Essure Removal for the Treatment of Device-Attributed Symptoms: A Multisite Prospective Cohort Study

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Disclosures

• None
Background

• An estimated 1.1-4.3% of women may experience complications with Essure sterilization [1][2]

• Potential adverse effects include pain, abnormal bleeding, allergic reaction, and multiple other reported symptoms [1]

Background

- Women suffering complications often seek removal of the device by means of hysteroscopy, salpingectomy, and/or hysterectomy [3]

Background

- Retrospective case series of 11 to 52 women who underwent Essure removal:
  - 88.5% had improvement in pelvic pain at their follow-up visit [4]
  - 87.5% reported some degree of improvement in QOL, sex life, pain and daily activities [5]
  - 31.3% reported ongoing or worse symptoms after Essure removal [5]

Objectives

• **Primary:** To prospectively assess the change in symptoms and quality of life (QOL) following Essure removal

• **Secondary:** To compare Essure removal methods (uterine-sparing versus hysterectomy) in terms of symptom changes, QOL, and surgical outcomes

• **Hypothesis:** Women undergoing Essure removal for device-attributed symptoms will experience an improvement in symptoms and QOL
Methods

• **Design:** Multi-site prospective cohort study
  - Surveys distributed by paper or electronically using REDCap
    - Preop
    - 16 weeks postop
  - Demographic info, operative and pathology reports collected from EMR and physician worksheet

• **Inclusion:** Women undergoing Essure removal for device-attributed symptoms (any surgical method)

• **Exclusion:** Women undergoing Essure removal for restoration of fertility or gynecologic procedures with incidental Essure removal
Survey

- Administered pre and postop
- Assess symptom severity and QOL
Preoperative Questionnaire: Essure Removal

The following questions ask about your symptoms. Please select “Yes” if you have a symptom and answer the questions that follow. Please give the best answer you can.

7. In the past 4 weeks, have you experienced an allergic reaction?  
   * must provide value
   - How often?  
   * must provide value
   - How distressing has it been?  
   * must provide value
   - Do you think the symptom is related to Essure?  
   * must provide value

8. In the past 4 weeks, have you experienced pelvic pain?  
   * must provide value

9. In the past 4 weeks, have you experienced painful periods?  
   * must provide value

10. In the past 4 weeks, have you experienced painful sex?  
    * must provide value

11. In the past 4 weeks, have you experienced heavy vaginal bleeding?  
    * must provide value

Survey

- Assesses 17 symptoms
  - Based on focus groups with patients who have had Essure removed
- Symptom severity index dependent on
  - Frequency of symptom
  - Severity of symptom
  - Suspected relation to Essure
**Survey**

- Assesses QOL using validated SF-8 questionnaire

**Preoperative Questionnaire: Essure Removal**

The following questions ask about your overall health in the past 4 weeks. Please give the best answer you can.

<table>
<thead>
<tr>
<th>Question</th>
<th>Excellent</th>
<th>Very good</th>
<th>Good</th>
<th>Fair</th>
<th>Poor</th>
<th>Very poor</th>
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<tbody>
<tr>
<td>27. Overall, how would you rate your health over the past 4 weeks?</td>
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<td>* must provide value</td>
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<td>28. Over the past 4 weeks, how much did physical health problems limit</td>
<td>Not at all</td>
<td>Very little</td>
<td>Somewhat</td>
<td>Quite a lot</td>
<td>Could not do physical activities</td>
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<td>your physical activities (such as walking or climbing stairs)?</td>
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<td>29. During the past 4 weeks, how much difficulty did you have doing</td>
<td>Not at all</td>
<td>Very little</td>
<td>Somewhat</td>
<td>Quite a lot</td>
<td>Could not do daily work</td>
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<td>your daily work, both at home and away from home, because of your</td>
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<td>physical health?</td>
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<td>* must provide value</td>
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<tr>
<td>30. How much bodily pain have you had over the past 4 weeks?</td>
<td>None</td>
<td>Very mild</td>
<td>Mild</td>
<td>Moderate</td>
<td>Severe</td>
<td>Very severe</td>
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<td>* must provide value</td>
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<tr>
<td>31. During the past 4 weeks, how much energy did you have?</td>
<td>Very much</td>
<td>Quite a lot</td>
<td>Some</td>
<td>A little</td>
<td>None</td>
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<td>* must provide value</td>
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</table>
Physician worksheet

Prospective Essure Removal Data Collection Sheet

Please return to Alexis Lindsey in person at BWH MIGS or by fax: 617-278-6954

1 Surgeon: ______________ 2 Patient MRN: ______________ 3 Date of Surgery: __/__/___

Hospital:  
BWH  
FH  
MGH

Procedure:  
Hysterectomy and salpingectomy  
Salpingectomy with cornuectomy  
Salpingectomy alone  
Other: _______________________

Approach:  
Laparoscopic  
Hysteroscopic  
Robotic

Indication:  
Pain  
Abnormal bleeding  
Allergic reaction  
Other: _______________________

Length of Procedure (incision to close): ___________ min

Essure coils in correct location?  
Yes  
No

If no, please describe: ________________________________________________

Other potential etiologies of symptoms:  
Yes  
No

If yes, please select all that apply:
Endometriosis  
Fibroids  
Adenomyosis  
Adhesions

Other: ______________________________________________________________

Comments: ____________________________________________________________
Methods

• Sample size
  • N = 100, 3-5 sites
  • Need to define clinically important difference in symptom severity index (SSI) and QOL score

• Statistical analysis
  • T-tests to compare SSI and QOL change scores for individual patients and across removal methods
  • Linear regression to adjust for baseline patient characteristics
Timeline

• Recruit sites: 6 months
• Recruit patients and collect results: 16 months
• Write-up: 4 months
• Total 24 months
Thank you

• Question?
• Recommendations?