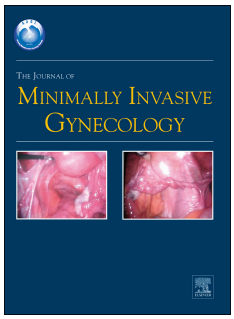
Accepted Manuscript



Essure Surgical Removal and Subsequent Symptom Resolution: Case series and follow-up survey

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PII: S1553-4650(15)00282-4

DOI: 10.1016/j.jmig.2015.03.018

Reference: JMIG 2534

To appear in: *The Journal of Minimally Invasive Gynecology*

Received Date: 27 February 2015

Revised Date: 27 March 2015

Accepted Date: 31 March 2015

Please cite this article as: Brito LGO, Cohen SL, Goggins ER, Wang KC, Einarsson JI, Essure Surgical Removal and Subsequent Symptom Resolution: Case series and follow-up survey, *The Journal of Minimally Invasive Gynecology* (2015), doi: 10.1016/j.jmig.2015.03.018.

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Disclosures: none declared

Abstract

Transcervical sterilization is a minimally invasive option for permanent contraception with high reported rates of patient satisfaction. A small percentage of women subsequently choose to have the tubal inserts removed due to regret or perceived side-effects. There is limited information regarding improvement in symptom profile following surgical removal of the tubal inserts. We present a retrospective case series of 11 women who underwent surgical removal of Essure by hysteroscopy, salpingectomy and/or hysterectomy. The predominant symptom upon presentation was pain (n=10; 90.91%), as well as bleeding (n=6; 54.54%) and/or dyspareunia (n=5; 45.45%). After surgical removal, the majority of patients (n=8; 72.72%)

reported an improvement of their symptoms. However, three (27.27%) patients continued to have persistent symptoms after surgery. Prior to surgical removal of Essure, it is important to thoroughly discuss with patients the risk for ongoing symptoms.

Keywords: Essure; survey; postoperative status; salpingectomy; hysterectomy; pelvic pain

Introduction

Essure ® (Bayer AG, Leverkusen, Germany) is a sterilization device which consists of an expanding micro-insert that is inserted into the cornual section of the fallopian tube during hysteroscopy.(1) The initial 5-year-placement success rates by tubal occlusion range from 84%-99.8% (2) and the US Food and Drug Administration (FDA) approved its use in the United States in 2002.

One important risk of the procedure is the chance of regret which is reported to be as high as 5.5% (3). Some patients present after Essure placement requesting removal of these devices due to complaints of pain, identification of a misplaced insert, the desire for fertility or presumed allergic reaction. The removal can be classified into two broad categories: hysteroscopic removal (typically preferred for the cases inserted less than 12 weeks) and laparoscopic extraction (in patients whose devices are outside the window for hysteroscopic removal or if the insert has perforated into the abdominal cavity) (4).

There is scant literature regarding outcomes of women who undergo Essure implant removal. Therefore, the primary objective of this study was to survey women regarding symptom resolution following removal of Essure devices.

Methods

This retrospective case series included women who sought surgical management for the removal of Essure between September 2012 and July 2014 with the Division of Minimally Invasive Gynecologic Surgery at Brigham and Women's Hospital in Boston, MA. The project was approved by the Partners Institutional Review Board. Women who underwent Essure removal due to desire for future pregnancy or sterilization regret were excluded.

The following demographic data were abstracted from the medical record: age, race, body mass index (BMI), parity, comorbidities, clinical symptoms after Essure placement, duration of symptoms, type of surgery, operative time, length of hospital stay and time from surgery to questionnaire response. An eight-question survey consisting of multiple choice and open-ended questions was created for this study. The survey addressed patients' feelings about removal of Essure implants and the surgery itself, family and/or partner support and symptom improvement after surgery.

Through review of surgical records, patients were identified as meeting the inclusion criteria for this study. These patients received an introductory letter with an explanation of the study and instructions for participation. Patients who chose to participate were mailed a paper version of the survey which included a REDCap (Nashville, TN, USA) online participation link (5). Descriptive analysis was performed with the use of Microsoft Excel (Redmond, WA, USA).

Results

Based on a review of surgical records, 11 patients were identified that met inclusion criteria. All patients invited to participate completed the survey (Table 1). The median age of the participants was 35 years (range 25-44) and majority of the women were caucasian (n=9; 81.8%). Median BMI was 24.7 (18.7-35) and median parity was 3 (2-7). Of the 11 patients, five reported a history of chronic pelvic pain.

The median timeframe between removal of the Essure implant and administration of the survey was five (range 1-23) months. Patients reported symptoms after Essure placement for a median of two (0.5-9) years. The most common surgery performed for removal of Essure devices was bilateral salpingectomy (n=7/63.6%), followed by total laparoscopic hysterectomy and bilateral salpingectomy (n=4/36.4%). One patient initially had undergone bilateral salpingectomy then seven months later underwent a laparoscopic hysterectomy due to persistence of pelvic pain. Only one Essure removal was done hysteroscopically. Median operative time was 60 (35-140) minutes and majority of the patients were discharged home the same day (n=9; 81.8 %).

