# Comparison of the ongoing pregnancy rate of in vitro fertilization following tubal occlusion by microcoil placement versus laparoscopic tubal ligation for hydrosalpinges

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**Abstract**

To compare the pregnancy outcomes of in vitro fertilization (IVF) following tubal occlusion by microcoil placement versus laparoscopic tubal ligation for hydrosalpinges. This is a single center retrospective study of 127 infertile women aged <43 years with unilateral or bilateral hydrosalpinges on transvaginal ultrasound underwent prior to IVF either tubal occlusion by the microcoil placement under X-ray control (the microcoil group, n=60) or laparoscopic tubal ligation (the ligation group, n=67) at the discretion of the attending physicians. In all women, laparoscopy was not considered to be contraindicated due to extensive pelvic adhesions. The pregnancy outcomes of the IVF cycle following the treatment for hydrosalpinges were compared. Both groups had comparable demographic and cycle stimulation characteristics. The positive pregnancy test [43.3% (26/60) vs 64.2% (43/67), P=0.02, RR=0.68(0.48-0.95)], ongoing pregnancy [35.0% (21/60) vs 58.2% (39/67), P=0.009, RR=0.60(0.40-0.89)] and implantation rates [33.3% (34/102) vs 49.5% (56/113), P=0.016, RR 0.67(0.48-0.94)] were significantly lower in the microcoil group than those in the ligation group. Both groups had similar miscarriage, multiple pregnancy and ectopic pregnancy rates. A multivariate logistic regression revealed that only the women's age and the treatment method of hydrosalpinx were significant factors in predicting the ongoing pregnancy. A lower ongoing pregnancy rate of IVF was found in women with hydrosalpinges following tubal occlusion by microcoil placement under X-ray when compared with laparoscopic tubal ligation.

Key words: microcoil, hydrosalpinges, IVF, laparoscopic tubal ligation, ongoing

pregnancy rate

## Introduction

Hydrosalpinges are found in 10–30% of infertile couples with tubal factors and have an adverse effect on the success of in vitro fertilisation (IVF) (Andersen, Yue, Meng, & Petersen, 1994; Blazar et al., 1997; Katz, Akman, Damewood, & Garcia, 1996; Strandell, Waldenstrom, Nilsson, & Hamberger, 1994). Live birth rates of infertile women with hydrosalpinges undergoing IVF are reduced by 50% in comparison to those women without hydrosalpinges (Camus et al., 1999; Zeyneloglu, Arici, & Olive, 1998). Management of hydrosalpinges usually by laparoscopic procedures such as salpingectomy and proximal tubal ligation prior to IVF leads to improved outcomes (Johnson, van Voorst, Sowter, Strandell, & Mol, 2010; Practice Committee of American Society for Reproductive Medicine in collaboration with Society of Reproductive, 2008). However, salpingectomy may affect ovarian function by interfering with ovarian blood flow (Dar, Sachs, Strassburger, Bukovsky, & Arieli, 2000; Lass et al., 1998). Laparoscopic proximal tubal ligation results in similar IVF outcomes as laparoscopic salpingectomy(Johnson, et al., 2010; Kontoravdis et al., 2006) and becomes an alternative treatment for hydrosalpinges prior to IVF (Johnson, et al., 2010).

Although laparoscopic proximal tubal ligation increase IVF outcomes in infertile women with hydrosalpinges, the intervention is invasive and carries anaesthetic and surgical risks, especially in the presence of extensive pelvic adhesions. An alternative but less invasive treatment for hydrosalpinges is needed. Placement of microcoil

under hysteroscopy or X-ray control occludes the tubes and may prevent leakage of hydrosalpingeal fluid into the uterine cavity.

