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ORIGINAL ARTICLE

Effect of time interval between human chorionic gonadotropin injection and intrauterine insemination on pregnancy rate

Badeea S. Soliman

Department of Obstetrics & Gynecology, Faculty of Medicine, Zagazig University, Egypt

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KEYWORDS

Intrauterine insemination;
hCG;
Timing;
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Abstract *Background:* Controlled ovarian stimulation with intrauterine insemination (COS/IUI) is an established tool in infertility treatment. There has been debate regarding the optimum time at which IUI can be done to yield the peak pregnancy rate.

Objective: To compare the effect of postponing IUI 48 h after hCG injection with current practice protocol, on pregnancy rate. *Study design:* A randomized, controlled study. *Setting* was at Cytogenetic and Endoscopy Unit, Zagazig University Hospital.

Material and methods: This study included one hundred and forty-one infertile couples that had been scheduled for artificial insemination by husband semen. Women were divided into 2 groups: the study group, including seventy women in whom IUI was performed 48 h after hCG injection and the control group, including seventy-one women in whom IUI was done 36 h after hCG injection.

Results: The total and clinical pregnancy rate was significantly higher in the study group compared to the control group (25% vs. 10.6% $p = 0.03$ and 20.31% vs. 7.57% $p = 0.03$ respectively).

Conclusion: This study showed a statistically significant increase in pregnancy rate in women with delaying IUI 48 h after hCG trigger, compared to the pregnancy rate in the women having the standard procedure.

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1. Introduction

Intrauterine insemination (IUI) with ovarian stimulation has been empirically applied for treatment of anovulation,

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unexplained infertility as well as mild male factor infertility (1). Unexplained infertility is defined as delayed conception in which all the standard investigation failed to detect a cause. Its prevalence ranges between 22% and 28% (2). The rationale for using of IUI in the management of unexplained infertility is deposition of a bolus prepared, motile, concentrated, morphologically normal sperm as near as possible to the oocytes. IUI in stimulated cycles may be considered when IVF is not affordable or while awaiting for IVF(3).

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Ovulation usually occurs from 24 to 56 h after natural LH surge with a mean time of 32 h (4). However, oocytes can only be fertilizable six hours after ovulation. Furthermore, oocytes are fertilizable for a short period (12–16 h) after ovulation (5). This means that, at the time of ovulation even if oocytes meet the spermatozoa in the fallopian tube still there are 6 h for starting the fertilizable period of the oocytes. Based on the above data, IUI should be done after observation of ovulation. Therefore, in the majority of IUI studies, the insemination is performed 32–36 h after hCG administration (6).

Endometrial receptivity remains a difficult dilemma, with the implantation window extending from days 20 to 24 in the natural cycles, which matches with 5–9 days after ovulation. This time frame is changeable, and many studies have shown successful pregnancies with longer or shorter time intervals (7). Higher cumulative pregnancy rate was reported when IUI is timed after follicular rupture in non-male factors as the only controlling factor is oocyte availability which has limited survival time (8).

Regardless the apparent efficacy of superovulation IUI, it has been difficult to select the best timing for insemination after hCG administration. It is supposed that IUI at 32–38 h after hCG injection would provide the best results (9). The scientific basis for selecting that timing for insemination is determined according to ultrasonography and hormonal studies that have shown that the occurrence of follicle rupture within 48 h after hCG is 68% in the spontaneous cycles (10) and 81% in the stimulated cycles (11). Ghanem et al. (12) reported that follicular rupture was observed by TVS at time of IUI (36 + 2 h later) in cycles ranged between 68% and 76%.

Optimal time of intrauterine insemination (IUI) is still a controversial topic in infertility treatment. Despite all efforts to improve pregnancy rates, overall success of IUI is still not acceptable. Many studies have tried exploring different choices regarding the scheduling of the procedure, while some encouraged performing IUI even before ovulation, others selected to wait after triggering of ovulation, and some even tried carrying out the procedure twice in the same cycle to improve the pregnancy rate. Hence, this study was designed to compare the effect of postponing IUI 48 h rather than 36 h after hCG injection (standard method) on the pregnancy rate.

