Surgical Tutorial 4:
Controversies and Removal of Essure

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Surgical Tutorial 4: Controversies and Removal of Essure

Linda D. Bradley, Chair

Faculty: Mark W. Dassel, John A. Thiel, Michael P.H. Vleugels

Hysteroscopic sterilization was approved in the United States in 2002. Many women have successfully undergone safe and effective procedures worldwide. Successful outcomes depend on choosing the right patient for the right procedure. Increasingly, we realize that the selection of the patient and informed consent improves outcome. This session will highlight the importance of choosing the ideal patient for the procedure. Contraindications will be reviewed. Aspects of the informed consent which should be reviewed in detail before recommending hysteroscopic sterilization will be discussed. Finally, a review of post procedural concerns that must be addressed by the physician will be outlined in this session. A summary of videos will demonstrate removal of hysteroscopic sterilization devices in patients who present with pain or discomfort.

Learning Objectives: At the conclusion of this course, the clinician will be able to: 1) Discuss techniques and issues related to Essure placement and removal.

Course Outline

3:25 Welcome, Introductions and Course Overview L.D. Bradley
3:30 Complications Related to Essure Placement M.W. Dassel
3:45 Nickel Allergy: What Does the Data Really Reveal? M.P.H. Vleugels
4:00 Your Patient Has Pain following Essure Placement – Now What Do You Do? J.A. Thiel
4:15 Clinical Pearls: Effective Ways to Remove Essure: Video Tips and Tricks from the Experts
• 5-Minute Video and Discussion J.A. Thiel
• 5-Minute Video and Discussion M.P.H. Vleugels
• 5-Minute Video and Discussion M.W. Dassel
4:30 Emerging Techniques to Evaluate Essure Placement: The Role of Dynamic HSG M.P.H. Vleugels
4:45 Questions & Answers All Faculty
5:05 Adjourn
PLANNER DISCLOSURE
The following members of AAGL have been involved in the educational planning of this workshop (listed in alphabetical order by last name).
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R. Edward Betcher*
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Consultant: Bayer Healthcare Corp., Bluespire, Boston Scientific Corp., Inc., Forrest Research Institute, Hologic, Medscape
Stock Ownership: CooperSurgical
Speakers Bureau: Smith & Nephew Endoscopy
Royalty: Elsevier, UpToDate
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Contracted Research: Allergan, Channel Medical, Minerva Surgical
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Michael P.H. Vleugels
Other: Trainer Advisor: Bayer Healthcare Corp.
Content Reviewer has no relationships.

Asterisk (*) denotes no financial relationships to disclose.
Complications Related to Essure Placement: Consider the Source

Mark Dassel, M.D.
Assistant Professor
Department of OB/GYN
University of Utah

Objectives

1. To identify the estimated adverse events and complications associated with the Essure device
2. To discuss the sources of adverse event data and the ways these data differ
3. To provide information regarding the current FDA plan to address Essure related issues
4. To counsel patients on possible adverse events related to Essure permanent contraception

The complications

- Pregnancies
- Malpositioning/expulsion/perforation
- Pain
- Bleeding
- Nickel/Autoimmune complications

Here’s another list

- Pregnancy
- Malpositioning/expulsion/perforation
- Pain
- Bleeding
- Nickel/Autoimmune complications

How do we counsel our patients? An imperfect system of data

- Phase I, II, III trials overseen by the FDA, run by the companies
- Independent researchers (small #s, company affiliations)
- MAUDE database (self report, selection bias)
- Citizen Action

Disclosures

- I have no financial relationships to disclose
Essure AE timeline

- (2001) phase 1 trial, Kerin et al., Conceptus
- (2003) phase 2 trial, Kerin et al., Conceptus
- (2003) phase 3 trial, Cooper et al., Conceptus
- (2007) Levy, A summary of reported pregnancies after HSG tubal sterilization, Conceptus
- (2011) Al-Safi reports 10 years of adverse events from the MAUDE database, (One author with prior research support and honoraria)
- (2013) Munro, 10 years of data on Essure
- (2015) FDA panel meets to re-evaluate
- (2015) ACOG release statement

