



Complete Essure Removal by Hysterectomy and Bilateral Salpingectomy for Treatment of Device-Associated Symptoms: A Case Series and Follow-up Survey

Brett J Cassidy*, James N Hawkins, Julie S Christopher and Mikayla S Cassidy

Department of Obstetrics and Gynecology, AMITA Health Mercy Medical Center Aurora, USA

Abstract

Study objective: To evaluate symptoms related to Essure and resolution of these symptoms after Essure removal performed by hysterectomy and bilateral salpingectomy.

Design: Single center retrospective case series and follow up patient survey.

Setting: Private Obstetrics and Gynecology practice in Yorkville, IL.

Patients: 85 Women who underwent removal of Essure coils from 2015-2018.

Interventions: Surgical removal of Essure was performed by robotic assisted total laparoscopic hysterectomy with bilateral salpingectomy in all patients.

Measurements: Telephone survey was performed for all patients. They were asked to rate the severity of their symptoms on a scale from 0 to 5 for the following symptoms: Brain fog, Dental problems, Dyspareunia, Fatigue, Gastrointestinal upset, Hair loss, Headaches, Joint pain, Menorrhagia, Pelvic pain, Skin rashes and Quality of life. Patients were asked for the severity before they had Essure placed, while Essure was in their body and after Essure was removed.

Main results: 85 patients had Essure removed through hysterectomy and bilateral salpingectomy. 98% of patients had an improvement in their quality of life. The mean quality of life score was 1.4/5 with Essure in place, which improved to 4.2/5 after removal. In every category of symptoms reported by patients, the average severity score improved after hysterectomy.

Conclusion: Essure removal performed by hysterectomy and bilateral salpingectomy is an effective treatment to improve quality of life and alleviate a multitude of symptoms in women suffering from Essure related problems.

Keywords: Essure removal; Laparoscopic hysterectomy; Quality of life; Symptom resolution

Introduction

Essure hysteroscopic sterilization was approved by the FDA via fast track in 2002. Approval was based on only 2 years of clinical data [1]. The Essure device is composed of a stainless steel rod wrapped in Polyethylene Terephthalate (PET) fibers and surrounded by a Nickel/Titanium alloy coil. The device is placed hysteroscopically into the fallopian tubes. The PET fibers then elicit an inflammatory reaction which causes the tubes to scar closed, thus preventing pregnancy.

There have been growing concerns over the safety of the Essure device. Some of the adverse events include: procedure failure, perforation, migration of the coils, increased vaginal bleeding, pelvic pain, allergic reactions and a multitude of auto-immune like symptoms [2]. The FDA performed a review of these safety concerns and issued a 'black box' warning, as well as requiring both patient and physician to sign a safety check list before allowing the device to be sold [3]. After these steps by the FDA, Bayer pulled the device from the market; citing reduced sales.

An increasing number of women have sought removal of their Essure devices in an attempt to alleviate symptoms attributable to their coils. Various methods have been used: hysteroscopic removal, laparoscopic salpingectomy, wedge resection of the cornua, and hysterectomy [4,5]. Hysterectomy with bilateral salpingectomy assures that no pieces, fragments or shards of coils are left behind. To date there are no studies reviewing the outcomes in patients who all had hysterectomy. Our objective is to evaluate patient's symptom severity after Essure removal through hysterectomy

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*Correspondence:

Brett J Cassidy, Department of Obstetrics and Gynecology, AMITA Health Mercy Medical Center Aurora, 654 W. Veteran's Pkwy, Ste A, Yorkville, IL 60560, USA,
E-mail: brettcassidy_1999@yahoo.com

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Table 1: Patient Characteristics.

	All Patients (n = 85)
Age, yr, mean ± SD	42.1 ± 6.4
Race, n (%)	
Caucasian	65 (76.5)
Hispanic	10 (11.7)
Black	8 (12.3)
Asian	1 (1.1)
Gravity, mean ± SD	3.2 ± 1.6
Parity, mean ± SD	2.5 ± 1.1
Years essure in place ± SD	6.2 ± 3.4
Months after removal to survey ± SD	16.3 ± 10.9

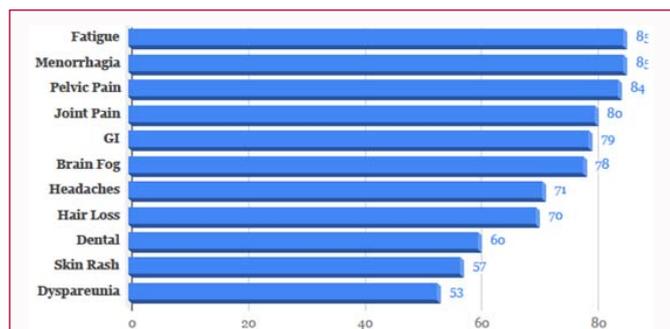


Figure 1: Patient adverse events.

and bilateral salpingectomy.

Methods

This retrospective case series included women who underwent laparoscopic hysterectomy with bilateral salpingectomy for removal of their Essure coils between October 2015 and October 2018. The study was approved by an internal ethics review committee at Aishling Obstetrics and Gynecology. All patients were eligible who had Essure coils removed by hysterectomy and bilateral salpingectomy. 85 women were followed after their surgical removal and asked a series of questions relating to the severity of their symptoms associated with Essure. Data was collected from review of patient’s medical records relating to patient’s demographics, time of Essure placement, time of Essure removal, and time between removal and questionnaire.