Since 2005, several case reports have described the treatment of hydrosalpinges by placing Essure under hysteroscopy prior to IVF in women who had high surgical risks because of dense pelvic adhesions (Galen, Khan, & Richter, 2011; Hitkari, Singh, Shapiro, & Leyland, 2007; Matorras et al., 2013; Mijatovic, Veersema, Emanuel, Schats, & Hompes, 2010; Ozgur, Bulut, Berkkanoglu, Coetzee, & Kaya, 2014; Rosenfield, Stones, Coates, Matteri, & Hesla, 2005; Thebault, Broux, Moy, & Vialard, 2012). A meta-analysis demonstrated that the Essure placement was feasible in these women and resulted in a 39% pregnancy rate, and 28% live birth rate per transfer(Arora, Arora, & Cahill, 2014). One randomized trial demonstrated that hysteroscopic tubal occlusion with Essure device (26.2%, 11/42) was associated a significantly lower ongoing pregnancy rate of IVF than laparoscopic salpingectomy (Dreyer et al., 2016)

As Essure was not available and a microcoil called "TORNADO" is available in China, some Chinese studies reported that the placement of microcoil under X-ray control in infertile women with hydrosalpinges was associated with good results compared with those with no intervention (Li et al., 2008). However, the effectiveness of this treatment has not been compared with laparoscopic tubal ligation or salpingectomy.

In the present retrospective study, we compared the ongoing pregnancy rate of IVF following tubal occlusion by microcoil placement versus laparoscopic tubal ligation for hydrosalpinges..

## Materials and Methods

### Study design and participants

A retrospective study of infertile women with hydrosalpinx attending the Assisted Reproduction clinic, Shanghai First Maternity and Infant Hospital for IVF from Jan 2014 to Jan 2016 was undertaken. Ethical approval was not required for the retrospective analysis.

Women who had undergone IVF in the Centre were included if they fulfilled the selection criteria. The inclusion criteria were (1) women aged less than 43 years; (2) having indications for IVF and (3) presence of unilateral or bilateral hydrosalpinges on pelvic scanning and confirmed by hysterosalpingography (HSG) or laparoscopy. Women were excluded if they had: (1) severe pelvic adhesion; (2) a history of pelvic infection in the last 6 months; (3) uterine fibroids distorting the uterine cavity and interfering with microcoil placement and 4) hydrosalpinges that were already blocked proximally.

Women were offered either the microcoil placement (the occlusion group) or laparoscopic tubal ligation (the ligation group) at the discretion of the attending

physicians or subject to the wishes of the couple after they were fully counselled.

**Surgical procedures**

**Tubal occlusion with placement of microcoil under X-ray control**

The woman was placed in the lithotomy position on the X-ray bed. After disinfection, a guiding tube passed through the cervix and the uterine cavity to the corner of the uterus under X-ray surveillance. Then a microcatheter entered the interstitial part of the Fallopian tube through the guiding tube. A 0.018 inch(0.46mm)diameter microcoil (TORNADO Embolization Microcoil$^{TM}$ ,MWCE-18S-4/2)(COOK MEDICAL, Bloomington, IN, USA) was inserted into the interstitial and isthmus of the Fallopian tube through a microcatheter to block the passage of the tubal cavity (uni- or bilateral depending on whether one or two hydrosalpinges were present). The proximal end of the micrcoil exceeded 5-10 mm from the distal end of the guiding tube. After exiting the catheter, the position of the micrcoil was rechecked by salpingography to confirm the success of the procedure. A tubal block was indicated when the distal end of the tube was not visible at the time of salpingography.

**Laparoscopic tubal ligation**

All women received antibiotic prophylaxis (cefuroxime 1500 mg and metronidazole 500 mg intravenously). During laparoscopy, tubal ligation was performed by bipolar diathermy applied at two separate sites on the isthmic segment of the hydrosalpinges, 1 and 1.5 cm from the corneal section of the Fallopian tube. Unilateral or bilateral

tubal ligation was performed, depending on whether unilateral or bilateral hydrosalpinges were present. Distal fenanstration of the the Fallopian tube was carried out to release the fluid inside.

