# Different factors affecting the success of intrauterine insemination

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## Abstract

**Objective:** The purpose of this study was to investigate the influence of various factors on the outcome of intrauterine insemination (IUI) as a trial for improving the quality of health care provided for women with infertility problems as well as infertility center outcomes.

**Methods:** Cohort study conducted over two years between December 2016 and December 2018 in IVF\ICSI center. Two hundred forty-nine couples diagnosed with different infertility etiologies underwent 487 cycles of IUI were enrolled. Ultrasound follicular measurements were recorded around time of ovulation as well as different factors were collected and compared between pregnant and non-pregnant groups. Main outcome measures were clinical pregnancy rate and risk of OHSS according to the woman's age, BMI, infertility type, different etiology of female infertility, the ovulation drug used and the quantity and size of ovarian follicles before hCG injection.

**Setting:** Department of Obstetrics and Gynecology, Suez Canal University Hospitals, Ismailia.

**Results:** Pregnancy was achieved in 21.4% of cycles enrolled in the analysis being significantly higher in women with mean follicular diameter of leading follicle of (19.8 +/- 1.97mm) in women with shorter infertility duration. The highest pregnancy rate was achieved in third IUI cycle.

**Conclusion:** Leading follicle mean diameter of 19.8 mm was the optimum diameter to trigger the ovulation and to have pregnancy. Early treatment of infertility is recommended as the success rate of IUI seems to get less with longer duration of infertility.

## Introduction

Numerous couples, as of late, are looking for clinical guidance for sub-fertility and its management. Intrauterine insemination (IUI) is one of the treatment modalities for helping fruitless couples [1].

IUI utilizing various strategies for semen readiness is viewed as a more affordable and less intrusive treatment choice than other assisted reproduction procedures [2]. Additionally, it tends to be performed with or without controlled ovarian hyperstimulation (COH). [1]

IUI is indicated for couples suffering unexplained infertility, anti sperm antibodies, endometriosis, cervical antagonistic vibe and male sexual dysfunctions like impotency, hypospadias, and retrograde ejaculation. [3]. The viability of IUI is generally acknowledged for couples in whom infertility is brought about by a male factor or whom etiology is unexplained. [4]

IUI joined with COH utilizing gonadotropins has been demonstrated to be increasingly viable treatment of sub-fertility when contrasted with

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planned vaginal intercourse [5,6], intra-cervical insemination [7], or with IUI in natural cycles [8], apparently on the grounds that it expands the quantity of accessible oocytes for fertilization as well as the quantity of spermatozoa that arrive at the oocyte.

Pregnancy rates after IUI could be impacted by numerous components, for example, maternal age, interval of sub-fertility, indication (etiology), number of pre-ovulatory (antral) follicles, endometrial thickness. [9,10] However, various specialists didn't concur the nature and validation of these criteria.

For instance, there are clashing information about the relationship between lady's age and pregnancy rates. [11] Furthermore, the count of pre-ovulatory follicles, [10] endometrial thicknesses [11,12] and absolute motile sperms that are inseminated [9,10] have likewise been accounted for as potential indicators for pregnancy rates.[10] Notwithstanding, the agreement is fading between them.[13,14].
This cohort meant to examine the value of different contributing factors in the prediction of IUI success and to assess their role regarding clinical pregnancy rate that resulted from IUI, for example; woman's demographics, infertility status, ovarian incitement technique and sperm quality parameters. The factors mulled over for our investigation depended on past productions and the individual experience.

## Research Design and Methods

Retrospective study among couples with a history of infertility (n=249) who were treated with IUI in IVF center. The data was collected between December 2016 and December 2018. The study protocol was approved by local institutional research ethics board in Benha University Hospital. Women underwent a basic fertility workup which was consisted of comprehensive medical history, hysterosalpingography (HSG), pituitary hormonal assays on the 1st five days of the menstrual cycle (FSH, LH and estradiol), semen analysis (the total motile sperms [TMS] count) and antral follicle count by transvaginal sonography (TVS).
Based on hospital data, there were 487 IUI cycles included. Women were excluded from the study if HCG trigger was postponed due to small follicular size, HSG showed bilateral tubal block, semen analysis of the partner showed sperm count of less than 5 million /ml , athsthenospermia more than 40% and women who lost follow up after the cycles.