The patient questionnaire was performed by telephone interview from the same medical assistant, as well as in person during postoperative visits. Patients were asked to rate the severity of 11 adverse reactions on a scale from 1 to 5; with 5 being the most severe. These 11 adverse reactions to Essure included: brain fog, dyspareunia (pain with intercourse), fatigue, gastrointestinal upset, hair loss, headaches, joint pain, menorrhagia, pelvic pain, skin rash and dental problems. Patients rated these symptoms before their Essure coils were placed, while the coils were in place and after they were removed. They were also asked to rate their quality of life from 1 to 5; with 5 being the best, during the same three time periods. Analysis of this data was then performed using Excel 2016 (Microsoft, Redmond, WA).

Results

A total of 85 patients who underwent laparoscopic hysterectomy with bilateral salpingectomy from October 2015 to October 2018

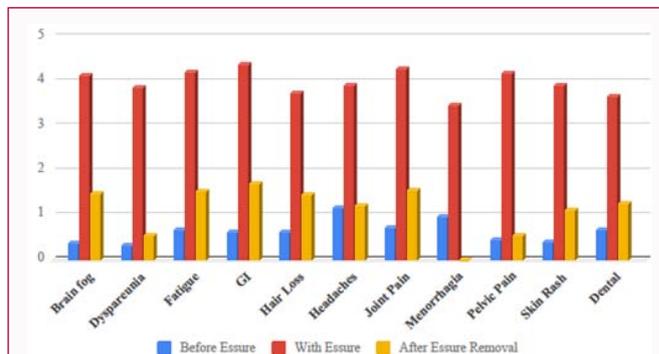


Figure 2: Results are displayed.

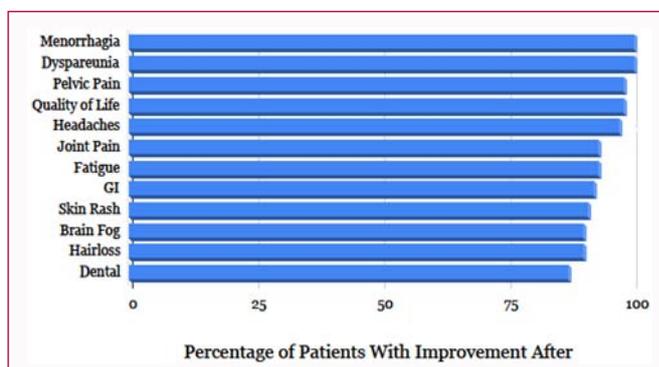


Figure 3: Represents the percentage of patients.

were surveyed to evaluate the relief of their symptoms after Essure removal. Patient demographics are presented in Table 1. The most common complaints related to Essure were fatigue and menorrhagia (85 of 85 patients; 100%), followed by pelvic pain (84 of 85 patients; 100%), followed by joint pain (80 of 85; 94%), followed by gastrointestinal upset (79 of 85 patients; 93%), followed by brain fog (78 of 85 patients; 92%), followed by headaches (71 of 85 patients; 84%), followed by hair loss (70 of 85 patients; 82%), followed by teeth problems (60 of 85 patients; 71%), followed by skin rashes (57 of 85 patients; 67%) and painful intercourse (53 of 85 patients; 62%). These patient adverse events are presented in Figure 1.

Patients rated their severity of each symptom from 0-5 before Essure, while they had Essure in place and then after it was removed. Results are displayed in Figure 2. In all categories patient’s mean symptom scores improved after their hysterectomy. Patients were also asked about their quality of life before Essure, with Essure in place and after their hysterectomy. The mean quality of life before Essure was 4.7/5, with Essure it was 1.4/5 and after removal the quality of life was 4.2/5. Quality of life improved in all but 1 patient after their hysterectomy.

Figure 3 represents the percentage of patients in each symptom category that had improvement after their hysterectomy. For patients presenting with brain fog 90% (72/78) had improvement, for dyspareunia 100% (53/53), for fatigue 93% (79/85), for gastrointestinal upset 92% (73/79), for hair loss 90% (63/70), for headaches 97% (69/71), for joint pain 93% (74/80), for menorrhagia 100% (85/85), for pelvic pain 98% (82/84), for skin rash 91% (52/57), for teeth problems 87% (52/60) and for quality of life 98% (84/85).

Discussion

This retrospective case series demonstrates the benefit of

removing Essure coils by hysterectomy with bilateral salpingectomy in patients who are suffering from a multitude of symptoms. The 11 most common complaints of patients presenting for Essure removal were surveyed. In all 11 symptoms, patient's mean severity scores improved after their surgery. In each category of symptoms an average of 94% of patients had improvement after their hysterectomies. In addition, 84 out of 85 patients (98%) had an improvement in their quality of life.

This is one of the largest studies following patients after Essure removal. It is also the only study in which hysterectomy with bilateral salpingectomy was the only procedure performed to remove the Essure coils. Other studies have demonstrated lower percentages of improvement in symptoms after removal [6,7]. In these studies multiple types of surgeries were utilized. Attempts to remove Essure by pulling the coils out from the tubes can leave fragments of the coils still in the uterus or flakes of nickel in the patient's abdomen. Attempts at performing wedge resections can be challenging, still having the potential for leaving small pieces behind. By performing a hysterectomy with the fallopian tubes attached, complete Essure removal is assured.

Our study is limited by the fact that it is retrospective and is subject to recall bias. Patients were asked to recall their symptoms from different time periods and it is possible that their memory was not completely accurate. It is also limited by the lack of a control group of patients who have no Essure complaints to compare similarly to the group with Essure complaints.

Conclusion

Essure removal performed by hysterectomy with bilateral salpingectomy is an effective treatment to improve quality of life and alleviate a multitude of symptoms in women suffering from Essure related problems.

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