**Measurement of ovarian reserve markers**

Women were checked for serum FSH levels and scanned for antral follicle count (AFC) in the follicular phase (cycle day 2–4) 4 weeks before and after the treatment for hydrosalpiniges. FSH levels were determined by immunometric assay (Delfia, PerkinElmer, Waltham, MA, USA), with a lower detection limit of 0.5 IU/L and an inter-assay coefficient of variation (CV) of 7%. E2 was determined by competitive immunoassay (Delfia, PerkinElmer), with a lower detection limit of 20 pmol/l and an inter-assay CV of 10%.

**Ovarian stimulation**

Women started their IVF with ovarian stimulation using either the long agonist or antagonist protocols 8-12 weeks after the treatment of their hydrosalpinges. For the long protocol, gonadotropin-releasing hormone analogue (GnRHa) was given for pituitary desensitization. On Day 2-3 of the menstrual cycle and they underwent transvaginal ultrasound examination and serum estradiol measurement. Human menopausal gonadotrophin (hMG)(Lebaode, Lizhu, china) or recombinant FSH (Puregon, Organon, Dublin, Ireland or Gonal F, Merck Serono S.p.A, Modugno, Italy) was given at 150–225 IU per day based on the AFC count, age of women and

previous ovarian response, according to the standard operation procedures of the centre. Ovarian response was monitored by serial transvaginal scanning with or without hormonal monitoring. Further dosage adjustments were based on the ovarian response at the discretion of the clinicians in charge. For the antagonist protocol, antagonist 0.25mg daily (Orgalutran, Organon, Dublin, Ireland) was given from the $6^{th}$ day of ovarian stimulation until the day of ovulation trigger.

When three leading follicles reached ⩾18 mm in diameter, hCG 10,000 IU (Lizhu, China) or Ovidrel 250 microgram (Merck Serono S.p.A., Modugno, Italy) were given to trigger final maturation of oocytes. Oocyte retrieval was performed around 36 hours later.

**Fertilization and embryo evaluation**

Semen samples were prepared by the swim-up procedure. About 2 hours after oocyte retrieval, each oocyte was inseminated with approximately 20,000–30,000 motile spermatozoa. If total number of motile sperm is $<10^5$ after washing or normal morphology is <4%, intracytoplasmic sperm injection (ICSI) was performed. Oocytes were decoronated and checked for the presence of two pronuclei to confirm fertilization. Embryos were graded on day 3 after retrieval as grade one to grade six according to the evenness of each blastomere and the percentage of fragmentation (Sparks, 2000). Embryos of 6-8 cells and of grade one or two were regarded as top quality embryos.

A maximum of two embryos was replaced on day 3 after retrieval under transabdominal ultrasound guidance. Luteal phase support was given by vaginal or intramuscular progesterone at the discretion of the attending physicians. A urine pregnancy test was carried out 2 weeks after the transfer. Those with a positive urine pregnancy test were scanned after 2 weeks to identify the number and presence of a gestation sac with a fetal pole. All pregnant women were contacted or traced for the pregnancy outcomes after delivery or miscarriage.

**Outcomes**

The primary outcome was the ongoing pregnancy rate and the secondary outcomes include positive pregnancy test, miscarriage, multiple pregnancy, ectopic pregnancy and implantation rates. Ongoing pregnancy was the presence of at least one fetus with fetal pulsation on ultrasound beyond 10 weeks. Miscarriage rate was defined as the number of miscarriages before 20 weeks divided by the number of women with positive pregnancy test. Multiple pregnancy was defined as a pregnancy with more than one gestational sac detected on ultrasound at 6 weeks. Implantation rate was calculated as the number of gestational sacs seen on scanning divided by the number of embryos replaced.

**Statistical analyses**

One sample of the Kolmogorov–Smirnov test was used to test the normal distribution of continuous variables. Continuous variables were given as mean ± SD if normally

distributed, and as median (interquartile range) if not normally distributed. Statistical comparison was carried out by Student's t-test, Mann–Whitney U-test for continuous variables and chi-square test for categorical variables, where appropriate. And logistic regression analysis was used to analyse factors predicting the ongoing pregnancy rate. Statistical analysis was performed using the Statistical Program for Social Sciences (SPSS Inc., Version 14.0, Chicago, USA). The two-tailed value of $P<0.05$ was considered statistically significant.