For each couple, we registered maternal age, duration of infertility, primary or secondary and cause of female infertility were also investigated and recorded. Other parameters including the number and size of pre-ovulatory follicles, endometrial thickness, type of medication used in controlled ovarian hyper stimulation, cycle number and semen parameters were also recorded.

**Ovarian Stimulation:**
It was achieved by oral clomiphene citrate (clomid), different type of gonadotrophins available in our hospital or combination of both. The induction was started on the second or third day of the cycle and women were monitored until follicular size of > 18 mm achieved.

We used highly purified urinary FSH, recombinant-FSH (Gonal-F; Ares-Serono, Geneva, Switzerland; or HMG (Menogon , Ferring SAS, St. Prex, Switzerland). The initial dose of gonadotropin prescribed was (75 IU/day) depended on the woman's hormonal status, age and the infertility duration. After calculation, the starting dose was kept for five days, there after left for the function of the ovarian response as monitored by vaginal ultrasound on alternate days evaluating follicles' number and their sizes as well as endometrial thickness.

Ovulation was triggered when at least one follicle reaching(>18mm) diameter. Timed ovulation was triggered intramuscular injection of Urinary hCG 10,000IU of choriomon (IBSA pharmaceutical company, Switzerland). Women underwent insemination after 36 hours of the hCG injection).

**Intrauterine insemination procedure:**
Semen was obtained in a specifically designed comfortable near the laboratory two hours before the insemination and after at least48–72 hours of abstinence and left for 30 minutes at room temperature for liquefaction. The semen quality parameters (count, morphology, vitality and motility)was assessed using WHO guidelines 2010. [15]

A soft catheter (Wallace IUI catheter ©Cooper Surgical Medical Devices, Knardrupvej Målov Denmark)was used for the insemination process. The prepared semen (0.2–0.4 mL.) was slowly injected throughout the catheter which was placed at mid-uterine cavityover15 seconds.

The woman, within two weeks interval, was asked to perform a serum pregnancy test (quantitative B-hCG assay). If positive, it was repeated after 48 hours to check the doubling. The clinical pregnancy rate (CPR), confirmed with a gestational sac and fetal heartbeat on ultrasonography at 7-8 weeks, was the primary outcome measured.

**Statistical method**

MedCalc© version 12.5 (MedCalc© Software bvba, Ostend, Belgium) and IBM© SPSS© Statistics version 21 (IBM© Corp., Armonk, NY) were used for statistical analysis. The normality of numerically distributed data was examined with the aid of Shapiro-Wilk test. Normally distributed ones were shown as mean±SD and differences between groups were compared using the independent-samples (t-test). Median and inter-quartile range were used to present skewed numerical data and comparisons between groups were performed by the Mann-Whitney U test non-parametrically. Qualitative data were presented in number and frequency. Comparison of the two groups was performed by chi square test or Fisher's exact test whenever appropriate.

## Results

We studied 487 IUI cycle in 249 couple between December 2016 and December 2018. On average each couple underwent 1.8 cycles. The descriptive data of the study participants and IUI cycles' details are shown in table (1). The couples included suffered from primary infertility (56.9%) more than secondary type. Ovarian etiology of infertility (26.9%) was the commonest among cases studied, while oligospermia was the most prevalent finding between male cases. One third of cases (30.6%) was diagnosed as unexplained infertility, on the other hand (7.4%) of cases had mixed etiologies.

Clomid was the most commonly used drug for induction of ovulation either alone or in combination (32.8% and 43% respectively). r-FSH was the commonly used form of injectable hormones followed by HPuFSH. 21.4% of our participants came pregnant within three cycles as per our hospital protocols. Moreover, 6.1% of women developed OHSS during their induction cycles.

Table (2) shows comparison between multiple parameters between women who achieved pregnancy and those who did not. The socio-demographic data as age, parity and BMI were not significantly different between both groups. Also, the infertility criteria such; type and etiology were comparable between pregnant and non-pregnant women. On the other hand, infertility duration was significantly shorter in couples with successful trials.

When we compared drug types used for induction of ovulation as well as natural cycles, there was no statistically significant difference. The mean ± SD diameter of the leading follicle was significantly larger in the pregnant group, while the thickness of endometrial line and the diameter of second follicles did not show the same difference. Pregnancy was successfully achieved in 98 cycles out of the enrolled 487 cycles with a rate of 21.4%. Moreover, the pregnancy rate was statistically significant higher in the third IUI trial. Finally, the incidence of OHSS was comparable between both groups.

