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Original Article

Predictive factors for pregnancy after controlled ovarian stimulation and intrauterine insemination: A retrospective analysis of 4146 cycles



Adélie Michau^{a,*}, Hady El Hachem^b, Julie Galey^a, Soizic Le Parco^a, Simone Perdigao^a, Bruno Guthauser^a, Agathe Rousseau^a, Mehdi Dahoun^a, Cindy Guillaume^a, Nicolas Tabchouri^c, Ibrahim Hammoud^a

^aART Center, Institut Mutualiste Montsouris (IMM), 42 Boulevard Jourdan, 75014 Paris, France

^bDepartment of Obstetrics and Gynecology, Clemenceau Medical Center, Beirut, Lebanon

^cDepartment of Digestive Diseases, Institut Mutualiste Montsouris (IMM), 42 Boulevard Jourdan, 75014 Paris, France

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ABSTRACT

Background: The variability in indications and low rate of pregnancy compared to IVF have led many authors to dismiss IUI and offer IVF first-line instead.

Objectives: To determine what are the predictive factors for clinical pregnancy (CP) and live birth (LB) in intrauterine insemination (IUI) cycles following controlled ovarian stimulation (COS).

Methods: Retrospective unicentric study, between January 2009 and December 2016. Patients aged 18 to <43 years who had an IUI following COS with gonadotropins. Statistical analysis was performed using Chi square and logistic regression.

Results: 4146 cycles (1312 couples) included. Mean age was 34.7 +/- 4 years. LBR per couple was 39% for anovulatory infertility compared to (p < 0.05) unexplained infertility (28.6%), mixed (23.4%), male factor (20.1%), unilateral tubal (14.2%), low ovarian reserve (13.2%), and endometriosis (stage I and II) (11.1%). Multivariate analysis showed the following factors were associated with CP: Cycle rank ≤3 (Odds ratio (OR) = 1.5, 95% CI: 1.2–1.9, p < 0.001), age <38 years (OR = 1.5, 95% CI: 1.2–2, p < 0.001), ≥2 preovulatory follicles (OR = 1.4, 95% CI: 1.1–1.8, p = 0.004), TMSC ≥ 5 millions (OR = 1.8, 95% CI: 1.3–2.4, p < 0.001). Endometriosis, low ovarian reserve, unilateral tubal and male factor had a negative impact on CPR (OR = 0.3, 95% CI: 0.1–0.5, p < 0.001; OR = 0.4, 95% CI: 0.3–0.7, p < 0.001; OR = 0.5, 95% CI: 0.3–0.9, p = 0.01; OR = 0.6, 95% CI: 0.4–0.8, p = 0.002 respectively) compared to anovulatory infertility.

Conclusion: We confirm that IUI can be an efficient treatment in selected indications. Young patients with anovulatory infertility seem to be the ideal candidates, with a 39% LBR per couple.

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Introduction

Infertility is a worldwide health care issue, approximately affecting 1 in 6 couples [1,2]. Intrauterine insemination (IUI) is usually offered before *in vitro* fertilization (IVF) in many indications [3]. In Europe, more than 175 000 IUI cycles are performed each year, with a live birth rate of around 8.5%, [3–5].

Overall pregnancy rates have varied from as low as 5% to as high as 30% [3,6]. Several factors affect the pregnancy rates, such as the patient's age, the type and duration of infertility, the quality of the inseminated sperm, the number of mature follicles and the serum estradiol levels on ovulation trigger day. For instance, pregnancy rates decrease significantly with woman age [5,7–12] whereas anovulatory infertility seems to be associated with good outcomes [8,9,13]. Moreover, the minimal total motile sperm count (TMSC) needed for IUI greatly differs among studies, varying from ≥1 million to ≥10 million [8,14–17].

The wide variability in indications and the low overall pregnancy rates compared to IVF have led many authors, physicians and fertility centers worldwide to dismiss IUI and offer IVF first-line instead. However, IUI is less expensive [11], less invasive and more patient friendly than IVF, and remains a valid option when the patients are properly selected. In the current

* Corresponding author.