**Results**

Out of 310 women screened, 157 women did not meet the selection criteria and therefore 153 women were included. Embryo transfer was either canceled or postponed in 20 women in the occlusion group and 13 in the ligation group because of failed fertilization or no transferable embryos and risk of ovarian hyperstimulation syndrome, or suspected endometrial polyps or elevated serum progesterone level. Therefore, 127 women having fresh embryos transfer were analysed.

No significant differences were found between the two groups with regard to age of women, basal FSH level, basal antral follicle count, duration of infertility, body mass index, primary infertility and proportion of unilateral or bilateral hydrosalpinges and duration between IVF and the tubal blockage.. Cycle characteristics such as the stimulation protocol, dosage/duration of FSH/hMG, the number of oocytes and the number of embryos transferred were comparable (Table I).

The ongoing pregnancy [35.0% (21/60) vs 58.2% (39/67), P=0.009, RR=0.60(0.40-0.89)], the positive pregnancy test [43.3% (26/60) vs 64.2% (43/67), P=0.02, RR=0.68(0.48-0.95)] and implantation rates [33.3% (34/102) vs 49.5% (56/113), P=0.016, RR= 0.67(0.48-0.94)] were significantly lower in the micrcoil group than those in the tubal ligation group (Table II). Both groups showed comparable miscarriage, multiple pregnancy and ectopic pregnancy rates. A multivariate logistic regression using the enter method by the women's age, duration

of infertility, stimulation protocol (agonist/antagonist), insemination method, antral follicle count, FSH/HMG dosage, the treatment method of hydrosalpingx, number of oocytes obtained, number of embryos replaced revealed that only age of women[OR=0.876(0.789-0.963)] and the treatment method of hydrosalpingx [OR=1.421(1.074-2.034)] predicted the ongoing pregnancy rate of IVF. (Table III)

There were no difference in serum FSH level and AFC before and after the treatment of the hydrosalpinges in both groups (Table IV).

**Discussion**

In the present study, we found that the ongoing pregnancy rate in the microcoil occlusion group was significantly lower than that in the tubal ligation group. Our results were in agreement with that of the randomized study (Dreyer, et al., 2016) which showed hysteroscopic proximal tubal occlusion with Essure device (26.2%, 11/42) was associated a significantly lower ongoing pregnancy rate than laparoscopic salpingectomy (55.8%, 24/43) in women with hydrosalpinges prior to IVF. However, only 87 women were recruited in the study and Essure device placed under hysteroscopy was recently withdrawn from the market.

The microcoils have been used for sterilisation for a long time (Hurskainen et al., 2010; Smith, 2010). It is 4 cm in length and 2 mm in diameter in its expanded form. The nickel titanium outer coil serves as an anchor within the uterotubal junction.

While polyethylene fibres run along through the inner coil and induce a tissue reaction leading to necrosis, fibrosis, adhesion of the inner wall of the Fallopian tube and eventually formate scars to block the tubal lumen. The role of the microcoil in hydrosalpinx is likely to be by a similar mechanism of tubal occlusion, which prevents hydrosalpingeal fluid from entering the uterine cavity.

The lower ongoing pregnancy of IVF following tubal occlusion by microcoil placement versus laparoscopic tubal ligation can be explained by a negative influence of the microcoil on the endometrial environment. The necrotic tissue caused by the embolization may release alkaline phosphatase, causing lymphocyte aggregation(Yang and Ma, 2015), and even extend to the uterine cavity leading to adverse endometrial environment for implantation.