Phase I, II, III Adverse Event data

<table>
<thead>
<tr>
<th>Trial numbers*</th>
<th>pregnancy</th>
<th>Device malfunction</th>
<th>perforation</th>
<th>Unsatisfactory placement</th>
<th>Tolerance of Insert</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>111</td>
<td>0</td>
<td>4</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Phase II</td>
<td>200</td>
<td>0</td>
<td>4</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Phase III</td>
<td>464</td>
<td>0</td>
<td>2</td>
<td>5</td>
<td>16</td>
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</tbody>
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Phase III: reported 0 cases of persistent pain, 10 cases of heavier bleeding, 7 cases of decreased bleeding
43 placement failures

*Total number of bilaterally correctly placed devices

The next generation, follow-up trials

- 2007 - Levy and Conceptus report 64 pregnancies after Essure placement (8 yrs)
  - Estimated 50,000 procedures performed

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<th>Unsatisfactory placement</th>
<th>Tolerance of Insert</th>
</tr>
</thead>
<tbody>
<tr>
<td>Al-Safi</td>
<td>457</td>
<td>61</td>
<td>121</td>
<td>90</td>
<td>33</td>
</tr>
</tbody>
</table>

Concentrated mortality outcomes with other types,
4. Thrombosis, Nodules, including infection
Unilateral or bilateral fallopian tubes
Multiple metallic-implanted in 1 or both fallopian tubes
Unknown

The next generation follow-up trials

- 2009, Connor and Conceptus, Review of the Data

<table>
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<th>Adverse events*</th>
<th>pregnancy</th>
<th>Device malfunction</th>
<th>perforation</th>
<th>Unsatisfactory placement</th>
<th>Tolerance of Insert</th>
</tr>
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</tbody>
</table>

217 (47.5%) of AEs had related pain, 24.9% from perforation
44 (9.6%) abnormal uterine bleeding
4 with + nickel allergies, 11 had coils removed

Industry Independent Research (for the most part)

- Al-Safi et al. reports 10 years of Adverse Events*
- Based on MAUDE database reports over 10 years

- 217 (47.5%) of AEs had related pain, 24.9% from perforation
- 44 (9.6%) abnormal uterine bleeding
- 4 with + nickel allergies, 11 had coils removed
Further Research

• (2014) Munro, et al. 10 years of pregnancy after Essure

The FDA, CDRH re-evaluation

• 9900 Medical Device Reports to the MAUDE database

<table>
<thead>
<tr>
<th>Issue</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal pain</td>
<td>889</td>
</tr>
<tr>
<td>Heavy menses</td>
<td>3210</td>
</tr>
<tr>
<td>Headaches</td>
<td>2900</td>
</tr>
<tr>
<td>Fatigue</td>
<td>2159</td>
</tr>
<tr>
<td>Weight Fluctuations</td>
<td>2088</td>
</tr>
<tr>
<td>Device incompatibility</td>
<td>2016</td>
</tr>
<tr>
<td>Device malfunctions</td>
<td>404</td>
</tr>
<tr>
<td>Device operating</td>
<td>490</td>
</tr>
<tr>
<td>Device breakage</td>
<td>429</td>
</tr>
<tr>
<td>Device difficult to remove</td>
<td>280</td>
</tr>
<tr>
<td>Malpositioned Devices</td>
<td>199</td>
</tr>
<tr>
<td>Difficult to insert</td>
<td>187</td>
</tr>
</tbody>
</table>

Extended follow-up results of phase III

• Chudnoff, et al., 2015 (data from 2002-2007)
• Conceptus assisted data collection
• Data were for women who had confirmed placement and perfect use

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<tr>
<th>Trial Numbers</th>
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<th>Device malfunction</th>
<th>perforation</th>
<th>Unsatisfactory placement</th>
<th>Tolerance of Insert</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chudnoff</td>
<td>366</td>
<td>5</td>
<td>NA</td>
<td>NA</td>
<td>99%</td>
</tr>
</tbody>
</table>

In steps social media

• Essure problems- facebook
• Essureproblems.webs.com
• Essureprocedure.net
  — Erin Brockovich

“Popular feeling is very often sentimental, muddle-headed, and eminently unsound, but it cannot be disregarded for all that.”
— Agatha Christie, Murder in the Mews

So who can we believe?

• Dhruva, et al. NEJM 2015- Multiple methodological issues with the series of Essure data from phase III trials to extended phase III analysis
• Gariepy, et al. Contraception 2014- Suggests differing data for Essure efficacy using Markov modeling
So do we believe the MAUDOE data?

