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Comparing the effect of office hysteroscopy with endometrial scratch versus office hysteroscopy on intrauterine insemination outcome: a randomized controlled trial☆,☆☆

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ABSTRACT

Objective: To evaluate the role of endometrial injury in the cycle preceding ovarian stimulation for intrauterine insemination (IUI) cycle on the clinical pregnancy rate.
Study design: This was a prospective randomized controlled trial which included three hundred and thirty two infertile women with an indication for IUI. The subjects were randomly divided into two groups. The intervention group (group A) ($n = 166$) subjects underwent office hysteroscopy with endometrial injury using grasping forceps with teeth, while the control group (group B) ($n = 166$) subjects underwent office hysteroscopy alone without endometrial injury. Primary outcome was clinical pregnancy rate.
Results: There were no significant differences in baseline or clinical characteristics between the groups. There were no significant differences in clinical pregnancy rate [13.8% (23/166) versus 12% (20/166); RR 1.15 (95% CI 0.66–2.01), $p = 0.62$]. The abortion rate [4.3% (1/23) versus 15% (3/20); RR 0.29 (95% CI 0.03–2.57), $p = 0.27$], the multiple pregnancy rate [13% (3/23) versus 15% (3/20); RR 0.87 (95% CI 0.20–3.83), $p = 0.85$] and the live birth rate [13.6% (22/166) versus 10.4% (17/166); RR 1.28 (95% CI 0.71–2.32), $p = 0.42$].
Conclusion: There is no evidence of significant difference on the clinical pregnancy rate when endometrial scratching during hysteroscopy is compared to only hysteroscopy in women undergoing IUI.

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Introduction

The first line of fertility treatment frequently applied in the world is intrauterine insemination (IUI) with ovarian hyperstimulation [1]. For pregnancy to occur we need a good quality oocyte and a good quality sperm to result in a good quality embryo to implant in a receptive endometrium [2]. An important cause of infertility would be a failure of uterine receptivity and failure of implantation [3]. Implantation divided into four steps: apposition, adhesion, attachment and invasion [3], every step of the implantation process depends on many enzymatic interactions [4–6].

The mid-secretory phase of the menstrual cycle (days 19–23), is the most receptive period of the endometrium which is called the window of implantation (WOI) [7].

A recent Cochrane review found that we can improve the endometrial receptivity by scratching the endometrium by any mean such as curette or biopsy [8].

A lot of researches done to evaluate the effect of endometrial scratching on the implantation rate on intra cytoplasmic sperm injection (ICSI) cycles especially in cases of repeated implantation failure (RIF) and found a beneficial effect of endometrial scratching [9,10].

In the contrary two studies failed to found a beneficial effect of endometrial scratching on ICSI outcome [11,12].

Following success of endometrial scratch prior to ICSI cycles, its application in couples trying to conceive by IUI was also investigated once by Abdelhamid among 150 patients [13].

☆ The study has been approved by the Institutional Review Board.
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Abdelhamid found that endometrial scratching prior to IUI significantly increases pregnancy rates [13], the main weakness of Abdelhamid study is the lack of sample size calculation and we calculated the sample size in our study to overcome this drawback.

We conducted a trial on a group of patients' candidate for intrauterine insemination (IUI), to evaluate the effect of endometrial scratch on the cycle preceding the IUI on the clinical pregnancy rate, ongoing pregnancy rate, live birth rate and abortion rate.

Materials and methods

This was a prospective, randomized; controlled study was conducted in accordance with CONSORT guidelines (http://www.consort-statement.org), carried out during the period from February 2012 to October 2014 at the Department of Obstetrics and Gynecology, Kasr Al-Aini Teaching Hospital, Cairo University, Cairo, Egypt; and Middle East IVF Center, Giza, Egypt. Institutional Review Board approval was obtained, and informed consents from participants were attained before randomization. The study protocol was registered at the clinical trial.gov clinical Trial Registry with clinical trial identifier (NCT01544426) in accordance with the Declaration of Helsinki and the recommendations of the Committee of Medical Journal Editors.

