information related to all types of reproductive health services, including referrals to institutions that perform the procedures.

Postpartum Sterilization - Techniques

- Intrapartum during CS
- Post vaginal delivery- Minilaparotomy
- Post vaginal delivery- Laparoscopy

- **Partial Salpingectomy**
  - Pomeroy
  - Irving
  - Uchida

- Bipolar, Clips, Rings ecc.
Postpartum Sterilization (Technique)

- Minilaparotomy after vaginal delivery:
  - Is generally performed before the onset of significant uterine involution through a small infraumbilical incision
  - Typically is performed with regional or general anesthesia, but may be performed using local anesthesia with sedation
  - In most cases, epidural anesthesia placed during labor can be left in place for the procedure
  - Partial Salpingectomy, Bipolar, Clips, Rings ecc.

Postpartum Sterilization (Technique)

- Post vaginal delivery- Laparoscopy:
  - Not very popular due to the fear of high uterine position
  - Bipolar, Clips, Rings ecc.

Failure Rate of Tubal Sterilization

<table>
<thead>
<tr>
<th>Method</th>
<th>5-year (per 1,000 procedures)</th>
<th>10-year (per 1,000 procedures)</th>
<th>Ectopic (per 1,000 procedures)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postpartum partial salpingectomy</td>
<td>6.3</td>
<td>7.5</td>
<td>1.5</td>
</tr>
<tr>
<td>Sigmoid coagulation*</td>
<td>16.5</td>
<td>24.8</td>
<td>17.1</td>
</tr>
<tr>
<td>Sclerotherapy</td>
<td>10.6</td>
<td>17.7</td>
<td>7.3</td>
</tr>
<tr>
<td>Spring clip</td>
<td>31.7</td>
<td>36.5</td>
<td>8.5</td>
</tr>
<tr>
<td>Hysteroscopy (Essure)?</td>
<td>1.64</td>
<td>No association</td>
<td></td>
</tr>
</tbody>
</table>

Conclusions and Recommendations

- Postpartum sterilization is a highly effective method of contraception
- Access to postpartum sterilization is an important strategy to reduce high rates of unintended pregnancy
- Postpartum sterilization should be considered an urgent surgical procedure
- Obstetrician–gynecologists should identify and eliminate barriers that restrict access to postpartum sterilization
- There are unfair differences in consent rules surrounding sterilization procedures based on insurance type

Thank You
CULTURAL AND LINGUISTIC COMPETENCY

Governor Arnold Schwarzenegger signed into law AB 1195 (eff. 7/1/06) requiring local CME providers, such as the AAGL, to assist in enhancing the cultural and linguistic competency of California’s physicians (researchers and doctors without patient contact are exempt). This mandate follows the federal Civil Rights Act of 1964, Executive Order 13166 (2000) and the Dymally-Alatorre Bilingual Services Act (1973), all of which recognize, as confirmed by the US Census Bureau, that substantial numbers of patients possess limited English proficiency (LEP).

California Business & Professions Code §2190.1(c)(3) requires a review and explanation of the laws identified above so as to fulfill AAGL’s obligations pursuant to California law. Additional guidance is provided by the Institute for Medical Quality at http://www.imq.org.

Title VI of the Civil Rights Act of 1964 prohibits recipients of federal financial assistance from discriminating against or otherwise excluding individuals on the basis of race, color, or national origin in any of their activities. In 1974, the US Supreme Court recognized LEP individuals as potential victims of national origin discrimination. In all situations, federal agencies are required to assess the number or proportion of LEP individuals in the eligible service population, the frequency with which they come into contact with the program, the importance of the services, and the resources available to the recipient, including the mix of oral and written language services. Additional details may be found in the Department of Justice Policy Guidance Document: Enforcement of Title VI of the Civil Rights Act of 1964 http://www.usdoj.gov/crt/cor/pubs.htm.

Executive Order 13166, “Improving Access to Services for Persons with Limited English Proficiency”, signed by the President on August 11, 2000 http://www.usdoj.gov/crt/cor/13166.htm was the genesis of the Guidance Document mentioned above. The Executive Order requires all federal agencies, including those which provide federal financial assistance, to examine the services they provide, identify any need for services to LEP individuals, and develop and implement a system to provide those services so LEP persons can have meaningful access.

Dymally-Alatorre Bilingual Services Act (California Government Code §7290 et seq.) requires every California state agency which either provides information to, or has contact with, the public to provide bilingual interpreters as well as translated materials explaining those services whenever the local agency serves LEP members of a group whose numbers exceed 5% of the general population.

If you add staff to assist with LEP patients, confirm their translation skills, not just their language skills. A 2007 Northern California study from Sutter Health confirmed that being bilingual does not guarantee competence as a medical interpreter. http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2078538.