E-mail addresses: adelie.louise.michau@gmail.com (A. Michau), hadyhachem@hotmail.com (H. El Hachem), julie.galey@imm.fr (J. Galey), soizic.leparco@imm.fr (S. Le Parco), simone.perdigao@imm.fr (S. Perdigao), brunoguthauser@gmail.com (B. Guthauser), rousseauagathe@gmail.com (A. Rousseau), mehdi.dahoun@imm.fr (M. Dahoun), cindy.guillaume@imm.fr (C. Guillaume), nicolastabchouri@gmail.com (N. Tabchouri), ibrahim.hammoud@imm.fr (I. Hammoud).

study, we aimed to identify the factors predictive of clinical pregnancy and live birth in intrauterine insemination cycles, in order to define a specific population that would benefit the most from IUI.

Material and methods

We performed a retrospective cohort study at Institut Mutualiste Montsouris, a university affiliated private infertility center in Paris, between January 2009 and December 2016. The institutional review board approved the study. We retrospectively included all patients with IUI cycles, data were stored using the software Medifirst® (Medifirst, France). The inclusion criteria were: age <43 years, at least one patent Fallopian tube, controlled ovarian stimulation (COS) cycles followed by IUI. We excluded all IUI cycles with donor sperm and patients with incomplete medical records.

All patients had an initial evaluation: detailed history and physical examination; a hormonal blood profile and transvaginal ultrasound performed between days 2 and 5 of the cycle; hysterosalpingography between days 7 and 14. All partners have an initial sperm analysis. All types of available gonadotropins were used: human menopausal gonadotropins (hMG) (Menopur®), recombinant FSH (Gonal-F®, Puregon®, Fostimon®, Bemfola®, Ovaleap®, or urinary FSH (Fostimon®). Patients were monitored with ultrasounds and blood measurements, ovulation was triggered with 5 000 IU of hCG or 250 µg of Choriogonadotropine alfa (Ovitrelle®) when 1–3 follicles >16 mm were recorded on ultrasound, with an endometrial thickness >7 mm. Cycles with ≥4 mature follicles were canceled. Patients with a serum LH > 10 IU/l had the IUI the day after triggering instead of 36 h, because of the higher risk of premature ovulation.

The partner's sperm was first collected and analyzed 30 min later, before being prepared using a two-layer density. The concentration and motility of all samples were checked to evaluate the postwash total motile sperm count (TMSC). The same soft catheter (Ellios®) was used for all IUI, except cases where access to the uterine cavity was difficult, where a rigid catheter (Frydman soft with guide catheter, CCD®) was used. The prepared sperm (0.2–0.4 ml) was slowly injected. Bed rest was maintained for 10 min. No luteal support was given, and patients were instructed to have a blood pregnancy test 14 days after with hCG follow up and an ultrasound at 7 weeks gestational age (GA) if positive. We defined clinical pregnancy as one or more gestational sac, miscarriage as loss of a clinical pregnancy prior to 20 GA, and live birth as complete expulsion or extraction from its mother of a product of fertilization, which breathes or show any other evidence of life (defined according to the recommendations of the International Committee for Monitoring Assisted Reproductive Technology [18]). Information on the evolution of pregnancy was collected via questionnaires.

Statistical analysis was performed using SPSS® program. Continuous variables were expressed as mean values and standard deviations (SD), compared with Student's t-test, whereas categorical variables were expressed as percentages and compared with chi-squared and Fisher's exact test. A P-value <0.05 was considered statistically significant. Multivariate logistic regression analysis was performed to define the factors associated with a pregnancy and live birth. Factors statistically significant and with no missing data in univariate analysis were included in multivariate analysis. Pregnancy and live birth rates were analyzed according to female age, indications of IUI, number of mature follicles on trigger day, total dose of gonadotropins used, and TMSC. Male infertility was defined according to WHO's criteria (1999 and 2010) with at least a postwash total motile sperm count (TMSC) ≥ 1 × 10⁶ spermatozoa on initial evaluation. Cervical fertility was defined if post coital test was negative. Patients with endometriosis were only patients with

stage I or II endometriosis. Partial tubal infertility was defined as an unilateral tubal obstruction in hysterosalpingography.