- MAUDOE data had methodological issues as well.
- Data is unsubstantiated, unproven and prone to selection bias.
- No causality can be established.
- Data is voluntary, so lack of data may represent non-reporting, too much can be manipulated by social pressures.

The take away

- Essure has revolutionized the sterilization market/options for women.
- There are methodological questions surrounding current Essure adverse events data.
- There are many happy patients that have received Essure, but also many related complications.
- Informed consent should be emphasized.
- Further data should be collected, preferably by an unbiased research consortium.

Social Pressures

- Majority of Essure MAUDOE submissions have been from patients after 2013.
- Essure Problems (facebook) Sept 30: 80,821 members
- Essureprocedure.net

The FDA agrees

- 1. Ordered Bayer to conduct a postmarket surveillance study to obtain more data about Essure’s benefits and risks.
- 2. Intends to require a boxed warning and Patient Decision Checklist as part of the labeling...
- 3. Is in the process of completing its evaluation of the trade complaint.

Sources

Nickel Allergy: what does the data really reveal?

MPH Vleugels MD PhD FRCG
Riverland Hospital Tiel Netherlands

Objectives:

• Define the clinically presentation of nickel allergy
• Explain the relation between nickel allergy and medical implanted devices in general and specifically Essure devices
• Discuss proper consultation of patients requesting Essure sterilization

What is nickel allergy reaction?

Nickel in jewelry = alloy material:
Release of Ni depends on structure of the alloy, corrosion and deformation
Cracking of the outer layer Ni+salt+protein complex trigger Langerhans cells
T-lymphocyte created, reacting on Ni/salt/protein complex

Nickel Skin patch test scores

Score 0: no reaction
Score 1: Erythema
Score 2: Erythema Papules
Score 3: Erythema Papules Vesicles

Facts to know!

➢ Allergic reactions in relation to stainless steel or platinum never have been mentioned/published but in practice most of these metals contain nickel elements even 316K

➢ Case reports on allergic skin reactions after placement of Nickel containing orthodontic, cardio vascular or orthopedic implants with a very low prevalence < 0.01%

➢ Coincidence? Or different immune reaction in these cases?
Facts to know!

- 24% of Caucasian women have a positive Nickel patch test
- Nickel skin reactions occur mostly on jewelry
- Daily diary intake of Nickel is 300 (150-900) µgr/day/person

What is the Essure material?

- Catheter covering the Essure® micro-insert
- Ostium positioning mark
- Curved end of the micro-insert

Material composition of Essure device

- Wound Deve Diameter 4.0 mm
- Expanded Diameter 1.5-2.0 mm
- Total length of the micro-insert: 3.75-3.95 cm
- Internal end (Steel 316L) Opaque to x-rays
- External nitinol coils (nickel and titanium alloy), not opaque on x-rays
- Polyethylene fibres
- Platinum marker, opaque to x-rays

Facts to know about the Essure material

- Essure alloy=Nitinol: 54.5% Nickel
- 45.5% Titanium
- Alloy covered by titanium to prevent leakage
- Daily release of Essure device 0.26µgr/day

Study objective:
evaluation of nickel sensitization after Essure sterilization.

Design: prospective cohort study to evaluate the relation between de novo sensitization or the increase of pre-existing nickel allergy and Essure sterilization

Setting: Two Dutch non-academic training hospitals.

Objectives:
- Primary objective:
  - Increase of Nickel sensitivity at skin test after Essure device placement.
  - Complaints after Essure device placement related to allergic nickel reaction
- Secondary objectives:
  - Background Nickel sensitivity in our population

Study set up

Questionnaire:

Set-up and after:
- Known nickel hypersensitivity
- Previous positive skin tests in history
- Dermatologic history
- Allergy, Eczema, Asthma

After three months extra attention:
- Complaints after Essure procedure
- Symptoms of generalized allergic reactions

Nickel patch test procedure:

- Concentrated 5% Nickel Sulfate in petrolatum solution
- 1 Patch left shoulder containing the solution
- 1 Control patch right shoulder
- After 72 hours results were observed and scored
Flow chart

Outcome of study questionnaire

- Non difference on allergic symptoms before and after Essure sterilization in the overall group
- No difference in allergic symptoms/complaints before and after Essure sterilization amongst women with a known allergic reaction on Nickel

Findings of this study

1. 3 months after Essure sterilization there was no statistically significant increase of new allergic skin reactions to nickel and nickel allergy related symptoms.
2. Among patients with a positive previous patch test the grade of reaction did not increase after Essure sterilization.
3. Patients with a previous proven Nickel allergy by patch tests did not have any complaints or symptoms after Essure placement.

