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Essure® hydrosalpinx occlusion prior to IVF-ET as an alternative to laparoscopic salpingectomy☆

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ABSTRACT

Objective: To investigate the success rate of proximal tubal occlusion with Essure® devices in subfertile women with unilateral or bilateral hydrosalpinx and to observe the results of subsequent treatment with IVF-ET and/or frozen embryo transfer.

Study design: Prospective, single-arm, clinical study in 20 women with unilateral or bilateral hydrosalpinges (all visible on transvaginal ultrasound) due to undergo IVF-ET and/or frozen embryo transfer. In all patients, laparoscopy was considered to be contraindicated due to extensive pelvic adhesions.

Result(s): In all patients the Essure® devices were placed in an ambulant setting without any complications. Proximal tubal occlusion was confirmed by hysterosalpingography in 19 out of 20 patients (95%) and in 26 of 27 treated tubes (96%). After 45 embryo transfer procedures in 19 patients, 18 pregnancies with 12 live births, 6 miscarriages and 1 immature delivery (probably related to cervical insufficiency leading to chorioamnionitis and subsequent rupture of the membranes) were observed.

Conclusion(s): Essure® devices are effective in inducing proximal tubal occlusion in subfertile patients with hydrosalpinges. After artificial reproductive treatments a cumulative live birth rate per patient of 63% and a cumulative live birth rate per transfer of 27% were achieved. The latter was related to the large proportion of patients with severe endometriosis.

1. Introduction

Hydrosalpinges are found in 10–30% of all patients undergoing IVF-ET [1]. Patients with hydrosalpinges show poorer IVF-ET results compared to tubal factor patients without hydrosalpinges [2,3]. In particular, hydrosalpinges visible on ultrasound have been associated with the poorest prognosis during IVF treatment [4,5]. The presence of hydrosalpinges affects the outcome of IVF-ET by having an effect on the endometrial environment, possibly through the tubouterine reflux of hydrosalpinx fluid, which disrupts implantation [6].

Laparoscopic salpingectomy before IVF treatment has been shown to restore IVF-ET outcomes in patients with a unilateral or bilateral hydrosalpinx [7]. Proximal occlusion of a hydrosalpinx by hysteroscopic insertion of an Essure® device may offer an alternative to laparoscopic surgery. As demonstrated in our recent report [8], Essure® treatment appears to be safe, effective and feasible in an ambulatory setting.

In a prospective, single-arm, clinical study, aiming to investigate the success rate of proximal tubal occlusion with Essure® devices in subfertile patients presenting with hydrosalpinges, in whom laparoscopy was considered to be contraindicated due to the presence of severe pelvic adhesions, we extended our original cohort with ten patients. This resulted in a group of twenty patients with a clinical relevant uni- or bilateral hydrosalpinx undergoing artificial reproductive treatments (ART) with follow-up including pregnancy and delivery.

2. Materials and methods

We refer to our previous report [8] with respect to the inclusion and exclusion criteria, the procedure used for the hysteroscopic placement of the Essure® devices, and the postoperative follow-up. Patients with severe endometriosis were pretreated with long-term (≥3 months) GnRH agonist prior to IVF-ET. Approval of the institutional review board was obtained. All patients agreed to participate in this study. Cases A–J were described in our previous publication [8]: see also Table 1.

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Table 1
Demographics and Essure® data.

Case	Age (years)	Duration subfertility (years)	IVF-ET prior to Essure®	Pathology	Hydrosalpinx (uni/bilateral)	Essure® coils in uterine cavity (*N*)	Tubal patency post-procedure[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[b])	Unilateral	4	No
I	37	4	Yes	Morbus Crohn	Bilateral	4 + 3	No
J	38	3	No	Frozen pelvis (post PID[b])	Unilateral	2	No
K	36	11	Yes	Frozen pelvis (post PID[b])	Bilateral	1 + 1	no
L	33	2	No	Frozen pelvis (post PID[b])	Unilateral	2	No
M	36	7	Yes	Endometriosis	Bilateral	4 + 1	No
N	32	3	No	Endometriosis	Unilateral	2	No
O	31	5	Yes	Endometriosis	Unilateral	1	No
P	35	1	No	Endometriosis	Unilateral	2	No
Q	38	1	No	Frozen pelvis (post PID[b])	Unilateral	4	No
R	34	8	Yes	Colitis ulcerosa	Bilateral	2 + 1	No
S	34	5	Yes	Frozen pelvis (post PID[b])	Unilateral	1	No
T	29	2	No	Frozen pelvis (post PID[b])	Unilateral	1	No

The grey cells in the table represent data from our initial report [8].
[a] Determined with hysterosalpingography 3 months after Essure® placement.
[b] PID: Pelvic inflammatory disease.

