Success of Essure® Micro-inserts in the Treatment of Hydrosalpinx Prior to In Vitro Fertilization (IVF) and Frozen Embryo Transfer (FET) Pregnancy Outcomes

John E. Nichols, Piedmont Reproductive Endocrinology Group, Greenville, SC
Jennifer R. West, Conceptus Incorporated, Mountain View, CA

Objective
Investigate pregnancy outcomes in women with hydrosalpinges treated with Essure® micro-inserts prior to IVF and FET.

Design
Prospective, single arm, clinical study. This study examined an off-label use of the Essure procedure.

Background
• Patients with hydrosalpinges undergoing IVF experience approximately one-half the pregnancy rate of patients who do not have hydrosalpinges.
• Salpingectomy performed for hydrosalpinx prior to IVF improves subsequent pregnancy, implantation and live birth rates.
• Current data are insufficient to permit recommendation of other treatment alternatives such as transvaginal aspiration of hydrosalpinx fluid or proximal tubal ligation.

Materials & Methods
Six women ages 34-41 with unilateral (N=1; prior LSO) or bilateral hydrosalpinges (N=5) diagnosed by HSG (hysterosalpingogram) scheduled to undergo IVF or FET following tubal occlusion by the Essure micro-insert during the time period 2005 – 2008.

Six (6) infertile patients: age ranged from 34 to 41 years old (mean 37.5, median 38.5):
• Six women ages 34-41 with unilateral (N=1; prior LSO) or bilateral hydrosalpinges (N=5) diagnosed by hysterosalpingogram prior to IVF improves subsequent pregnancy, implantation and live birth rates.
• Salpingectomy performed for hydrosalpinx prior to IVF improves subsequent pregnancy, implantation and live birth rates.
• Current data are insufficient to permit recommendation of other treatment alternatives such as transvaginal aspiration of hydrosalpinx fluid or proximal tubal ligation.

Essure placements were performed by one physician in an office setting using local anesthetic (N=4) or in an out-patient surgery center with conscious sedation (N=2). Essure placements were performed by one physician in an office setting using local anesthetic (N=4) or in an out-patient surgery center with conscious sedation (N=2). Five patients had bilateral successful placement on first attempt. One patient had unilateral placement on first attempt and one month later underwent a successful second placement procedure. Tubal occlusion was confirmed by HSG in all patients. Three patients became pregnant on their first IVF treatment cycle; two delivered full-term without complications and one had a fetal demise at 8 weeks due to trisomy 13. Subsequently she conceived on a FET with twins and then had an uneventful fetal demise of one twin; the other was delivered at term without complications.

• Essure treatment of hydrosalpinges.
• 3/6 patients delivered, (50% live birth rate), with no pregnancy complications.
• 4/6 patients conceived (66.6% pregnancy rate).

Results

<table>
<thead>
<tr>
<th>Age</th>
<th>Parity</th>
<th>D3 FSH</th>
<th>AFC</th>
<th>IVF cycles</th>
<th>FET</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>34</td>
<td>G0 4.8</td>
<td>18</td>
<td>1 (Negative)</td>
<td>4 frozen embryos</td>
<td>Gestational carrier</td>
<td></td>
</tr>
<tr>
<td>37</td>
<td>G1 3.2</td>
<td>6</td>
<td>1 (Negative)</td>
<td>Donor embryo</td>
<td>Adoption</td>
<td></td>
</tr>
<tr>
<td>40</td>
<td>G1 0.9</td>
<td>4 (1st and 2nd cycle – negative; 3rd cycle – twins)</td>
<td>(Negative)</td>
<td>39 G7P1Ab3 3.9 1 (Trisomy 13) 1 (Twins) Singleton</td>
<td></td>
<td></td>
</tr>
<tr>
<td>41</td>
<td>G1 8.6</td>
<td>1</td>
<td>Singletons</td>
<td></td>
<td></td>
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</tbody>
</table>

Results (continued)

One patient (age 40) underwent four IVF cycles; the first two cycles were unsuccessful. The third cycle resulted in a twin pregnancy that miscarried at 6 weeks and her last cycle resulted in a chemical pregnancy. The patient is now pursuing adoption.

Six patients (age 34 with recurrent fibroids) had a single unsuccessful IVF cycle but has four frozen embryos available and is now pursuing a gestational carrier.

Essure placement for hydrosalpinx prior to IVF-FET results in excellent pregnancy rates and outcomes:
• 4/6 patients conceived (66.6% pregnancy rate).
• 3/6 patients delivered, (50% live birth rate), with no pregnancy complications.
• Mean age 37.5 years old.

Conclusion
Essure placement for hydrosalpinx prior to IVF-EFT results in excellent pregnancy rates and outcomes:
• 4/6 patients conceived (66.6% pregnancy rate).
• 3/6 patients delivered, (50% live birth rate), with no pregnancy complications.
• Mean age 37.5 years old.

Placement of the Essure micro-inserts in patients with hydrosalpinges provides a minimally invasive option for proximal tubal occlusion prior to IVF and FET and appears to result in excellent pregnancy rates and outcomes. There were no complications related to Essure.

References

Figure 1: HSG of Unilateral Hydrosalpinx before (L) and after (R) Essure micro-insert placement.