# Laparoscopic hysterectomy for the treatment of Essure-attributed symptoms.

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## Introduction

The Essure device is a flexible metal coil implanted via hysteroscopy into the fallopian tubes for sterilisation. It was withdrawn from the Australian market in 2018 due to significant adverse events reported to the Therapeutic Goods Administration including pregnancy, chronic pain, device migration and immune-type reactions. Salpingotomy, salpingectomy, cornuectomy and hysterectomy have all been described for the removal of Essure. Hysterectomy is the most common procedure performed for the removal of Essure. [1] This is probably because it has the lowest risk of leaving Essure fragments in the pelvis and hysterectomy can treat multiple symptoms including menses-related complaints.

The number of Australian women with Essure is unknown because there is no Australian Essure registry. Two outstanding questions exist; what symptoms are experienced by Australian women after placement of Essure and to what extent do these symptoms resolve after removal of Essure? Furthermore, is hysterectomy a safe and effective option to reduce the burden of symptoms in these women? Currently, there is no consensus from Australian medical bodies to guide clinicians on how to best treat women suffering the adverse side-effects of Essure.

This retrospective case series examined 11 women who underwent hysterectomy at Gold Coast University Hospital between 2019 and 2020 due to unacceptable side-effects from Essure. Surgical data and outcomes were examined to assess the safety of hysterectomy. A questionnaire was administered retrospectively to determine the burden of symptoms from Essure and the degree of resolution following hysterectomy.

## Materials and Methods

### Identification of participants

In this retrospective case series, all patients who underwent insertion of Essure between 2000 and 2017 at the Gold Coast University Hospital were included. Details were obtained from records held by the Department of Gynaecology, Gold Coast University Hospital. The department had distributed letters to 65 women who had Essure inserted at the Gold Coast University Hospital, inviting them to attend a consultation with a senior gynaecologist.

### Extraction of surgical data

Patients medical records were examined, and data regarding patient's characteristics, insertion procedure, hysterectomy and histopathology results were obtained from the records. 2 patients had their Essure inserted at Gold Coast University Hospital but had a hysterectomy performed elsewhere. Their surgical data was not included in the study but they were invited to complete the questionnaire.

### Telephone questionnaire

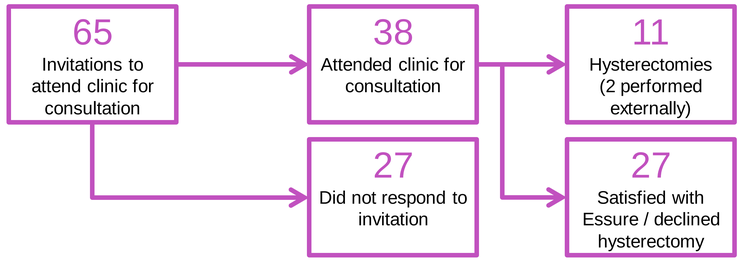
Participants were contacted by telephone by the first author and verbal consent to participate in the study was obtained. A 20-minute telephone questionnaire was completed a minimum of three months after hysterectomy. The questionnaire was composed of two sections. The first section detailed symptoms experienced after placement of Essure and the degree of resolution following hysterectomy (ranked total, near total, partial or none). The second section elicited the degree of improvement in quality of life, pelvic pain, sex life and ability to perform daily activities, which was rated on the same scale as section 1. Patient data was de-identified

## Results

8 of 11 patients opted to complete the retrospective questionnaire. Abdominal pain was the most commonly reported symptom from Essure. Every patient had some improvement in abdominal pain post-operatively and it totally resolved for 75% of patients. Aside from menses-related complaints that logically resolved with hysterectomy, dyspareunia was the only other symptom that totally resolved in all affected patients. Quality of life was improved somewhat in all patients following hysterectomy.

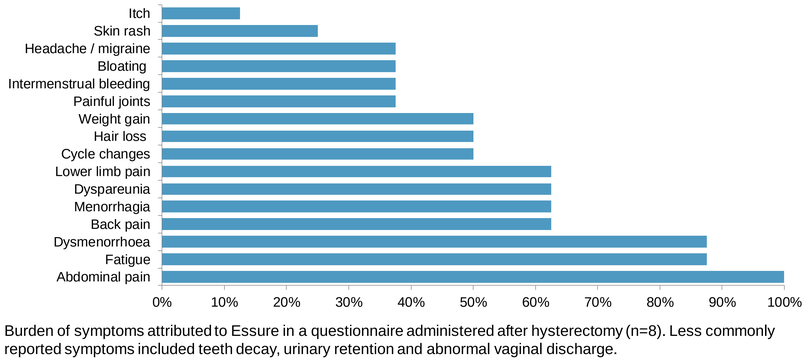
One patient required an extended stay (17 nights) after concurrent extensive excision of stage 4 endometriosis that required formation of a stoma, which needed to be modified in a second operation on day 13 of admission. Otherwise, there were no readmissions within 3 months of surgery despite 56% of patients (5/9) being discharged the same day of surgery.