The success rate of tubal occlusion with microcoil was reported to be 81-98% and about 3.5% of women were found to have incomplete tubal obstruction 3 months after the microcoil placement (Mijatovic, et al., 2010). In the present study, the tubal occlusion effect was confirmed in all women by HSG at the end of the intervention but we did not further evaluate the tubal occlusion three months later prior to IVF. It is possible the expulsion or shifting of microcoils in some women may affect the tubal occlusion status. This may be another reason explaining the lower ongoing pregnancy rate in the microcoil group.

At present, there is a controversy whether microcoils should be placed under X-ray or

hysteroscopy. Most international studies used hysteroscopy (Arora, et al., 2014) while some Chinese reports used X-ray with good results. Ma et al compared the efficacy of intervention under X-ray or hysteroscopy for women with hydrosalpinges in dense pelvic adhesions (Yang and Ma, 2015), the microcoil placement may also be less accurate than direct viewing under a hysteroscopy. The comparison of X-ray and hysteroscopy has not been performed in women with hydrosalpinges.

The most common complication of tubal occlusion by microcoil placement is tubal perforation, which was 1-3% after use of Essure. Other complications include movement to abdominal cavity (3%) and shifting to other positions (0.5%) (Cooper, Carignan, Cher, Kerin, & Selective Tubal Occlusion Procedure Investigators, 2003; Kerin et al., 2003). TORNADO was used in the present study and is softer than Essure. In particular, the fibres run along through the inner coil can increase the compatibility with inner wall of the Fallopian tube, reduce the mobility, and effectively prevent the microcoil from expulsion when it stretches 30-50mm's long. There is no study reporting the expulsion, shifting or other complications of TORNADO.

Some studies suggested that salpingectomy may affect ovarian function by interfering with ovarian blood flow (Gelbaya et al., 2006; Lass, et al., 1998; Ye, Yang, & Sun, 2015). Our study showed no differences between serum FSH levels and AFC before and after the intervention.

Our study is limited by its retrospective design, a small sample size and reporting ongoing pregnancy rates. Therefore further large randomised trials would be needed to confirm these findings.

In summary, we found a lower ongoing pregnancy rate of IVF in women with hydrosalpinges following tubal occlusion by microcoil placement under X-ray when compared with laparoscopic tubal ligation.

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Table I. Demographic and cycle stimulation characteristics

| | Microcoil group (n=60) | Ligation group (n= 67) | P value |
|---|---|---|---|
| Female age (years) | 32 (29 - 36) | 33 (29 - 37) | 0.476 |
| Infertility duration (years) | 4 (2 - 6) | 4 (2 - 6) | 0.457 |
| Primary infertility n (%) | 36(60.0) | 38(56.7) | 0.708 |
| Bilateral hydrosalpinges (%) | 34(56.7) | 35(52.3) | 0.617 |
| Basal antral follicle count | 13.0 (9.0 - 20.0) | 14.0 (8.0 - 16.0) | 0.432 |
| Basal FSH level (IU/L) | 6.2 (5.2 - 7.0) | 6.3 (5.3 - 7.2) | 0.543 |
| Body-mass index (kg/m2) | 21.8 (20.1 - 23.8) | 21.6 (20.0 - 23.7) | 0.578 |
| Duration between IVF and the tubal blockage (weeks) | 10 (8-12) | 9(7-11) | 0.550 |
| Stimulation protocol (%) | | | 0.964 |
| Long agonist | 32(53.3) | 36(53.7) | |
| Antagonist | 28(46.7) | 31(46.3) | |
| Insemination method(%) | | | 0.621 |
| IVF | 41(68.3) | 43(64.2) | |
| ICSI | 19(31.7) | 24(35.8) | |
| Days of stimulation | 10 (9 - 11) | 10 (9 - 11) | 0.654 |
| Endometrial thickness (mm) | 11.9 (10.0 - 13.7) | 11.7 (10.2 - 13.3) | 0.676 |
| Total FSH dosage (IU) | 2228 (1650 - 3000) | 2400 (1800 - 3000) | 0.285 |
| Oestradiol level on HCG day (pg/ml) | 1540(1235-3435) | 1689(1134-3459) | 0.454 |
| No. of oocytes obtained | 11 (7 - 15) | 11 (7 - 14) | 0.935 |
| No. of oocytes fertilized | 6 (4 - 10) | 7 (4 - 10) | 0.765 |
| No. of embryos transferred | 1.6(1.2-1.9) | 1.7(1.3-1.9) | 0.895 |
| No. of transferrable embryos | 4 (3 - 6) | 4 (3 - 6) | 0.455 |