## Discussion

IUI is commonly performed initially as1stlinemanagement option for subfertile couples complaining of because of ejaculatory dysfunction, cervical hostility; moderate degree impaired semen parameters as well as mainly unexplained infertility. For decades, continuous work on various predictive factors that could influence the successful pregnancy rates and live birth ratio after IUI was published.

Different articles reported the influence of covariates such as female age, BMI, infertility duration, infertility type, hormone levels, different ovarian stimulation protocols, timing/induction of ovulation, pre-ovulatory follicles, endometrial thickness, frequency of IUI(once or double), sperm parameters and sperm washing procedures. [16]

Among those who achieved pregnancy, the woman's age was not significantly influencing the result (P value 0.544) this may be attributed to the relatively young age group of the studied population (29.74+/-5.24 year). Similar to our study, Brzechffa et al. [17] reported that the women's age lower than 40 years did not significantly affect the clinical pregnancy rate after IUI.

On the other hand, Bronte et al. [18] noticed a difference in the pregnancy rate in examined 9963 cycles that was age-related: (18.9%)below 26 years, (13.9%)between 26 and 30 years, (12.4%) between 31 and 35 years, (11.1%) between 36 and 40 years and declined to reach(0.5%)at 45 years or more (P<.001). Moreover, Goverde et al. [19] stated that, whatever the applied management (IUI or IVF), the case's age remained the most determinant factor for pregnancy chances. A meta-analysis showed that both woman's age as well as partner's age showed inverse relationship with clinical pregnancy rate. [16]

BMI did not significantly differ between both groups in our results. Although Dodson and Legros [20] observed that the obese woman needed higher doses of gonadotropin, they did not find any difference regarding BMI. A higher woman's BMI,up to 30 kg/m2, resulted in a significantly higher pregnancy rate (P = 0.0319). [16]

Different causes of infertility whether male, female, combined or even unexplained infertility did not significantly differ between groups. Our data showed that the longer the period of infertility the significantly lower possibility for the pregnancy to result from an IUI cycles.

Different results were found by Vlahos et al. who achieved pregnancy in 19.1% of their study population suffered anovulation Vs11% sub-fertile male factor, 10% in unexplained infertility and 9.1% in endometriosis. [21] The same result appeared by Dickey et al. who presented that the pregnancy was achieved in (46%) anovulation, (38%) male factor, (34%) endometriosis and (26%) tubal factor. [22] However, a univariate analysis revealed no statistical significant difference among couples complained of1ry or 2rysub-fertility. [16]

Other factors related to mode of induction of ovulation before insemination which might have an impact on pregnancy rate. When we compared the natural cycle versus stimulated cycle, there was no significant difference. In other studies evaluating this issue, Gallot-Lavallee et al. showed that when IUI was performed after monitoring natural cycles, the mean pregnancy rate was lower than gonadotropin stimulated cycles. [23]On the other hand, other reports revealed that the cumulative pregnancy rate reached 43% whether IUI was or was not preceded by ovulation induction. [24]Thus, in our center the regular practice is induction of ovulation in IUI cycle, and hence we don't have enough data (only nine women were followed up during natural cycles) to draw a conclusion on the pregnancy rate associated with natural cycle.

Ovarian stimulation seemed to be the only IUI contributing variable that significantly influenced pregnancy rate per cycle. IUI cycles associated with ovarian stimulation using clomid resulted in a significantly lower pregnancy rates(P = 0.0102) than HMG/r FSH stimulated ones. Hormonal measurements of estradiol or progesterone during stimulation as well as interval period between HCG injection and insemination process did not significantly influence on pregnancy rate. [16]

In contrast, our results did not show any significant difference between pregnant and non-pregnant participants regarding the drug used for ovarian stimulation. Also, the incidence of OHSS occurrence was comparable between groups and not related significantly to one drug or other. OHHS seems to be related more to the case demographics, number of pre-ovulatory follicles and the number of growing follicles during ovulation induction.

When we studied further procedure-related factors during ovulation induction follow-up using transvaginal ultrasound, the mean primary follicle diameter was the only factor that showed significant difference between both groups. The diameter of primary follicle was significantly larger among pregnant women. However, the diameter of secondary follicles or endometrial line thickness did seem to show the same significant difference.

