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Pregnancy Predictors after Intrauterine Insemination in Case of Unexplained Infertility

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ABSTRACT

Background: IUI procedure is widely applied around the world. The aim of IUI is to put a prepared small volume of active motile sperm high in the uterine cavity, on the period of ovulation. In many centers IUI is usually applied in combination with ovulation induction or Controlled ovarian hyperstimulation (COH). however, the successful rate of getting pregnancy with IUI remains unchanged.

Aim of study: To clarify the prognostic factors effect in cases of unexplained infertility offered intrauterine insemination with controlled ovarian stimulation.

Patients and methods: This is a prospective cohort study has been conducted in Salahadeen General hospital (Iraq/Tikrit City) from December 2017 to August 2018. A 45 couples of unexplained infertility were included, a maximum of 3 cycles of IUI were done with clomiphene citrate, HMG. Ovulation trigger was given when the largest follicle diameter around 18 mm. and IUI was planned within 36hrs. later

Results: A50 cycles of IUI were entered into the study among 45 couples. From these cycles, conceptions resulted, giving an overall total pregnancy rate per cycle of 12%. Cycles per couple were ranged from one to three. The mean age of the male patients was (37year) and (33year) for the female patients. The mean of duration of infertility was (9.5year) in couples who got pregnancy while was (5.04year) in those who got no pregnancy. The pregnancy rate was higher in the age group of (25-29 yrs) and (more than 35ys). The pregnancy rate was higher in cycle with one follicle.

Conclusion: In this study different factors had been studied like couple's age, duration of infertility, number and size of follicles, number of treatment cycles, semen parameters and duration of stimulation were used to predict the success rate but all were not significant. There was significant difference in the pregnancy rate in cases of primary (12.5%) and secondary infertility (11.5%) group (p value=0.042). The overall pregnancy rate per cycle in our study was 12%.

Introduction:

Infertility is a common public health problem that may drives a lot of couples to seek assisted reproductive technology (ART) therapies. However, because the high cost of *in vitro* fertilization (IVF), more affordable and less invasive procedures like intrauterine insemination (IUI) now become more popular (Ashrafi *et al.*, 2013; Fauque *et al.*, 2014) ^(1,2). Therefore, IUI procedure is widely applied around the world. The available data from the European Society of Human Reproduction and Embryology (ESHRE) revealed that in 2009, 162,843 IUI cycles were performed compared with 135,621 IVF cycles during the same period ^(3,4).

The aim of IUI is to put a prepared small volume of active motile sperm high in the uterine cavity, on the period of ovulation. In many centers IUI is usually applied in combination with ovulation induction or Controlled ovarian hyperstimulation (COH). In IUI, the best sperm are introduced at the

optimal time in the cycle, which physically near to the fallopian tubes and passing cervix and cervical mucus, and at the same time, the number of available oocytes in the ovaries is increased ⁽⁵⁾. The preparation techniques of sperm have been improved much in the last years ^(6,7), however, the successful rate of getting pregnancy with IUI remains unchanged ⁽⁸⁾. According to the reports from a large number of fertility centers, the successful rate with IUI per cycle is ranged between 11.4% and 12.6%. therefore, how to improve the IUI outcome still remains challenging for all fertility doctors ⁽⁹⁾.

Recent updated guidelines on fertility released by the National Institute for Health and Care Excellence (NICE) advising that couples with mild endometriosis, mild male factor, unexplained subfertility or, who have failed to become pregnant after two years of expectant management should proceed to IVF treatment ⁽¹⁰⁾. These instructions are based on very low

quality evidence stated that treatment with IUI {with or without COH} reveals no significant increase in live birth over expectant management⁽¹¹⁾. This update represents a dramatic shift in treatment algorithm for most fertility specialists, many of whom continue to recommend at least 3 cycles of IUI/COH for these patients⁽¹²⁾. Initial strategies to improve IUI timing relative to ovulation included the use of urine luteinizing hormone (LH) detection kits⁽¹³⁾, which resulted in superior success rates in comparison to more traditional means of IUI timing including basal body temperature and prior cycle length⁽¹⁴⁾

PATIENTS AND METHODS

This is a prospective study had been conducted in Salahadeen General hospital / obstetrical department, from December 2017 to August 2018. There was no specialized infertility center neither in our hospital nor in our governorate. Some of our patient had been collected from obstetrical Out Patient Department(OPD) while the

majority were from the private clinics. Couples with unexplained infertility undergoing IUI with COS were involved in this study. Many of those couples had visited many infertility consultants and centers before and all basic simple investigations such as hormonal assays, semen analysis, postcoital test, antisperm antibodies, microbiological studies, thyroid function test, random blood sugar and abdominal and transvaginal ultrasound (TVU) that done in the last three months were normal. Also at least one tube proved to be patent by hystrosalpingography and laparoscopy. Some of our patient were first time seeking for fertility advice so all the above investigations were done in the private sector apart from TVU and laparoscopy were done in our hospital.