Results

4146 IUI cycles performed in 1312 couples were included. Patients' characteristics are shown in Table 1. The mean total dose of gonadotropin injected was 539 ± 424 IU, and the mean duration of stimulation was 8.2 ± 3.5 days. The mean number of mature follicles on trigger day was 1.2 ± 0.4, (3392 cycles with 1 follicle, 728 with 2, 36 with more than 2 follicles) and the mean TMSC was 10.9 ± 6 millions.

We recorded 478 clinical pregnancies, and the clinical pregnancy rate (CPR) was of 11.5%. There were 336 deliveries (8.1%), including 20 twin pregnancies, and 328 live births (live birth rate (LBR) was 7.9%). The CPR per couple was 36.4% and the LBR per couple was 25%. The miscarriage rate was 14.6%.

Rank of insemination

The CPR after the first IUI was 15%, 13% after the second and 10% after the third. When a pregnancy occurred, it was in 34.7% of cases after the first IUI, in 29.5% after the second and in 17.15% after the third, for a cumulative rate of 81.4% after three trials. The pregnancy rates per IUI after the fourth trial were lower than 9%.

Univariate analysis

We analyzed clinical pregnancy and live birth rates according to female age, serum AMH levels, indication of IUI, number of mature follicles on trigger day, total dose of gonadotropins used, and TMSC.

- Results for CPR and LBR according to age are presented in Table 2. When all patients <38 years of age were grouped together, the CPR was 12.6%, significantly higher than patients >38 years (8.3%, p=0.0001). There was no significant difference between the age groups for miscarriage.
- The CPR was significantly higher in cycles with two mature follicles on trigger day compared to cycles with one follicle (14.4% vs 11%, p=0.01), as well as the twin pregnancy rate (13.6% vs 3.9%, p=0.006). No clinical pregnancies were recorded in cycles with 3 mature follicles (36 cycles).
- There was no significant difference of total dose of gonadotropin between patients who had a clinical pregnancy and those who did not (456 vs 508 IU, p=0.06, respectively).
- Compared to anovulatory infertility, CPR and LBR per couple were significantly lower in patients with endometriosis, partial tubal infertility, low ovarian reserve, male infertility and unexplained fertility (Table 3).

Table 1
Patient's characteristics.

Age (years) [*]	34.7 ± 4
BMI (kg/m ²) [*]	22.7 ± 4
Number of IUI cycles [*]	2.5 ± 1.5
Indication per couple n(%)	
- Female factor	542 (41.4%)
- Male factor	273 (20.8%)
- Mixed	64 (4.8%)
- Unexplained	433 (33%)
Female factor infertility n(%)	
- Anovulatory	194 (35.8%)
- Tubal partial	36 (9%)
- Cervical	82 (15.2%)
- Endometriosis	81 (15%)
- Low ovarian reserve	136 (25%)

^{*} Mean ± Standard deviation.

Table 2
Comparison of clinical pregnancy rates (CPR) according to patients' age χ^2 test.

CPR/age	<30 years	30-35 years	35-38 years	38-40 years	>40 years
χ^2 test (p)					
CPR	13.6 %	12.8 %	11.8 %	8.5 %	8.3 %
<30 years		0.68	0.31	0.07	0.004
30 - 35 years			0.44	0.007	0.03
35 - 38 years				0.048	0.03
38 - 40 years					0.88

Table 3
Comparison of clinical pregnancy rates (CPR) and live birth rates (LBR) according to the cause of infertility χ^2 test.