Several studies tested the leading follicle size as a predictor of determining the IUI success. [25] Silverberg et al. reported that ovulation was successfully achieved better in cases with follicles (> 20 mm) on the hCG administration day during IUI cycles using human menopausal gonadotropins for ovulation induction and, but that was not related to the cycle outcome. [26]

Ghosh et al. reported that women with smaller follicle size (15 and 19.99 mm) achieved pregnancy in a higher rate when compared with cycles with the leading follicle of 20 mm, but they used clomid and gonadotropins. [27] Iberico et al. stated that the larger leading follicle (>20 mm) was associ-

ated with statistically non-significant higher pregnancy rates. [10]

Regarding number of follicles (>14 mm) in diameter priors to HCG administration, our study didn't show a significant effect on pregnancy rate. In contrast to our findings, Plosker and Amato showed when at least two follicles were recruited during induction of ovulation, the success possibility of IUI increased significantly (P<.006) from 2% for one follicle to reach 15% for at least two follicles. [28] Similarly, the study results of Iberico et al. and Erdem et al. who reported that the antral follicle count and number of dominant follicles before hCGare both significant independent factors for live birth ratio prediction. [10, 29]

In this work, endometrial thickness did not impact the pregnancy rate. Endometrial thickness in our studied groups recorded to be (11.18 +3. 03 mm). Although pregnancy was achieved in a higher rate among women with thicker ET (12.17 +-2.86) mm versus ET (11.47+-2.83mm), but this didn't significantly differ (P value = 0.156). In study done by Zenke et al. documented significant pregnancy rates' differences above and below a cut-off endometrial thickness of 8-10mm. [30]

Pregnancy rate rose successively with increasing order of IUI cycle (16%, 18% and 49%) respectively, presumably because of the improvement of ovulation with successive stimulation. Thus, (>80%) of pregnancies were achieved within three cycles. For that some authors like Plosker and Amato advised shifting treatment to IVF\ICSI cycle after three unsuccessful IUI trials. [28]

Although in 2013, the UK National Institute for Health and Care Excellence (NICE) recommended that IUI should not be routinely performed for couples with unexplained infertility, the study of Farquhar et al.,[31]showed that IUI with ovarian stimulation is a safe and effective treatment for women with unexplained infertility and an unfavorable prognosis for natural conception .Nevertheless, recently published higher quality multi-center RCTs fail to devalue IUI in the world of more advanced medically ART. Therefore, IUI, often in combination with OS, remains a first line treatment option for many infertile couples as this strategy is supported by the results of cost-effectiveness trials.

This study was conducted to find out the influence of different contributing factors for IUI, which is widely used for infertility management, success as well as risks as OHSS. IUI with clomid or any other stimulation drug, before using IVF/ICSI, is relatively cheaper and many couples will conceive without requiring extra management. IUI in stimulated cycles might not be effective in patients with long duration of infertility. In conclusion, duration of infertility and size of leading follicle at the time of ovulation triggering were the significant contributors for pregnancy in our study population. There is a rising need for bigger trials to investigate the order of treatment and efficacy of management options based on clinical outcomes as well as cost settings

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**Table (1):** shows the descriptivestatistics of study participants and IUI cycle details.