### Responses to invitation for consultation



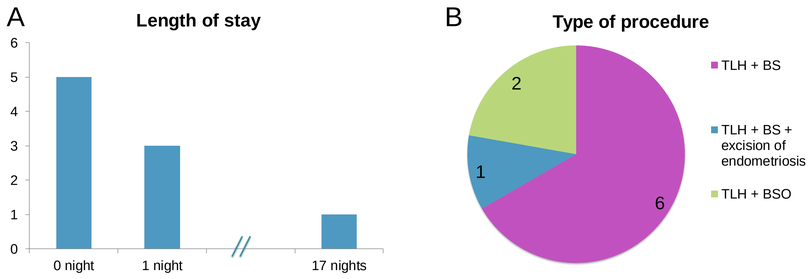

Participant response to invitation for consultation to discuss Essure with a gynaecologist.

### Symptoms attributed to Essure



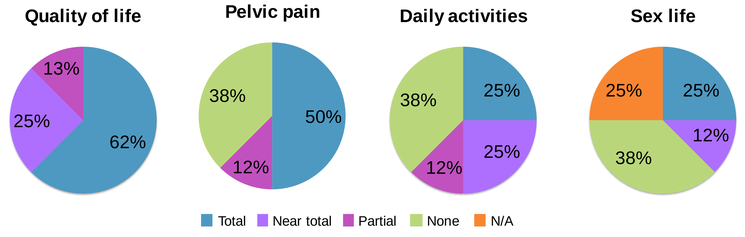

Burden of symptoms attributed to Essure in a questionnaire administered after hysterectomy (n=8). Less commonly reported symptoms included teeth decay, urinary retention and abnormal vaginal discharge.

### Day-case hysterectomy is a feasible option for appropriate patients



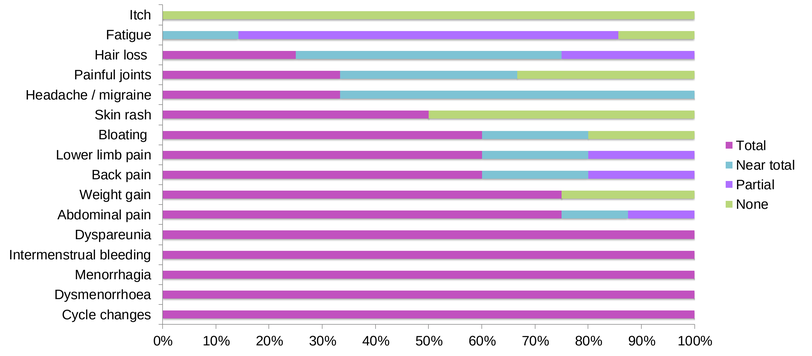

A) Length of stay in hospital post-operatively (n=9). 5 patients (56%%) were discharged the same day of surgery. 1 patient who required extensive excision of stage 4 endometriosis stayed 17 nights after requiring a second operation due to a compromised stoma. B) Type of procedure performed for removal of Essure. TLH: total laparoscopic hysterectomy, BS: bilateral salpingectomy, BSO: bilateral salpingo-oophrectomy.

### Hysterectomy improved quality of life for all participants




Subjective improvement in quality of life, pelvic pain, ability to perform daily activities and sex life was assessed with a questionnaire completed 3 months after surgery. QOL was improved in all participants following hysterectomy. 'N/A' refers to patients whom had not recommenced sexual activity following hysterectomy at the time of interview.

### Degree of symptom resolution following hysterectomy




Degree of symptom resolution was quantified with a questionnaire at least 3 months after hysterectomy. The most common pre-operative complaint, abdominal pain, improved to some degree in every patient. Dyspareunia totally resolved in all patients who had resumed sexual activity following surgery.

## Conclusions

This retrospective case series suggests that the majority of women with Essure are sufficiently satisfied with the side effect profile to not seek its removal. The response rates reported here should guide other Australian health services on what resources would be required if they chose to offer surgery to women who have had Essure inserted at their institutions.

The array of symptoms reported by women suffering from Essure is vast. The degree of symptom resolution reported here is similar to that reported elsewhere following hysterectomy.[2] The results reported here should guide Australian clinicians on which patients are most likely to benefit from hysterectomy i.e. women suffering menstrual complaints and dyspareunia. Conversely, women suffering itch and fatigue are least likely to benefit from hysterectomy.

A hysterectomy no longer carries the high morbidity rates and long stays in hospital that it once did. Some hospitals are supporting same-day discharge following hysterectomy for carefully selected patients. The data presented here supports same-day discharge as a safe practice.

## Future Directions

A larger prospective study with a longer period of follow-up is required to determine the final degree of symptom resolution following hysterectomy versus other methods of surgical removal. This data will guide patients and clinicians to make well-informed decisions on the risk of hysterectomy versus the expected benefit due to resolution of symptoms. The small number of devices inserted at our institution made it difficult to obtain any significant statistical power from the data. It calls for a multi-institutional study that would be difficult to facilitate currently because there is no national Essure registry. A national registry for implantable medical devices would facilitate collaborative research long after the medical records are destroyed and bridge the current gap between the initial data from clinical trials and the actual performance of the device in the real world.

## Acknowledgments

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### Literature Cited

(1) Sills ES, Li X, Wood SH, Jones CA. Analysis of surgeries performed after hysteroscopic sterilization as tabulated from 3,803 Essure patient experiences. Obstet Gynecol Sci. 2017 60(3)296-392.
(2) Maassen LW, van Gastel DM, Haveman I, Bongers MY, Veersema S. Removal of Essure sterilization devices: a retrospective cohort study in the Netherlands. J Minim Invasive Gynecol. 2019 26(6):1056-1062.