Inclusion Criteria:-

- 1- All patient with unexplained and more than 2 years infertility.
- 2- Patients of unexplained infertility of the mean age

(**33yrs**) as those who are more than (**35yrs**) they request to offer IUI rather than IVF for the economical purposes.

- 3- Those who have undergone \leq **2** IUI cycles in the past.

Exclusion Criteria:-

- 1- Patients with uterine pathology diagnosed on TVU like fibroid, adenomyosis, or endometrioma were excluded from the study.
- 2- Patients who developed features of ovarian hyperstimulation syndrome were excluded from the study.
- 3- A **6** patients had been lost after offering COS so were excluded.

So that the total number was **45** couples were enrolled in this study offered **50** cycles of intrauterine insemination. A **35** couples with no history of previous IUI had been offered the **1st** IUI cycle. The **2nd** IUI cycle was offered for **10** couples, **6** couples of them had a history of previous IUI trial so directly

calculated with our **2nd** IUI cycle. The **3rd** IUI cycle was offered for **5** couples, **4** couples of them had a history of previous **2** IUI trial so directly calculated with our **3rd** IUI cycle. A maximum of **3** cycles of IUI were done.

Patient Preparation:-

COS protocol was offered for **5** days using clomiphene citrate from day **2** of menses **100** mg (after confirming absence of ovarian cyst and endometrial thickness <5 mm) . From day **7**, follicular growth monitoring had been started in order to determine the day of ovulation trigger. Those who did not achieve sufficient follicular stimulation with clomiphene citrate alone, we added Human Menopausal Gonadotropin (HMG) **75** IU every alternate day starting from day **7** till the day of ovulation trigger. When the largest follicle diameter was ≥ 18 mm ovulation trigger was planned by using injection hCG **5000** IU through intramuscular rout and then IUI planned **24-36** hours later.

Semen Preparation:-

Instruction had been explained to the husband about how to give the sample of semen by masturbation in a wide mouth sterile container and with 2–7 days abstinence. By using a **density gradient** and **swim up** method. Semen preparation was done. The sample had allowed to be liquefied and then layered over **80** over **40** , in a ratio of **1 : 1** density gradient and about **10** min centrifuged at **2000** rpm. The pellet was mixed with **0.5** mL sperm preparation medium (SPM) after discarding the supernatant; then it was mixed with **2.5** mL SPM in another tube and centrifuged for **5** minutes at **1500** rpm. Again the supernatant was been discarded and the pellet had been layered with **0.5** mL of SPM then at **37** degrees Celsius the sperms were allowed to swim up for **15** minutes. **0.5-1** mL of supernatant is then loaded in a special soft IUI catheter.

IUI Procedure :-

IUI was done using **Gynetic** IUI catheter. The catheter passed through

cervical canal and the sperm is expelled in to uterine cavity. Woman was asked to lie down with slight low head position for **20** minutes. A micronized progesterone vaginal suppository for **15** days **200** mg twice daily was offered as a luteal phase support. The pregnancy detected **biochemically** by serum beta hCG which had been done after **15** days of insemination. BMI, age of both couple, days of stimulation, infertility duration, number and size of dominant follicles, % of semen normal morphology, semen total motility fraction, number of cycles, pregnancy rate all were been noted. The patients with positive pregnancy test result on day **15** were placed in the group “**A**” while those with negative test were placed in the group “**B**” and the two groups were been compared.

Statistical analysis:-

Clinical data were recorded on an Excel (Microsoft) spreadsheet. By using a statistical IBM-SPSS software package {version 22 , SPSS for Windows , IBM-SPSS} ;the

statistical analysis was performed. Quantitative variables were expressed as a mean \pm standard deviation and then compared with groups that using a Student's t-test. Categorical variables were expressed as frequency distributions and single percentages, and the comparison between groups has been done by using Chi-square test, and using the Fisher's exact test for dichotomies variables when Chi square test assumptions was violated. Considering P value of < 0.05 as a statistically significant.