Final test?

Case: proven nickel allergy by dermatologists, reaction on applied Essure device 72 hours

Conclusion:

Essure sterilization is probably not related to nickel sensitization

Accidental allergic reaction after Essure placement might be caused by any other agent which has to be ruled out

In case another cause has been excluded and persistent skin reactions continue an abnormal immunologic reaction might be present (< 0.01%) and tubectomy with removal of the devices can be performed.
References:

Technical Document 2925 rev.0 Nickel leaching rates; March 2006 Conceptus Ltd


Questions:

Which of the following statements are not true:

1. Nickel allergy is not common amongst women
2. Stainless steel coil in Essure device can cause allergic symptoms
3. Women with a positive skin patch test to nickel are not eligible for Essure sterilization
4. Exposure to Nickel in the dietary diet exceeds 7× times the exposure to released Nickel ion of Essure devices
5. Women with Nickel allergy will have severe skin reactions on any applied Essure device on her skin
Pain following Essure placement – what to do
Surgical Tutorial 4: Controversies and Removal of Essure

John Thiel MSc, MD, FRCSC
Clinical Professor and Unified Department Chair
University of Saskatchewan
Regina, Saskatchewan, Canada

Objectives
• Outline the risks of pain after Essure placement
• Discuss approach before and after Essure placement to help set realistic expectations
• Review options for management of patients who experience pain after Essure placement

Patient presents at age 47 having had bilateral Essure placement 7 years previously, confirmed by ultrasound
• Presented with 6 months of bilateral tingling sensation in hands and feet, after looking online she wondered if this was her Essure
• Had been well prior to this, referred to Neurology for an opinion
• Diagnosis – Lead intoxication

Dr. Google weighs in
• Almost 150 different symptoms reported following Essure placement including both gynecologic and non-gynecologic pain
  – Endometriosis, adenomyosis, ovarian and fallopian tube cysts
  – Fibroids
  – Back, joint, chest, leg, breast, neck, spine and hip pain
  – Trigeminal neuralgia
  – Rheumatoid arthritis, fibromyalgia, Reynaud’s syndrome

Disclosures
• Consultant: Bayer Healthcare Corp., Halt Medical
• Contracted Research: Allergan, Channel Medical, Minerva Surgical
• Other: Advisory Board: Hologic

Reported adverse events
• MAUDE reporting not a reflection of worldwide events and thus underestimates total adverse events
• MAUDE database to April 2016
  – 3353 reports of abdominal pain
  – 1400 reports of heavy or irregular menses
  – 1383 reports of headache
  – 966 reports of fatigue
  – 936 reports of weight gain
Is the pain always caused by Essure

• Kamencic et al, JMG 2016
  – 62/1430 patients with second surgery following Essure placement
  – 38 (2.7%) had pain as an indication, 27 (1.9%) had new onset pain, 11 (0.7%) had worsening of a pre-existing pain
  – New onset pain
    • 15 (1%) had a surgical or pathologic diagnosis consistent with a painful gynecologic condition
    • 12 (0.8%)
      – 8 appeared related to perforation/migration and salpingitis (1)
      – 4 (0.3%) were appropriately placed with no other pathology noted, pain resolved on removal

Does removal help

• 29 patients had Essure removal by laparoscopy because of pain
  – 10% had additional or misplaced inserts
  – 17% had endometriosis
  – 10% required adhesiolysis before removing the coils
  – 50% reported pain in the first month
  – 23/26 patients reported relief of pain following excision

Approach to patient requesting Essure

• Starts with the first visit and informed consent
• Set appropriate expectations and discussion of the social media claims, requires a clear understanding of the current literature
• Document any reported pain associated with menses, coitus or other areas ie joint, back, neck
• Discuss risk of new onset pain and the possibility of worsening a pre-existing pain condition

Approach to patient requesting Essure

• Offer alternatives to Essure including laparoscopic tubal sterilization, discuss risks of laparoscopy and failure rate
• Vasectomy
• The risk of developing pain may increase in those patients who discontinue hormonal contraception after the confirmation test is complete

