Essure hysteroscopic tubal occlusion device for the treatment of hydrosalpinx prior to in vitro fertilization-embryo transfer in patients with a contraindication for laparoscopy

Velja Mijatovic, M.D., Ph.D.,[a] *Sebastiaan Veersema, M.D.,*[b] *Mark Hans Emanuel, M.D., Ph.D.,*[c] *Roel Schats, M.D., Ph.D.,*[a] *and Peter G. A. Hompes, M.D., Ph.D.*[a]

[a] VU University Medical Center, Amsterdam, The Netherlands; [b] Sint Antonius Hospital, Nieuwegein, The Netherlands; and [c] Spaarne Hospital, Hoofddorp, The Netherlands

Objective: To investigate the success rate of proximal tubal occlusion with Essure devices in subfertile women with hydrosalpinges, and to observe the results of subsequent treatment with IVF.
Design: Prospective, single-arm, clinical study.
Setting: University hospital and teaching hospital.
Patient(s): Ten women with uni- or bilateral hydrosalpinges prior to IVF. In all patients laparoscopy was felt to be contraindicated.
Intervention(s): Hysteroscopic placement of Essure devices in an office setting.
Main Outcome Measure(s): Placement rate, successful proximal tubal occlusion, and pregnancy rate after IVF.
Result(s): All patients had successful placement of the Essure devices without any complications. Proximal tubal occlusion was confirmed by hysterosalpingography in 9 out of 10 patients. A 40% ongoing pregnancy rate was achieved with 20% life births after one IVF cycle and/or frozen embryo transfer.
Conclusion(s): Proximal occlusion of hydrosalpinges with Essure devices before IVF is a successful treatment for patients with a contraindication for salpingectomy. (Fertil Steril® 2010;93:1338–42. ©2010 by American Society for Reproductive Medicine.)

Key Words: Essure hysteroscopic tubal occlusion, hydrosalpinges, IVF-ET

The tubal factor accounts for up to 35% of female infertility, and is the most obvious indication for in vitro fertilization-embryo transfer (IVF-ET). Distal tubal occlusion may lead to formation of hydrosalpinges, which are found in 10% to 30% of all patients undergoing IVF-ET (1).

Patients with hydrosalpinges have been identified as a subgroup with significantly poorer outcomes of IVF-ET compared to tubal factor patients without hydrosalpinges. This has been demonstrated in two meta-analyses of retrospective studies concluding that hydrosalpinges were associated with a reduced chance of implantation and a increased risk of miscarriage (2, 3). Especially patients with hydrosalpinges large enough to be visible on ultrasound are associated with the poorest IVF-ET prognosis (4, 5).

The theories explaining the harmful effect of hydrosalpinges on IVF outcomes are multiple, and include the following: [1] a mechanical washout of the transferred embryos through tubouterine reflux of hydrosalpinx fluid, [2] a direct embryotoxic effect even when a low concentration of hydrosalpinx fluid is present in the uterine cavity, [3] a lower endometrial receptivity as an effect of disturbed expression of the cytokine and integrin system by the presence of a hydrosalpinx, thus impairing the implantation potential.

Laparoscopic salpingectomy before IVF-ET has been shown to restore IVF-ET outcomes in patients with hydrosalpinges (6–10). However, this procedure is associated with an increased risk for complications in patients with severe pelvic adhesions. Proximal occlusion of a hydrosalpinx by hysteroscopic placement of an Essure device may offer an alternative to laparoscopic surgery in these patients. Therefore, we conducted a prospective, single-arm, clinical study aiming to investigate the success rates of proximal tubal occlusion with Essure devices in subfertile women presenting with hydrosalpinges in which laparoscopy was felt to be contraindicated, as well as to observe the results of subsequent treatment with IVF-ET or frozen embryo transfers with follow-up including pregnancy and delivery.

MATERIALS AND METHODS

Ten patients with uni- or bilateral hydrosalpinx undergoing IVF-ET or frozen embryo transfers were included in this clinical study. A hydrosalpinx was defined as a distally occluded

Received August 31, 2008; revised November 2, 2008; accepted November 20, 2008; published January 14, 2009.
V.M. has nothing to disclose. S.V. has nothing to disclose. M.H.E. has nothing to disclose. R.S. has nothing to disclose. P.G.A.H. has nothing to disclose.
The authors report no financial support for this article.
Reprint requests: Velija Mijatovic, M.D., Ph.D., Department of Reproductive Medicine, VU University Medical Center, De Boelelaan 1117, 1081 HV Amsterdam, The Netherlands (FAX: +31 20 4440045; E-mail: mijatovic@vumc.nl).