RESULTS

A **45** couples have been offered **50** cycles of IUI out of which **6** had

serum HCG positive after **15** days. Depending on the result of serum beta hCG ; the cycles were subdivided into two groups: negative and positive. With regarding to the demographic distribution like BMI, age , duration of stimulation, duration of infertility, number of follicles/cycles, all except the infertility type {primary or secondary}, there was no statistical significant differences between the two groups. A **24** were of primary infertility while **26** were of secondary infertility. There was significant difference in the pregnancy rate in cases of primary (**12.5%**) and secondary infertility (**11.5%**) group (p value=**0.042**). **Table (1A &B)**

Table (1A): general Descriptive variables for IUI cycles in both groups.

Parameters	Positive Mean\pmSD	Negative Mean\pmSD	P. value
Wife Age (years)	35\pm6.28	31.11\pm7.10	0.174
Husband age (years)	38.83\pm7.44	36.72\pm7.60	0.527
Duration of infertility (years)	9.5\pm5.54	7.50\pm6.01	0.446
Duration of stimulation (days)	5.0\pm0.0	5.04\pm0.30	0.716
Number of follicles/cycles	2.16\pm0.98	2.84\pm1.81	0.380

Table (1B): general Descriptive variables for IUI cycles in both groups.

Parameters	Positive(%)	Negative(%)	P. value
BMI %<18.5	%0	%0	0.325
18.5-24.9	%0	%100	
25-30	%15.2	%84.8	
>30	%20	%80	
Primary infertility %	12.5%	87.5%	0.042
Secondary infertility %	11.5%	88.5%	

There was an increasing trend in pregnancy rate with increasing age (**7.7%** in <**30** years age group while was **16.7%** in age group of >**30** years though the difference was not significant (p value=**0.329**). **Table (2)**

Table (2): The clinical pregnancy rate according to female age, male age and duration of infertility.

	Female age (y) %		Male age (y) %		Duration of infertility (y) %	
	≤ 30	> 30	≤ 30	> 30	≤ 2	> 2
Pregnant group	7.7%	16.7%	10%	12.5%	9.1%	12.8%
Non-pregnant group	92.3%	83.7%	90%	87.5%	90.9%	87.2%
P value	0.329		0.828		0.737	

Number of dominant follicles on the day of trigger were different in both the groups and the finding was not significant.(P value= **0.365**). **Table (3)**

Table (3): follicles NO. description of IUI outcomes.

Follicles NO.	Positive	Negative	Pregnancy rate	P value
1	1	1	50%	0.365
2	4	32	11.1%	
3	0	3	0%	
4	1	8	11.1%	

Pregnancy rate was higher with follicular size of **21-24** mm size but still statically not significant (p value =**0.811**)

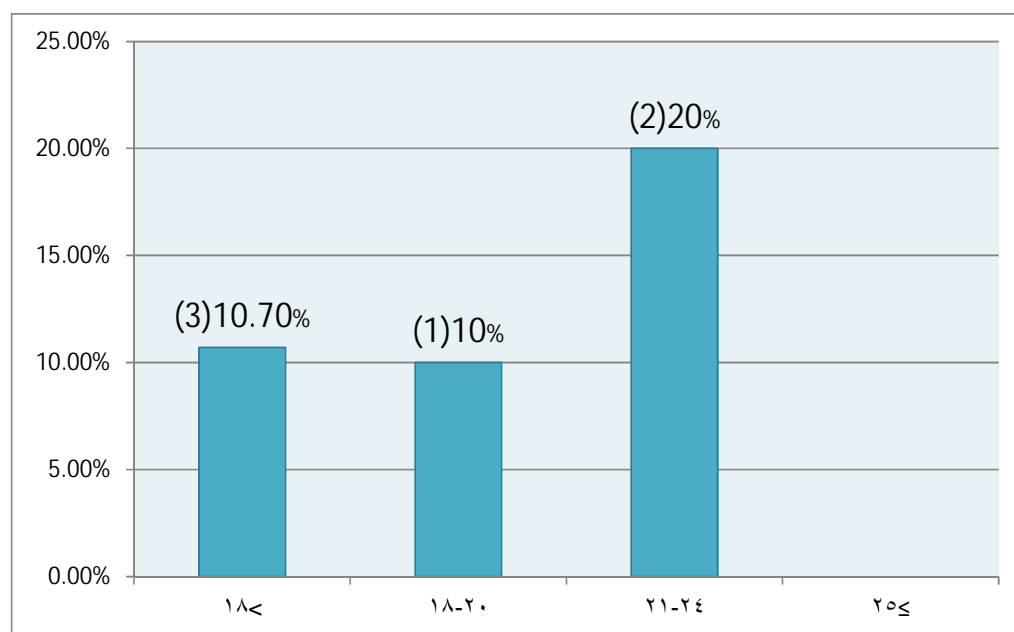


Figure (1): pregnancy (NO.) rate in different follicle size.