Table 2 shows the results of the survey answered by the patients who underwent Essure removal. A majority of patient had symptoms of pelvic pain (n=10;90.9%), abnormal bleeding (n=6;54.5%) and pain during intercourse (n=5;45.4%) which were thought to be related to the Essure devices. Most patients reported physician agreement with the decision to remove Esssure implants (n=8; 72.7%) as well as sufficient parental and partner support (n=7; 63.6%) regarding their decision.

After surgery, most of the patients (n=8; 72.72%) reported an improvement in all domains which were queried (pelvic pain, daily activities, sexual life, quality of life, healing and recovery), as seen in Figure 1. However, three patients reported

ongoing symptoms after surgery and two reported worsening symptoms of pain and dyspareunia.

Discussion

In this case series, most patients experienced improvement of symptoms following surgical removal of Essure via salpingectomy and/or hysterectomy. This study differs from previous studies on this topic (6, 7) as it surveyed patients' feelings during the postoperative period following surgery for symptoms that they believed to be Essure-related. Usually, satisfaction indexes after placing Essure are high and patients are happy with their decision (6, 7). However, it is also well established that Essure placement can be associated with side-effects after placement.

Pain was the most commonly reported symptom in our patient cohort. Pelvic pain may develop after hysteroscopic sterilization (incidence of 8.1%), with fifty percent of these cases resolving in 3 months (8). One of the first reports for Essure removal due to pain showed resolution of the symptoms with two weeks of removal (9). It is important to note that the causal relationship between Essure placement and symptoms of pain cannot be validated by a retrospective study design. Moreover, five of the patients in this study had preexisting chronic pelvic pain, which confounds pain reported after Essure placement. It has been reported that patients with previous chronic pelvic pain are more likely to report both acute and chronic pain after hysteroscopic sterilization (8).

An analysis of the Manufacturer and User Facility Device Experience (MAUDE) database has found 63 records for this device from 2001 to 2010 (10). Twenty of these cases were related to allergic dermatitis due to nickel hypersensitivity. In our case series, there were three (27.27%) cases associated with

allergic reaction. One of these cases is not entirely thought to be associated with the device, since this patient was diagnosed with Hodgkins lymphoma concurrent to symptom development. Bleeding was another commonly reported issue during this survey. This was not a complaint found in a recent systematic review about Essure complications, however (11).

A unique aspect of this report is the exploration of patients' feelings regarding having to undergo surgery as well as their fears. Patients presented mixed feelings (happy and sad) about undergoing surgery. This is an important issue, because it has been demonstrated that patient perception is directly correlated with both their postoperative status and with physicians' communication. Limitations include the retrosepctive study design and small number of cases (12).

The majority of patients in this series who underwent surgery for symptoms related to Essure experienced improvement. However, a small percentage continued to have symptoms. It is an important part of the informed consent to discuss with patients the risk of ongoing symptoms prior to performing Essure implant removal.

Acknowledgments

We would like to thank Sao Paulo Research Foundation (FAPESP) grant n. 13/25956-0, which sponsored Dr. Brito´s post-doctoral research fellowship.

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Figure 1. Rating of how important the following factors have improved after removing Essure due to symptoms (n=11)

Table 1. Patient baseline characteristics

	Age	Race	Parity	BMI (kg/m^2)	Comorbidities	Duration of symptoms*
1	35	White	3	24.7	Asthma, chronic low back pain	5
2	44	White	3	35	Migraine, chronic low back pain	9
3	28	Declined	2	24.7	Constipation, chronic low back pain	7
4	35	White	7	19.7	Chronic low back pain	2
5	41	White	2	26.6	Chronic headache	5
6	42	White	5	32.8	Diabetes, hypertension, depression	2
7	44	White	2	21.5	Constipation, chronic low back pain, asthma	2
8	25	White	2	21.3	None	1
9	30	White	4	25.3	None	0.5
10	34	Black	4	21.6	Joint pain, Chronic headache	1
11	40	White	2	18.7	None	0.5