Approach to the returning patient

• Patient who returns with a concern, especially pain, needs to be reassured that you hear what she is saying, and that you are going to investigate her concern
• Acknowledge that there may be a grain of truth in some social media claims about physicians not listening
• There is a difference between not listening and a proper investigation prior to attributing her symptoms to the Essure placement

Approach to the returning patient

• Can be difficult to try and address non-evidence based concerns by citing evidence that social media has labeled as biased
• Use best evidence available
• Listen to concerns and discuss the diagnostic method and the risk of immediately attributing all symptoms to the Essure inserts
• Ensure the patient is aware that the reason for looking at all diagnostic possibilities is not because you don’t believe it could be related to the Essure
Approach to the returning patient

• If a patient returns with pain following Essure placement
  – Start over with a careful history of the pain
  – Obtain appropriate imaging ie 3D ultrasound to determine position of the insert
  – Imaging should also investigate for other causes of pain such as fibroids or adenomyosis
  – Appropriate consultation for non-gynecologic pain
  – Discussion of options for treatment
    • Trial of medical management vs removal of inserts

Surgical removal of the Essure inserts

• Removal by a modified cornuectomy method will ensure that the insert is removed intact, including the PET fibers
• Careful evaluation and photographic/video documentation of pelvic structures during laparoscopy
• Hysterectomy is not required unless felt necessary to manage other painful conditions ie fibroids, endometriosis or adenomyosis
• Non-gynecologic pain should be evaluated and managed with appropriate consultation

References

1. Essureproblems.webs.com

1. A 37 year old gravida 1 para 1 presents to your office with new onset bilateral pelvic pain over the past year. It is present on a daily basis. Her history is unremarkable, she had bilateral Essure placement 3 years ago with the hysterosalpingogram showing bilateral occlusion. Which one of the following is the best next step?

1. Reassure and offer a trial of the combined oral contraceptive pill.
2. Obtain consent for laparoscopic removal of Essure inserts.
3. Repeat hysterosalpingogram to assess for insert migration.
4. Arrange for 3D ultrasound to assess insert migration.
5. Explain social media issues that exaggerate Essure problems and discharge.

Answer - 4
Emerging technique to evaluate Essure placement; The role of Dynamic HSG

- MPH Vleugels MD PhD FRQG
- Riverland Hospital Tiel Netherlands

Disclosures:

Other: Trainer Advisor: Bayer Healthcare Corp.

Objectives:

- Discuss the specific value of each confirmation test
- Describe indications for Dynamic HSG
- Explain how to perform a Dynamic HSG

3 Months Control Essure Confirmation Test

Confirmation Test Protocol
Transvaginal Ultrasound (TVU)
- Plain x-ray
- Hysterosalpingogram

All these tests have in common their dynamic performance; that means that not only the TVU is dynamic to show the 3-dimensional position on a two dimensional screen but also the Plain x-ray and the HSG have to be performed as a dynamic test; (see below)

Each of these tests have unique value in the control protocol as shown

Each of these confirmation tests must be evaluated by the surgeon who performed the Essure procedure

Essure Confirmation Test Flow Chart

Material and timing procedure location of sterile tools, 15.6.0
Material and timing procedure location of sterile tools, 15.6.0
Material and timing procedure location of sterile tools, 15.6.0
Material and timing procedure location of sterile tools, 15.6.0

Unsuccessful sterilization

Successful sterilization

Successful sterilization

Successful sterilization

Successful sterilization

Successful sterilization

Successful sterilization

Successful sterilization

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Control at three months= ECT
Essure Confirmation Test

Hysterosalpingography
FDA, 2002

ASC
CE, 2001

ultrasound
NL, 2005

CE, 2011

TVU = first line ECT

X‐Ray

Satisfactory Position
- Implants are quite symmetric
  - The linear axis of both implants is harmonious: straight or slightly arched
  - The distance between the proximal ends (4th marker) is not over the size of one implant, less than 4 cm
  - The 4th marker must be aligned with the 3 others

Suspicious Position
- One implant seems too distal or too proximal to the other implant
  - Or; The implants are not symmetric
  - Or; The distance between both implants is more than 4 cm
  - Or; The 4th marker is not aligned with the others; the position may deviate between 0 and 90 degrees with the third marker

Unsatisfactory Position
- Implants position is wrong when distance, alignment, symmetry criteria are not met. HSG is indicated.