Data are median (25th and 75th percentile)or number (%)

Mann-Whitney U test or chi-square test

Table II. Comparison of pregnancy outcomes

| | Microcoil group (n=60) | Ligation group (n=67) | P value | Relative risks (RR) | 95% CI for the RR |
|---|---|---|---|---|---|
| Positive pregnancy test (%) | 26/60 (43.3) | 43/67 (64.2) | 0.02* | 0.68 | 0.48-0.95 |
| Ongoing pregnancy rate(%) | 21/60 (35.0) | 39/67 (58.2) | 0.009 * | 0.60 | 0.40-0.89 |
| Implantation rate (%) | 34/102 (33.3) | 56/113 (49.5) | 0.016 * | 0.67 | 0.48-0.94 |
| Multiple pregnancy rate(%) | 9/26(34.6) | 14/43(32.3) | 0.861 | 1.06 | 0.54-2.10 |
| Miscarriage (%) | 4/26 (15.4) | 4/43 (9.3) | 0.46 | 1.6 | 0.45-6.05 |
| Ectopic pregnancy rate (%) | 1/26 | 0/43 | 0.38 | 0.96 | 0.89-1.03 |

Data are number (%)
using Chi-square test or Fisher's exact test

Table IV. Comparison of ovarian reserve tests before and after treatment of hydrosalpinges

| | Before treatment | After treatment | P value |
|---|---|---|---|
| Occlusion group (n=60) | | | |
| FSH (IU/L) | 6.5 (5.2 - 7.1) | 6.6 (5.2 - 8.3) | 0.52 |
| AFC | 13.3(9.0 - 20.3) | 14.2 (8.0 - 16.0) | 0.12 |
| | | | |
| Ligation group (n=67) | | | |
| FSH (IU/L) | 6.3 (5.3 - 7.4) | 6.6 (4.8 - 7.9) | 0.22 |
| AFC | 14.2(10.1 - 16.2) | 14.0 (9.1 - 18.3) | 0.10 |

Data are median (25th and 75th percentile), using Mann-Whitney U test

Table III. Logistic regression analysis of factors predicting ongoing pregnancy

| | B | OR | P value | 95.0%C.I.for EXP(B) | |
|---|---|---|---|---|---|
| | | | | Lower | Upper |
| Women's age | -0.070 | 0.876 | 0.025 | 0.789 | 0.963 |
| Duration of infertility | 0.003 | 1.003 | 0.441 | 0.995 | 1.012 |
| Stimulation protocol | 0.070 | 1.073 | 0.928 | 0.232 | 4.952 |
| Insemination method | 0.016 | 1.017 | 0.268 | 0.987 | 1.047 |
| Antral follicle count | -0.002 | 0.998 | 0.880 | 0.972 | 1.025 |
| FSH/HMG dosage | 0.013 | 1.013 | 0.979 | 0.387 | 2.662 |
| Treatment method of hydrosalpingx | 1.813 | 1.421 | 0.015 | 1.074 | 2.034 |
| No. of oocytes obtained | 0.020 | 1.020 | 0.470 | 0.966 | 1.077 |
| No.of embryos replaced | 0.239 | 1.270 | 0.352 | 0.768 | 2.100 |
| Oestradiol level on HCG day | 0.420 | 1.522 | 0.077 | 0.955 | 2.425 |
| Endometrial thickness | 0.036 | 1.037 | 0.809 | 0.773 | 1.392 |
| No. of transferable embryos | 0.565 | 1.760 | 0.136 | 0.837 | 3.703 |