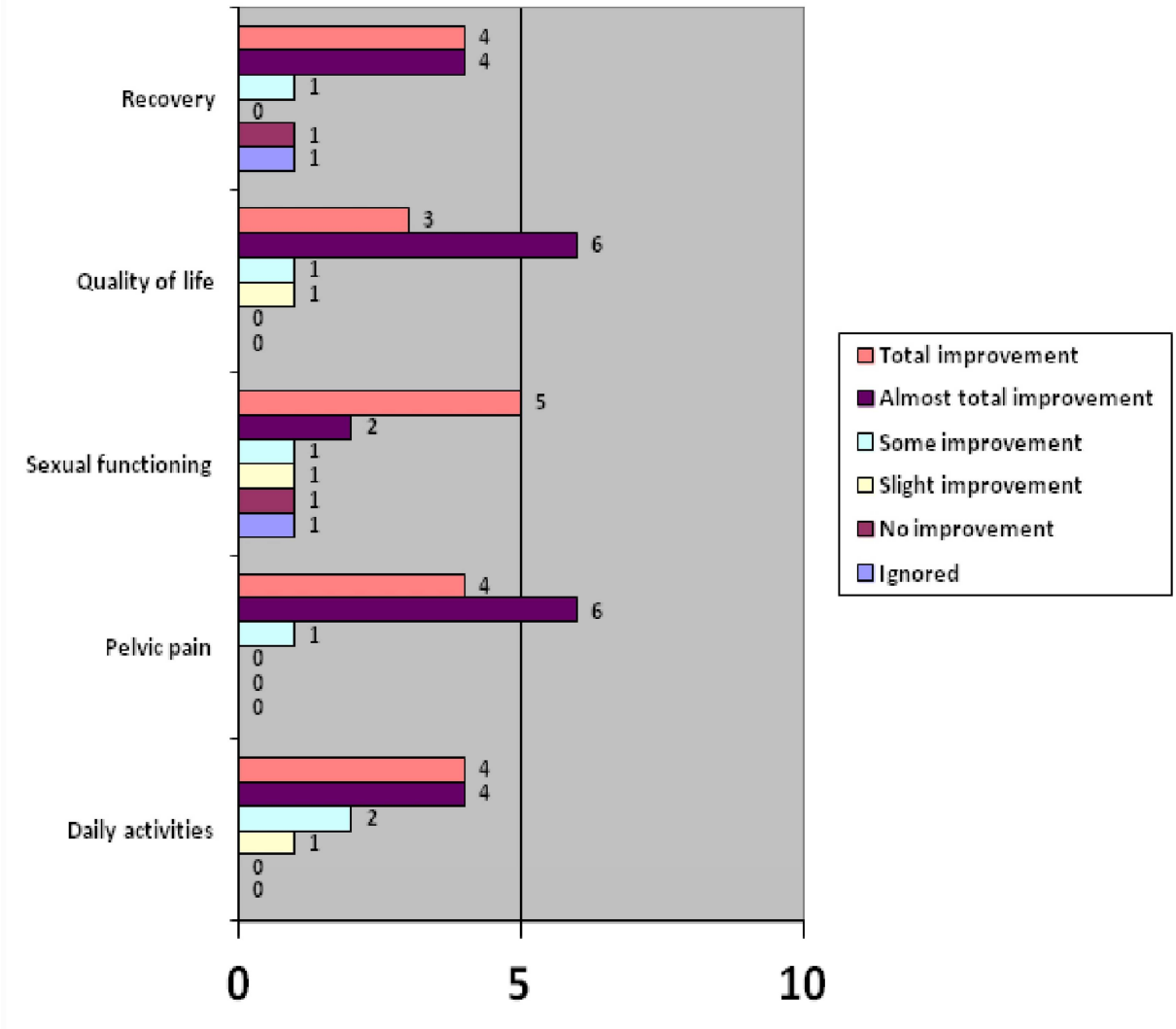
* in years, until surgery date

Table 2. Survey questions sent by survey to patients that performed Essure removal due to symptoms (n=11)

What were your symptoms before removing Essure? *	**n**
Pain	10
Allergic reaction	3
Pain with intercourse	5
Bleeding	6
Other	7
What did you feel when he/she said your would have to operate/remove Essure? *	n
Happy, because I would solve this problem	6
Happy, because my life was horrible at that point	6
Happy, because I would have to take out my uterus (for hysterectomy patients)	0
Sad , because I did not want to do another procedure	4
Sad, because I would have to take out my uterus (for hysterectomy patients)	3
Other	3
What did your partner and family think about your choice? Did they support you?	**Total**
Both gave all support	7
My partner gave all support; my family did not/was not involved with my decision	3
My family gave all support; my partner did not/was not involved with my decision	0
None had influence towards my decision	1
Other	0

Did you have any fears concerning the procedure? *	**n**
No, I did not; I was confident about my doctor's ability.	4
No, I did not; I was certain that my symptoms were related with Essure	4
Yes, I did; I was afraid of not relieving my symptoms	4
Yes, I did; I was afraid of having problems regarding the procedure	5
Yes, I did; I was - afraid of worsening my situation	1
Other	3
Did you have any new symptoms after surgery?	**Total**
Yes	3
No	8
Did you have any symptoms that worsened after surgery?	**Total**
Yes	2
No	9

*More than one response


Recovery
4
4
1
0
1
1
Quality of life
3
6
1
1
0
0
Sexual functioning
5
2
1
1
1
1
Pelvic pain
4
6
1
0
0
0
Daily activities
4
4
2
1
0
0
0
5
10
Total improvement
Almost total improvement
Some improvement
Slight improvement
No improvement
Ignored

http://www.AAGL.org/jmig-22-5-JMIG-D-15-00135

Precis

Essure removal by surgery improved pain in most of patients