0015-0282/10/$36.00
doi:10.1016/j.fertnstert.2008.11.022

fallopian tube that was pathologically dilated or became pathologically dilated when patency was tested by hysterosalpingography (HSG). We included patients in this study after confirming the presence of hydrosalpinges with transvaginal ultrasound (midcyclic) and when laparoscopic surgery was considered to be contraindicated because of extensive pelvic adhesions. Patients were excluded if their age was ≥40 years and if they were not suitable for IVF treatment. Approval of the institutional review board was obtained.

The Essure device was approved by the U.S. Food and Drug Administration in 2002, and indicated for hysteroscopic tubal sterilization. Essure (Conceptus Inc., San Carlos, CA) is an expanding spring device (diameter: 2 mm; length: 40 mm) made of Nitinol and stainless steel, which contains Dacron fibers that induce a local inflammatory response and subsequent fibrosis of the proximal part of the tube. Nitinol consists of nearly equal atomic nickel–titanium (NiTi) alloy. The presence of nickel is a cause of concern related to embryologic development, but the NiTi alloy showed no cytotoxic, allergic, or genotoxic activity in animal studies, and was similar to the clinical reference material, 316 stainless steel (11). The hysteroscopic placement of the Essure devices was done under antibiotic prophylaxis (Doxycyclin: 200 mg, 5 days) in the second week of the patient's menstrual cycle. The Essure devices were placed with up to four coils visible in the uterine cavity under direct hysteroscopic view using a special delivery system. Three months postprocedure an HSG was performed to evaluate proximal tubal occlusion. Thereafter, all patients underwent IVF-ET and/or frozen embryo transfer. Patients with severe endometriosis were pretreated with long-term (≥3 months) GnRH-agonists before IVF-ET according to Sallam et al. (12).

RESULTS

Ten women (mean age: 33.5 years; range: 28–38 years) with unilateral (N = 7) or bilateral hydrosalpinges (N = 3), because of undergoing IVF, were included (Table 1). Laparoscopy was felt to be contraindicated because of previous extensive pelvic surgery because of endometriosis (N = 7) and Crohn's disease (N = 1) or frozen pelvis as a result of pelvic inflammatory disease (N = 2). Before the placement of the Essure devices six patients underwent unsuccessful IVF treatment.

All Essure procedures were performed in an office setting. No anesthetics were administered, except for two cases where a paracervical block was needed. Successful placement was achieved in all patients. A mean number of three coils (range: 1–4 coils) of the device spring were left protruding into the uterine cavity. No intraoperative or postoperative complications occurred. The procedure times ranged between 5 and 8 minutes. An HSG was performed after 3 months, demonstrating tubal occlusion in 9 patients.

IVF was started after a mean duration of 4.5 months following the Essure procedure (Table 2). The first two patients (cases A and B) became pregnant on their first IVF treatment cycle. The course of these pregnancies was normal, and both patients had a spontaneous term vaginal delivery of healthy infants. Postpartum hysteroscopy showed in both cases complete tissue encapsulation of the Essure devices (Fig. 1).

In case C, the patient experienced a miscarriage nearly 7 weeks after oocyte retrieval in her first IVF cycle. Frozen embryo transfer is now pending for this patient.

Case D involved a patient in which two Essure devices were placed bilaterally. One of them (the left side) showed tubal patency at the HSG (Fig. 2). A repeat HSG has not

TABLE 1

Demographics and Essure data.

Case	Age (y)	Duration subfertility (y)	IVF-ET prior to Essure	Pathology	Hydrosalpinx (uni/bilateral)	Essure coils in uterine cavity (N)	Tubal patency postprocedure[a]
A	32	2	Yes	Endometriosis	Unilateral	1	No
B	30	5	Yes	Endometriosis	Bilateral	3 + 3	No
C	32	3	Yes	Endometriosis	Unilateral	4	No
D	38	9	Yes	Endometriosis	Bilateral	2 + 3	Yes (left side)
E	34	8	No	Endometriosis	Bilateral	4 + 4	No
F	36	3	No	Endometriosis	Unilateral	3	No
G	28	4	No	Endometriosis	Unilateral	3	No
H	30	2	Yes	Frozen pelvis (post-PID)	Unilateral	4	No
I	37	4	Yes	Morbus Crohn	Bilateral	4 +3	No
J	38	3	No	Frozen pelvis (post-PID)	Unilateral	2	No

Note: PID = pelvic inflammatory disease; IVF-ET = in vitro fertilization-embryo transfer.
[a] Determined with hysterosalpingography 3 months after Essure placement.

Mijatovic. Essure hydrosalpinx occlusion prior to IVF. Fertil Steril 2010.