Semen parameters like total motile fraction and morphology were different in both the groups but non-significant (p value= **0.330** and **0.071** respectively).

Table (4). Other semen parameter analysis showed in Table (5) and (6)

Table (4). total motile fraction and morphology in both groups.

Parameters	Positive(%)	Negative(%)	P. value
Semen: total motile fraction %	43.5%	48%	0.330
Semen: normal morphology %	3.83%	2.76%	0.211

Table (5). Concentration, motility and morphology in both groups.

NO of Patinet	Concentratio n (mlx1)	Motility %	Morphology (normal form) %	Pregnancy rate %
4	1-10	36%	3.26%	50%
8	11-20	47.6%	1.95%	0%
38	>20	48.9%	5.39%	10.5%

There were **35** first-treatment cycles, **10** second-treatment cycles, and **5** third-treatment cycles. Clinical pregnancy rate was **8%** and **20%** per cycle during the first and second cycle, respectively, while during the third cycle is also **20%**. This difference was non-significant with a p value (**0.552**). **Figure (2)**

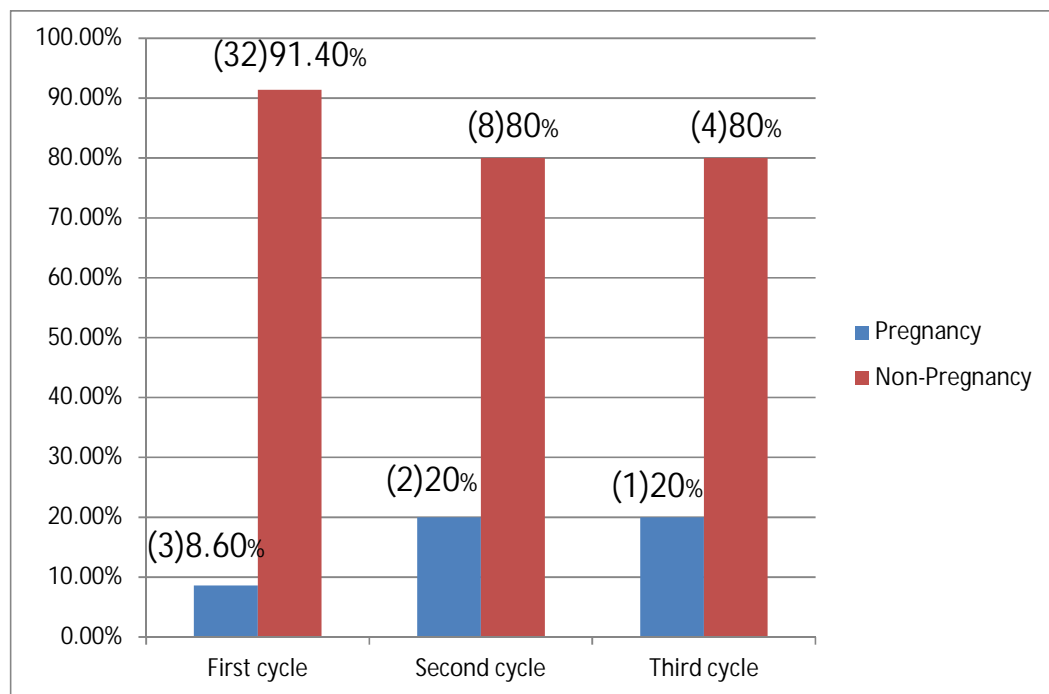


Figure (2) : Total pregnancy (No.)rate per cycle in both groups with P value (**0.552**)

Discussion

Ashrafi et al.⁽⁵⁾ found best results were found in patients of unexplained, primary infertility, less

than 5-year duration, and IMC (inseminated motile sperm count) > **30 × 10⁶** ⁽¹⁾; while in the present study best results were found in

patients of unexplained primary infertility of mean age **9.5** years duration, one follicle number of **21-22** mm size and **43.5%** total semen motile fraction.