Inclusion criteria

All patients were subjected to careful history taking, general examination, and local gynecologic examination. Inclusion criteria were mild male factor or unexplained infertility, women partner aged <39 years with regular menstrual cycles, body mass index (calculated as weight in kilograms divided by the square of height in meters) <32 kg/m^2, normal uterine cavity with normal thin endometrium (less than 5 mm; to exclude the presence of endometrial lesion as polyp) on day 4 of menstruation, and normal fallopian tubes as documented by hysterosalpingography, and/or laparoscopy, and normal hormonal profile including follicle stimulating hormone (FSH), luteinizing hormone (LH), thyroid stimulating hormone (TSH), testosterone (T), and prolactin (PRL) serum levels. Male factor infertility was defined as a sperm count of less than 15×10^6/mL, a total motility of less than 40%, or normal forms less than 4%—per WHO criteria [14], mild male factor infertility was defined as the presence of abnormal semen parameters but with >5% normal morphology and $>5 \times 10^6$/mL motile spermatozoa recovered after sperm preparation.

Ovulation was documented with midluteal serum progesterone (P) levels exceeding 5 ng/ml. The diagnosis of unexplained infertility was based on normal semen analysis using World Health Organization criteria, documentation of ovulation with a midluteal serum P level exceeding 5 ng/ml, normal hysterosalpingography and/or diagnostic laparoscopy.

Exclusion criteria

Couples were excluded if they were diagnosed with infertility due to other causes, significant cardiovascular, pulmonary, renal, neurologic, or hepatic problems, or presence of ovarian cyst >2 cm before stimulation or abnormal endometrial cavity due to submucous myoma encroaching on the cavity, endometrial polyp, intrauterine synechia (Asherman syndrome), septate or bicornuate uterus.

Sample size calculation

Prior data indicated that the clinical pregnancy rate in IUI cycles was 12% [15]. If we assume that the clinical pregnancy rate in IUI after endometrial scratch will double, we will need to study 160 cases in each arm to be able to reject the null hypothesis that the failure rates for experimental and control subjects are equal with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05. We will use an uncorrected chi-squared statistic to evaluate this null hypothesis. Additionally, to compensate for discontinuations, we recruited 175 women in each arm.

Randomization

Three-hundred thirty two eligible patients were randomly allocated to either the intervention group (group A) or the control group (group B; Fig. 1); with the use of computer-generated random number tables and opaque sealed envelopes containing the participants' group allocation. The envelopes were prepared every 24 h at a location different from the study site and sent to an assigned nurse, who opened each envelope just before the office hysteroscopy (OH).

Office hysteroscopy technique

All patients underwent postmenstrual OH between days 4 and 7 of the cycle preceded the IUI cycle (except in patients with irregular bleeding). The patients were blinded to group allocation. A rigid 30° 4-mm hysteroscopy (Karl Storz Endoscopy) was used without anesthesia or analgesia. The uterine cavity was distended with normal saline solution at a pressure of 100–120 mmHg. The vaginoscopic "no touch" technique was followed; no speculum or tenaculum was used.

In the intervention group (A), office hysteroscopy and endometrial scratching were done once in the follicular phase at day 4–7 (D4–D7) in the cycle preceding the IUI cycle using a grasping forceps with teeth.

In the control group (B), office hysteroscopy was done without endometrial scratching.

Outcome measures

The primary outcome measure was clinical pregnancy rate, and the secondary outcome measures were abortion rate, multiple pregnancy rate and live birth rate.

Ovarian stimulation

All women underwent the same mild controlled ovarian stimulation protocol. Clomiphene citrate (Clomid; Aventis Pharma, Cairo, Egypt) 100 mg/day was administered orally from day 3 to day 7 of the cycle. Human menopausal gonadotropin (hMG [Merional; IBSA, Lugano, Switzerland]) 75 IU/day was administered intramuscularly from day 6 to day 8. Transvaginal ultrasonography was performed on day 9 of the cycle for assessment of the number and diameter of follicles, as well as endometrial thickness and pattern. The administration of hMG was continued and the dose was adjusted, if necessary. When 2–3 follicles with a diameter of at least 18 mm were present, human chorionic gonadotropin (hCG [Choriomon; IBSA, Lugano, Switzerland]) 10 000 IU was administered intramuscularly. A single insemination was performed 36 h after hCG administration.

Oral supplementation with 30 mg of dydrogesteron was given daily (Duphaston; Abbott Healthcare Products B.V., The Netherlands, Packed by Pharco Pharmaceuticals, Alexandria, Egypt) to support the luteal phase, which started two days after the administration of hCG, and this was continued until a pregnancy test was performed.

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