	CPR per couple	p/anovulatory infertility	LBR per couple	p/anovulatory infertility
Anovulatory	53%	–	39%	–
Cervical	47.5%	0.4	29.3%	0.11
Mixed	40%	0.08	23.4%	0.02
Unexplained	39%	10^{-3}	28.6%	0.008
Male factor	31.8%	$<10^{-4}$	20.1%	$<10^{-6}$
Partial tubal	26%	$<10^{-3}$	14.2%	$<10^{-3}$
Low ovarian reserve	22%	$<10^{-4}$	13.2%	$<10^{-7}$
Endometriosis	13.5%	$<10^{-4}$	11.1%	$<10^{-6}$

- AMH < 1 ng/ml is usually considered as a marker of poor ovarian reserve [19,20]. CPR per couple was significantly higher in patients with AMH > 1 ng/ml, compared to AMH < 1 ng/ml (12.5% versus 8.5% p = 0.01).
- We first compared cycles with a TMSC > 5 million compared to ≤ 5 million. CPR were significantly higher in the > 5 million group (12.4% vs 7.7%, p = 0.0002). We then further divided the two groups as follows: < 1 million; 1–2 million; 2–5 million; 5–10 million, and > 10 million. < 1 million threshold was chosen according to French national practices guidelines [21], while the other thresholds were chosen based on the current literature [8,14–16,22]. CPR were significantly higher in the 5–10 million and > 10 million groups, compared to 1–2 million and 2–5 million

groups (p < 0.05) (Table 4). Couples with a TMSC < 1 million the day of first IUI were then oriented to IVF or ICSI.

Multivariate analysis

Multivariate analysis is presented in Table 5. The factors that were associated with a significantly higher chance of clinical pregnancy were: Rank of IUI ≤ 3 (OR 1.5, 95% CI 1.2–1.9), age < 38 years (OR 1.5, 95% CI 1.2–2), anovulatory infertility (OR 1.4, 95% CI 1.1–1.8), 2 or 3 mature follicles on trigger day (OR 1.4, 95% CI 1.1–1.8), and TMC > 5 million (OR 1.8, 95% CI 1.3–2.4). Cervical factor infertility was not an independent factor, whereas endometriosis

Table 4
Comparison of clinical pregnancy rate according to total motile sperm count (TMSC).

Pregnancy /TMC	<1 million	1 - 2 million	2-5 million	5-10 million	>10 million
Fischer's test (p)					
Number of cycles	58	136	594	1085	2273
CPR	5.2%	4.4%	8.8%	12.2%	12.5%
<1 million		1	0.46	0.14	0.1
1 à 2 million			0.11	0.005	0.002
2-5 million				0.03	0.009
5-10 million					0.77

Table 5
Multivariate analysis.

	Odds Ratio	95% CI	p
Insemination rank ≤ 3	1,5	1,2-1,9	<0001
Age < 38 years	1,5	1,2-2	0001
Female factor infertility			
- anovulatory	1,4	1,1-1,8	0,002
- cervical	1	0,7-1,3	0,9
- endometriosis	0,3	0,2-0,6	0,001
- Low ovarian reserve	0,5	0,4-0,8	0,003
TMSC >5 million	1,8	1,3-2,4	<0,001
2–3 mature follicles	1,4	1,1-1,8	<0,001

(OR 0.3, 95% CI 0.2–0.6) and low ovarian reserve (OR 0.5, 95% CI 0.40–0.8) were associated with a significantly lower chance of clinical pregnancy.

Discussion

Our retrospective study has shown that several factors are associated with pregnancy rates in IUI cycles following COS. The rank of the insemination cycle is an important factor, with more than 80% of pregnancies occurring during the first 3 cycles. This is in accordance with other studies that also reported that most pregnancies occur after 3 [8,13,23,24] or 4 IUI cycles [9]. Based on our finding, we believe the number of IUI cycles could be limited to 3, and that IVF can be discussed as an alternative option if no pregnancy occurs after 3 cycles, especially in older women.