In the present study pregnancy rate per cycle was **12%**. Isa et al. found pregnancy rate of **8.45%** in cases of unexplained infertility⁽¹⁵⁾. Ashrafi et al. found pregnancy rate/cycle as **19.9%**⁽⁵⁾.

The couple's age; particularly female age, has found to be a significant predictor in different studies like: M. Montanaro Gauci et al. in 2001 and K. R. Hansen et al in 2016^(16,17). However study by Isa et al. in 2014⁽¹⁵⁾ found no association of pregnancy rate with age but in our study the best pregnancy rate was with age of **> 30** years of both couples. Although the pregnancy rate was slightly higher in **>30** years' age group compared to **<30** years; it could be due to the small sample size in this group, even so the difference was not statistically significant.

Duration of infertility is another prognostic factor studied

with conflicting findings in different studies. Hansen et al., Kamath et al., Tomlinson et al., and Ashraf et al. in their studies showed that when the duration of infertility is prolonged, it will be accompanied with low success rate^(17-19,5). Anyhow, Zainul et al. and Tay et al.^(20,21) failed to find any significance relation with infertility duration while in our study, in long duration of infertility, the pregnancy rate was higher.

A studies of Nuojuua-Huttunen et al., Iberico et al., and Dickey et al.⁽²²⁻²⁴⁾ showed multiple follicles found to be associated with increase chances of pregnancy. Meanwhile, the risk of multiple pregnancy appear to be higher with growth of multiple follicles. In the present study the number of dominant follicles/cycles; (two follicle) was more among the patients who conceived but the difference was not significant.

BMI as a prognostic factor had been studied. In study by Wang et al. and Dodson and Haney^(25,26) no association with BMI was found

which is similar to our study (p value=**0.325**), although they observed that the dose of gonadotropin had to be increased to stimulate obese woman and increase BMI.

Among the male factors total motile fraction and morphology were studied but no significant difference (p value=**0.330** and **0.071** respectively) was found similar to study by Nuojua-Huttunen et al.⁽²²⁾. Data analyzed by M. Montanaro Gauci et al. showed this parameter to be an independent, significant prognostic indicator in IUI.⁽¹⁶⁾

In our study, the number of IUI cycles has been found to be not significant with a (p value=**0.552**); majority of those who got pregnancy was during the 1st cycle (**5/6**) and then in the 2nd cycle (**1/6**) while it was zero in the 3rd cycle which was same with study by Ishita Ganguly⁽²⁷⁾. The principal weakness of this study is the small sample size and high dropout rate as only few patients were got more than one cycle.

Duration of stimulation was found to be not significantly

associated with success of pregnancy (p value=**0.716**) which was disagreed with study by Ishita Ganguly et al⁽²⁷⁾.

In the present study pregnancy rate per couples was higher with follicular size of **21-22** mm size but still statically not significant (p value =**0.811**). Palatnik et al⁽²⁸⁾ found optimal size with higher pregnancy rates were achieved with the leading follicle being in the range of **23-28** mm. but was not statistically significant. Larger follicles would be expected to produce higher levels of estradiol that would then stimulate the endometrial lining more, and smaller follicles would produce lower levels of estradiol and thus produce a thinner lining. When this coordination is disrupted, lower pregnancy levels are the result.⁽²⁸⁾

In our study the pregnancy rate was higher in cases of primary than secondary infertility group (**12.5% vs 11.5%**) which is statistically significant (p value=**0.042**). Our result was in

agreement with the result reported by Ashrafi et al.⁽⁵⁾

Conclusion

In this study different factors had been studied like couple's age, duration of infertility, number and size of follicles, number of treatment cycles, semen parameters and duration of stimulation were used to predict the success rate but all were not significant. There was significant difference in the pregnancy rate in cases of primary (12.5%) and secondary infertility (11.5%) group (p value=0.042). The overall pregnancy rate per cycle in our study was 12%.

RECOMENDATIONS

we RECOMMEND :-

- 1- To increase the size of the study.
- 2- Farther investigations to identify other causes of unexplained infertility like electronic microscope for diagnosis abnormal sperm head.

- 3- To predict a model for IUI, it would be helpful for the clinicians and couples, also it would help to develop guidelines regarding course of infertility treatment depending on different factors of the couples.
- 4- To offer more than 3 cycle {4-6 cycle}.
- 5- We recommend that all trials to be done in specialized infertility center.

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