Comment on 'End of the road for Essure®?'

We read David Horwell's letter 'End of the road for Essure®?' published in the July 2017 issue of this journal with interest.[1] While Bayer's decision is understandable, it is also disappointing. Essure's withdrawal from the market leaves laparoscopic clip sterilisation and open tubal ligation (at caesarean delivery), as the only methods for female sterilisation available in UK. Clinicians will have to wait for future hysteroscopic alternatives to emerge to broaden the choice for women once more. This will be difficult in the light of the lawsuits attracted by Essure and the withdrawal of Adiana in 2012 due to its high failure rate and the manufacturer's inability to keep up with legal costs over patent infringement litigation.[2]

Having offered the Essure device to our patients we had the opportunity to appreciate first-hand the advantages of the hysteroscopic approach, especially in those who preferred or needed to avoid abdominal incision or general anaesthesia (GA) and who wanted to use the ambulatory setting to be sterilised.

We found that with adequate counselling, the hysteroscopic approach was popular with women, despite our informing them of the gradually emerging adverse evidence, reported adverse events and the Faculty of Sexual & Reproductive Health (FSRH) recommendation to avoid its use in women with nickel allergy, heavy menstrual bleeding, chronic pelvic pain, pelvic infections and autoimmune conditions.[3]

Between September 2009 and June 2017, 200 Essure procedures were performed in our department instead of laparoscopic sterilisations. To gain confidence the first 10 Essure cases were done under GA. The remaining 190 procedures were done by two operators in our out-patient hysteroscopy suite. Of the 200 women, a majority (175) had no previous abdominal surgery. Twenty-five (12.5%) had had

laparotomies (three via midline and 22 via low transverse incisions). Generally, women were happy to use additional contraception until the necessary confirmatory test. A total of 185 women attended follow-up; 120 had a hysterosalpingogram (HSG) and 65 had pelvic ultrasound scans. Of these, 10 needed an HSG as we failed to obtain the ideal views on USS. Two cases after an HSG showed possible unilaterally patency and had a further HSG 3 months later, confirming bilateral occlusion. Fifteen women were lost to follow-up.

To date, five of the 200 women (2%) have undergone further surgery – three for pelvic pain, one for menorrhagia and fibromyalgia-like symptoms and one for bilateral perforation. Four had bilateral salpingectomy and one a hysterectomy and bilateral salpingectomy. Two pregnancies have occurred following the procedure, one after a misdiagnosed HSG and the other a luteal phase pregnancy.

Essure will be missed, especially as a choice for permanent birth control for high-risk women – the very obese, those with one or more midline laparotomies, those who cannot accept or have contraindications for using hormonal methods or where GA is contraindicated. The ease of recovery in women accepting the hysteroscopic versus the laparoscopic approach is also relevant.

We agree that it is unlikely that a new office-based procedure will become available very soon. We hope that a future device will not need post-procedural confirmation and continuing use of contraception, and of course will not have the perceived or real side effects reported by women using Essure and Adiana.

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