We also confirmed the impact of age, with pregnancy rates significantly lower after the age of 38. Several age thresholds have been proposed across studies to define which patient population benefits the most from assisted reproductive technologies (ART), and the most frequently used are 35, 38, 40, and 42 years. Merviel et al. [8] and Nuojua-Huttunen et al. [9] found that age <40 years was associated with the occurrence of a pregnancy (OR 2.84, $p < 0.05$ and 4.1% vs 13.5%, $p < 0.05$). Stone et al. [10] found a very low pregnancy rate of 4.1% between the ages of 41 and 45. We further divided the age groups and found the threshold of 38 years to be more clinically relevant. We found that the number of mature follicles on trigger day was a notable factor, with significantly higher pregnancy rates in cycles with two mature follicles compared to one. This finding was reported by Monraisin et al. [7] (15.6% vs 9.4%, $p < 0.001$), van Rumste et al., 2008 (15% versus 8.4%) [25], and Merviel et al., 2010 (14.5% vs 9.8%, $p < 0.01$) [8]. Nuojua-Huttunen et al. [9] found that pregnancy rates with three follicles were significantly higher than one (16.3% vs 5.7%, $p = 0.03$). It is common practice to aim for 2 or 3 follicles in IUI cycles [7] and cancel cycles with 4 follicles or more. Indeed, the multiple pregnancy rate significantly increases with the number of mature follicles, as reported by many studies [8,10,23]. In our study, we noticed an increased twin gestation rate with 2 follicles compared to 1, but we believe having 2 or 3 mature follicles to be the best option in stimulated IUI cycles, except in cases with contraindications to twin gestations.

About half of the patients with anovulatory and cervical factor infertility had a clinical pregnancy following COS and IUI, with a statistically significant difference compared to other indications, such as endometriosis, low ovarian reserve and partial tubal infertility. Merviel et al., [8] Soria et al. [13] also found that the highest pregnancy rates were obtained in patients with anovulatory infertility secondary to polycystic ovarian syndrome (PCOS). Multivariate analyses showed that patients with low ovarian reserve and endometriosis had the lowest pregnancy rates, as reported elsewhere [9]. We also found partial tubal factor infertility to be associated with lower pregnancy rates in the univariate analysis, but the difference was not significant in the

multivariate analysis. Cochet et al. [26] recently found that pregnancy and live birth rates were reduced by half in women with unilateral tubal abnormalities, and suggested as we believe that they be treated immediately with IVF. Serum AMH levels >1 ng/ml were associated with increased pregnancy rates in the univariate but was excluded from the multivariate analysis due to missing data. AMH is a confirmed marker of ovarian reserve, its direct impact on pregnancy and live birth rates remains following ART remains debated [20,27,28].

Finally, we analyzed pregnancy rates according to the TMSC inseminated, and found that TMSC >5 million were associated with significantly higher pregnancy rates. The TMSC threshold for IUI varies widely between studies and recommendations. For instance, several studies reported significantly lower pregnancy rates with a TMSC <1 million, a threshold also recommended by the national French guidelines [21]. Some studies found the threshold of 2 million to be significant [24] whereas others reported a minimum of 5 and even 10 million for positive outcomes [8,14–16,29]. Van Weert et al. [30] found lower cut off levels between 0.8 and 5 million. Many of these studies are limited by their retrospective design, and more prospective and randomized studies are required in order to define a TMSC threshold [31]. At our center, and based on our recent findings, we recommend IVF for couples when the TMSC is lower than 5 million on initial evaluation.

The main limitation of our study is the retrospective and single center design. However, we used strict inclusion criteria, which allowed for an analysis of a very well-defined cohort of patients. Moreover, we have included more than four thousand cycles in more than thirteen hundred couples, making our cohort one of the largest on IUI following COS, and our main outcome was the live birth rate, the most relevant outcome to study when assessing ART. All these characteristics give more power to our conclusions.

Conclusion

Our study confirms that IUI following COS is an effective infertility treatment in carefully selected cases, with one couple out of four taking home a live baby. The highest pregnancy and live birth rates were obtained in the first 3 insemination cycles in women younger than 38 years of age, having anovulatory infertility with no endometriosis, with 2 mature follicles on trigger day and adequate semen parameters (TMSC >5 million). Compared to IVF, IUI is less invasive, more patient-friendly, and more cost-effective, and should therefore be offered in first line in properly selected cases.

Conflict of interest

The authors declare no conflicts of interest.

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