Implant’s x‐ray

Outer coil is (almost) never visible

Inner coil is fully visible with the 4 platinium bands

4th marker is free, on a circle in front of the 3th mark with maximum of 90 degrees

Wrong implants’x‐ray

The inner coil is not into the outer coil.

4th marker is free, on a circle in front of the 3th mark with >>90 degrees; by moving the uterus this marker will change position.
Indications for an HSG

HSG must be done if the following situations are present during initial placement:

- **Difficult placement:**
  - No visibility of one or both ostia,
  - Difficulty identifying the tubal ostia during placement due to anatomical variation or technical factors such as poor distension, suboptimal lighting or endometrial debris,
  - Difficult insertion,
  - Sudden loss of resistance: suspicion of perforation

- **Unilateral placement** (salpingectomy, unicornual uterus)

- **Zero coil or more than 8 into the uterine cavity**

- **Procedure time > 15 minutes** (hysteroscope in, hysteroscope out)

- Pain during procedure time or after the procedure

- Surgeon is uncertain about placement

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HSG Procedure

* The **first** goal is to confirm the position of both micro inserts

* The **second** goal is to confirm occlusion of the tubes

In case a micro-insert is in a wrong position on the HSG, a patient can not rely on her sterilization even if the tubes do not show passage of the contrast medium !!

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Dynamic HSG Procedure

* Perform a « dynamic HSG » to create the « wings » view of the two devices in the two tubes

* With the Pozzi clamp on the cervix the uterus has
  - to be pushed up,
  - pulled down
  - Patient turned on her left and right side in 45 degrees;

* Very low pressure has to be used (just visualise the cornua)

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HSG Procedure

* Start with a plain X ray (see elsewhere)
  - Only one implant is visible, enlarge the image to find the other

* Slowly fill the cavity with contrast medium under low pressure

* Use intra uterine balloon: preferably not the old hysterophore

* Perform the Dynamic HSG

* Find the 4th marker (proximal end of implant) and analyse the movement during the above mentioned actions; symmetrical moving while the 4 markers are still aligned?

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HSG Procedure

**Take 5 pictures**

* 1 picture centralized on the pelvis
* 1 picture pushing up the uterus
* 1 picture pulling down the uterus
* 1 picture ¼ at the left side
* 1 picture ¼ at the right side

**THE HSG MUST BE READ BY THE SURGEON WHO HAS DONE THE PROCEDURE.**
The ultimate confirmation test to prove correct Essure sterilization; the “wings” sign at the dynamic HSG.

Cases:

Ideal Dynamic HSG

Pulling down;

Pushing up

Filling fase uterus;
Pushing up; wings=tubes up symmetrical

Pulling down; wings=tubes down symmetrical

Patient turns on left side; right tube stretched with device in detail

Patient turns on the right;

Dynamic HSG
NO wings sign, == perforation!

A blocked tube does not correlate with correct position

Only a correct position and no passage is required to rely on the Essure sterilisation
Difficult case?

Take home message:

- Always dynamic HSG
- Negative “wings sign” = perforation
- Positive “wings sign” = position in tubes

Intravasation or patent tubes?
Intravasation or patent tubes?

Device to deep in tube;
Overview neutral position

Pushing up

Traction down

Filling cavity; neutral position

Filled cavity, low pressure pushing up

Filled cavity, low pressure traction down
Filled cavity, low pressure pushing up, wait few minutes no passage and filling tube right till the 4th marker

**Conclusion:**

- Can patient rely on her Essure???
  - YES!!
  - position in the tube,
  - no perforation
  - No passage

**Take home message:**

- In case there is an indication to perform HSG, do not hesitate to assure the patient that she can rely on her sterilization; a small diagnostic tool for a lifetime reliability
- Using the ECT flowchart, 8-12% of all women will need a HSG
- The group which needs HSG is the at risk group for improper placement
- HSG primary goal is prove of correct placement and second blocked tubes

**References:**

**QUESTION:**

- After a painless quick procedure with 0 coils on the right side, there is no need for HSG
- To test the patency of the tubes, high pressure is allowed during the filling fase
- Blocked tubes are a prove that the patient can rely on her sterilization
- **Even without a filled cavity with contrast medium the Wings sign can prove dislocation**
- In case 3 of the 4 markers are on line, the position of the device is correct
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.

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