| Parameter | | | |
|---|---|---|---|
| **Age*(years)** | | | 29.74 ± 5.2 |
| **Parity#** | | | 0 ( 0- 2 ) |
| **BMI*(kg/m2)** | | | 28.39 ± 5.5 |
| **Infertility duration#(years)** | | | 4 (3- 7 ) |
| **Type of infertility** | **Primary infertility (n, %)** | | 260 (56.9%) |
| | **Secondary infertility(n, %)** | | 197 (43.1%) |
| **Etiology of infertility** | **Female factors** | **Unilateral tubal(n, %)** | 20 (4.4%) |
| | | **Ovarian(n, %)** | 123 (26.9%) |
| | | **Uterine(n, %)** | 7 (1.5%) |
| | | **None(n, %)** | 307 (67.1%) |
| | **Male factors** | **Oligospermia(n, %)** | 107 (23.4%) |
| | | **Asthenospermia(n, %)** | 59 (12.2%) |
| | | **Mixed(n, %)** | 33 (7.2%) |
| | | **None(n, %)** | 258 (56.5%) |
| | **Combined factors(n, %)** | | 34 (7.4%) |
| | **Unexplained(n, %)** | | 140 (30.6%) |
| **Induction of ovulation medications** | **None(n, %)** | | 9 (2%) |
| | **Clomid alone(n, %)** | | 150 (32.8 %) |
| | **Clomid ± others(n, %)** | | 198 (43%) |
| | **r-FSH alone(n, %)** | | 114 (24.9 %) |
| | **r-FSH ± others(n, %)** | | 141 (30.9 %) |
| | **HPuFSH alone(n, %)** | | 74 (16.2 %) |
| | **HPuFSH ± others(n, %)** | | 95 (20.8 %) |
| | **HMG alone(n, %)** | | 43 (9.4 %) |
| | **HMG ± others(n, %)** | | 76 (16.6 %) |
| | **Combined(n, %)** | | 67 (14.7%) |
| **Ultrasound findings at time of triggering ovulation** | **Endometrial line*(mm)** | | 11.18 ± 3.03 |
| | **Leading follicle*(mm)** | | 18.53 ± 2.54 |
| | **2nd Leading follicle*(mm)** | | 17,18 ± 1.98 |
| **Outcomes** | **Pregnancy(n, %)** | | 98 (21.4 %) |
| | **OHHS(n, %)** | | 28 (6.1 %) |
| **No. of follicles at triggering in cycles of OHSS#** | | | 3( 3 – 4 ) |

*mean and SD, #median and interquartile range

**Table (2):** shows Comparison between successful and non-successful IUI trials.

| Parameter | | | Pregnancy n=98 | No pregnancy n=389 | P value |
|---|---|---|---|---|---|
| **Age*(years)** | | | 29.75 ± 4.36 | 29.06 ± 4.98 | 0.544 |
| **Parity#** | | | 0 ( 0-2 ) | 0 ( 0-2) | 0.79 |
| **BMI*(kg/m2)** | | | 27.73 ± 5.81 | 28.68 ± 5.14 | 0.301 |
| **Infertility duration#** | | | 4 ( 3-5 ) | 4( 3-7 ) | 0.013 |
| **Type of infertility** | **Primary infertility (n, %)** | | 203 (56.5 %) | 57 ( 58.2 ) % | 0.774 |
| | **Secondary infertility(n, %)** | | 156 (43.5) % | 41( 41.8) % | |
| **Etiology of infertility** | **Female factors** | **Unilateral tubal (n, %)** | 3 (3.1%) | 17 (4.7%) | 0.746 |
| | | **Ovarian(n, %)** | 18 (18.4%) | 105 (29.2%) | |
| | | **Uterine(n, %)** | 2 (2.0%) | 5 (1.4%) | |
| | | **None** | 232 (64.6%) | 75 (76.5%) | |
| | **Combined factors(n, %)** | | 6 (6.1%) | 28 (7.8%) | 0.575 |
| | **Unexplained(n, %)** | | 37 (37.8%) | 103 (28.7%) | 0.084 |
| **Induction of ovulation medications** | **None(n, %)** | | 2 (2.0%) | 7 (1.9%) | 0.176 |
| | **Clomid alone(n, %)** | | 32 (32.7%) | 115 (32.0%) | |
| | **r-FSH alone(n, %)** | | 35 (35.7%) | 82 (22.8%) | |
| | **HPuFSH alone(n, %)** | | 10 (10.2%) | 64 (17.8%) | |
| | **HMG alone(n, %)** | | 6 (6.1%) | 37 (10.3%) | |
| | **Combined(n, %)** | | 13 (13.3%) | 54 (15.0%) | |
| **Ultrasound findings at time of triggering ovulation** | **Endometrial line*** | | 12.17 ± 2.86 | 11.47 ± 2.83 | 0.156 |
| | **Leading follicle* (mm)** | | 19.80 ± 1.97 | 18.8 ± 2.9 | 0.033 |
| | **2nd Leading follicle*(mm)** | | 17.58 ± 1.62 | 17.03 ± 2.07 | 0.104 |
| **OHHS** | | | 8 (8.2%) | 20 (5.6%) | 0.343 |
| **Cycle order** | **1st trial(n, %)** | | 39 (16%) | 210 (84%) | 0.001 |
| | **2nd trial(n, %)** | | 27 (18%) | 116 (82%) | |
| | **3rd trial(n, %)** | | 33 (51%) | 32(49%) | |

*mean and SD, #median and interquartile range