2. Patients and methods

The study was conducted in the Cytogenetic and Endoscopy Unit, Zagazig University Hospital, as a randomized controlled trial between February 2013 and May 2015. After approval of the local ethics committee, a written informed consent was obtained from all women before starting. The flowchart of contributors had been shown in Fig. 1.

The study included 141 referred women those with either unexplained or mild male factor infertility who underwent ovulation induction and intrauterine insemination. They fulfilled the following inclusion criteria: female age 20–37 years with normal hormonal profile [FSH, LH] 3–10 mIU/ml and 1.8–8.5 mIU/ml respectively which were done at cycle day 2–5 of the menstrual cycle, patient's both tubes and normal uterine cavity as assessed by HSG, and accepted semen analysis in cases with mild male factor. Exclusion criteria were patients with endometriosis, a history of ovarian hyper stimulation syndrome (OHSS), or female factor. The following

criteria were mandatory for diagnosis of unexplained infertility (13): Acceptable seminal analysis, bilateral patent tubes, no tubal kinking and no peritubal adhesion according to hysterosalpingography and/or laparoscopy and confirmed ovulation as supported by regular cycles and mid luteal serum progesterone levels >10 ng/ml. Mild male factor infertility is well-defined when 2 or more semen analyses have 1 or more items below the 5th centile as defined by the WHO, 2010 (14); therefore, in post-processing semen sample a sperm count more than 10 million per ml and sperm motility grade (a) and (b) $\geq 50\%$ were essential.

2.1. Ovarian stimulation, folliculometry and insemination

Basal transvaginal pelvic ultrasonography (TVS) was mandatory before starting. Controlled ovarian stimulation (COS) was done by combined sequential protocol: Clomiphene Citrate (Clomid 50 mg, sanofi aventis LLC. USA.) starting 2 tablets daily from 2nd day till the 6th day of the menstrual flow followed by Human Menopausal Gonadotropins (hMG) (Menogon, Ferring) 75 IU/day IM. The dose of hMG ranged from 75 to 225 IU/ml according to the patient's response. Serial TVS started at cycle day 7 for assessment of follicular growth and endometrial thickness and continued every other day till a mean follicular diameter reaching ≥ 18 mm (1 – 3 follicles). Then 10,000 units of hCG (Choriomon, IBSA, Institut Biochimique SA) was given IM, and IUI was performed either 48 h or 36 h later, according to which group the patients were randomized to. Patients were divided randomly by using random number table (computer), software Open Epi version 3.21 into two approximately groups: study group 70 women in whom insemination was done 48 h after hCG while in the control group 71 women in whom insemination was done 36 h after hCG. Patients were assigned to either group by the randomization known while allocation concealment concentrated on preventing selection and confusing biases.

In all cases sperm preparation was done by double wash swim-up technique using Ham's F10 culture media. The final sperm pellet was suspended in a total of 0.5 ml sperm wash media. Insemination was done in the lithotomy position with an empty bladder. After insertion of Cusco speculum, the cervix was cleaned with a sterile saline. The cervical lip may be held by a volsellum if necessary. The washed sperm sample was loaded into a IUI catheter, and after that the catheter was inserted through the cervical canal and into the uterine cavity. Used IUI catheter was Sperm TRANS IUI CATHETER (Garkheda Aurangabad 431005, INDIA). Without touching the fundus, the sperm suspension was gradually released. Immediately following the IUI the patient was discharged and normal activity could be resumed.

Luteal phase support by vaginal progesterone suppositories 200 mg (Prontogest, GMP Marcyrl) twice daily was started at day of insemination for two weeks till pregnancy test and continued for 2 weeks more if it is positive. The main outcome measurements were the total pregnancy rate and biochemical and clinical pregnancy rates. A total pregnancy (all cases with a positive pregnancy test) was defined as a finding of plasma β -hCG concentration >10 mU/ml two weeks after IUI. Chemical pregnancy is unsuccessful pregnancy and the only evidence that an early pregnancy existed is the measurement of hCG in a woman's blood or urine. A clinical pregnancy

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