3. Results

This survey includes twenty patients (mean age: 33.7 years; range: 28–38) with unilateral (13 patients) or bilateral hydrosalpinges (7 patients), due to undergo ART (Table 1). For all these women laparoscopic salpingectomy was felt to be contraindicated because of extensive endometriosis (11 patients), a frozen pelvis resulting from pelvic inflammatory disease (7 patients) or inflammatory bowel disease with a history of multiple abdominal operations (2 patients) and they were offered off-label hysteroscopic placement of Essure® devices instead of incisional surgery. Eleven patients underwent IVF-ET before treatment with an Essure® device. Three of these patients became pregnant after IVF treatment but all these pregnancies resulted in a miscarriage.

3.1. Essure® placement data

All Essure® insertions were performed in an ambulatory setting with only 5 patients needing a paracervical block. We inserted 27 Essure® devices, with a mean number of coils protruding into the uterine cavity of 3 (range: 1–4 coils). The procedure times ranged between 5 and 11 min. No complications occurred during or after Essure® insertion.

Successful placement of the Essure® devices was achieved in all patients except one. In this patient (Case R), a unilateral hydrosalpinx was initially found on the hysterosalpingogram (HSG), but transvaginal ultrasound performed thereafter showed a bilateral hydrosalpinx. Therefore we intended to treat her with a bilateral placement of Essure® devices. During the procedure we concluded that one tube was proximally occluded, which resulted in unilateral treatment. The HSG performed 3 months after the procedure confirmed proximal occlusion of the non-treated hydrosalpinx, which was reassuring.

Three months after each procedure we performed a transvaginal ultrasound as well as an HSG. We used this ultrasound investigation only as a tool to evaluate the position of the Essure® device. A correct position, defined as a deep intramural location, of the Essure® device was found in all patients. Proximal occlusion of the treated hydrosalpinges checked with an HSG occurred in 19 out of 20 patients and in 26 of 27 treated tubes. One-sided patency of a treated hydrosalpinx was observed in one patient (Case D) who underwent a bilateral Essure® placement.

3.2. ART and obstetrical outcomes after Essure® treatment for hydrosalpinx

After Essure® treatment, 18 patients underwent a fresh cycle of IVF-ET (*N* = 28) and/or frozen embryo transfer (*N* = 14) using their own eggs. One patient (Case M) was treated by egg donation (three embryo transfer procedures) and another patient (Case S) did not undergo ART at all because of partner separation prior to the start of IVF treatment. In total, 45 embryo transfer procedures were performed in 19 patients (Table 2).

In the follow-up of the initial ten patients, four patients underwent 10 more IVF-ET (6 fresh cycles and 4 frozen ET). Three miscarriages and two live births occurred in these four patients (Cases A, D, G and J). The first patient (Case A) underwent IVF treatment four more times after her first uncomplicated pregnancy and delivery described in our first report. In both the second and the third IVF-ET cycles she experienced a miscarriage. In the fourth treatment cycle she became pregnant again. During this ongoing pregnancy she developed a pregnancy-induced hypertension at term. After induction of labor she gave birth to a healthy daughter by a vaginal delivery.

Case D became pregnant, 8 months after her preterm delivery described in our first report, after a second frozen embryo transfer. She carried almost to term with a primary cerclage and delivered a healthy infant in breech presentation by cesarean section. Case G was treated with three more embryo transfers (1 fresh and 2 frozen). Her only pregnancy ended in a miscarriage. Case J underwent two additional IVF-ET cycles without getting pregnant.

After our initial report [8], Cases B, C, E, F, H and I did not proceed with further treatment. The reproductive outcomes of the additional ten patients (Cases K–T) showed eight live births and two miscarriages after 19 embryo transfers (13 fresh and 6 frozen embryo transfers) (Table 2).

Case K became pregnant following a frozen embryo transfer. She had a normal pregnancy and gave birth to a healthy daughter at 37 weeks of gestation. Cases L, P and T became pregnant after their first IVF-ET cycle and their pregnancies reached term. Cases L and P delivered by cesarean section due to fetal distress and breech