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Effects of Vaginal Misoprostol after Intrauterine Insemination IUI

Zahraa H. Mohan[*1], Nadia M. Al-Hilli [¥2], Mohammad Oda Selman[*3]

[*] The High Institute of Infertility Diagnosis and Assisted Reproductive Technologies, Al-Nahrain University, Baghdad, Iraq. [1]drzahraahamid948@gmail.com, [3]drMohammedoda@gmail.com, [¥]College of medicine, University of Babylon, Babylon, Iraq. [2] dr.nadia5@yahoo.com

Abstract

Intrauterine insemination has an important role in the treatment of infertile couples. Usage of vaginal misoprostol therapy at the time of intrauterine insemination has been investigated, and its tolerability and effects on clinical pregnancy rates still questionable. To assess the effectiveness of vaginal misoprostol on some demographic characteristics and hormones level with a success rate of Intrauterine Insemination. the period of collection of patients extended from Sep. 2018 until May 2019. Eighty-one infertile couples who attended Al Nahrain University, High Institute for Diagnostic Infertility and Assisted Reproductive Technologies, and private fertility clinics were enrolled through this study. Divided into two groups, the next group received 100 µg vaginal misoprostol immediately after completion of the IUI procedure, while the control group was subjected to ordinary IUI procedure without adjunctive therapy. The mean of demographic data of body mass index, age, and duration of infertility was statistically insignificant in control, Misoprostol post-intrauterine insemination. The percentage of pregnancy rate in the control group 5.0% and it 19.5% in the Misoprostol post-intrauterine insemination group. Moreover, there are significant differences in pregnancy rates among all study groups. According to this study, there is no significant result of pregnancy occurrences correlated with, female age, male age, and body mass index, duration of infertility or type of infertility, hormone levels. Misoprostol use after intrauterine insemination has a positive impact on pregnancy outcome in the control group 5.0% and it 19.5% in Misoprostol post-intrauterine insemination group. Smaller doses (100 µg) of misoprostol can decrease side effects without affecting the outcome.

Keywords: Misoprostol post IUI, Infertility, Hormones levels, Intrauterine insemination.

1. Introduction

Infertility is a failure to give birth after one year or longer is defined (Who [1]). The major reasons for the infertility of the lady will vary in different societies. Ovulatory disorders, tubal damage, and uterine disorders are the most common causes (Bickerstaff, HMD [2]). Menstruation is the repeated, Organizer shedding of the uterine coating in response to the hypothalamus, pituitary, and ovarian hormone interactions. The menstrual cycle can also be divided into two stages: follicular or proliferative, luteal, or secretory (Abbara, et al. [3]). Ovulation is the release of a single mature oocyte from a follicle that developed in the ovary (Sarapik, et al. [4]). Intrauterine Insemination (IUI) is the first-line procedure of assisted reproductive technologies, IUI treat couples with mild male infertility (oligozoospermia, asthenozoospermia, and teratozoospermia) and female infertility (Cervical Factors, and Vaginal Factors and uterine factor), (Liu, et al. [5], Cytotec [6]). Misoprostol is a synthetic prostaglandin E1 analog, its binds with myometrial cells to cause strong myometrial contractions this agent causes softening and dilation of the cervix (Yount and Lassiter [7], Bygdeman, M. [8]).

2. Materials and Methods

The period of collection of patients extended from Sep. 2018 until May 2019. Couples were randomly selected after the explanation of the procedure and taking their verbal Agreement to take part in this research. Eighty-one infertile couples who attended at the High Institute for Diagnostic Infertility and Assisted Reproductive Technologies, Al Nahrain University and This research included private fertility clinics. Patients are split into two groups, the first group received 100 µg vaginal misoprostol immediately after completion of the IUI procedure, while the control group was subjected to ordinary IUI procedure without adjunctive therapy. A detailed history is taken from all couples involved, examination including general, abdominal and genital

tract for any abnormality, Measurements of body mass index (Nuttall, FQ [9]), Hormonal profile tests (Hull, et al. [10]), Hysterosalpingogram for assessment of tubal patency, SFA for male, Ovulation Induction program (Nelson, et al. [11]), In vitro activation technique for intrauterine insemination (Hindal, et al. [12]), intrauterine insemination protocol (Dujaily and Al–Dahan [13]) and Follow up of pregnancy and pregnant female (Gardner, et al. [14]).

3. Statistical Analysis

Data were summarized, analyzed, and presented using statistical package for social sciences (SPSS) version 23 and Microsoft Office Excel 2010. Quantitative variables were expressed as mean and standard deviation (SD); whereas, categorical variables were expressed as number and percentage. Independent samples t-test was used to compare mean values between two groups, while Chi-square test was used to study associations between any two categorical variables; however, Yates correction was used instead when more than 20 % of cells have expected count less than 5 and Fischer exact test when a cell or more contain an observed value of zero. The level of significance was set at $P \leq 0.05$.

4. Results

a. Demographic characteristics of patients enrolled in the present study

The demographic characteristics of subfertile patients were shown in Table (1). The means of female age of control and Misoprostol post IUI groups were statistically insignificant (P = 0.846). Besides, there was no important difference mean age of male partners among study groups. Also, there was no significant difference in mean BMI among study groups (P = 0.627). Regarding the duration of infertility, there was also no important variance in the duration between study groups (P = 0.250). Moreover, the variance in the distribution of couples according to the type of infertility was also insignificant among study groups (P =

0.868). The distribution of couples according to the number of previous IUI trials is demonstrated in Table (1) with no significant variation (0.392).

b. Serum hormonal levels in subfertile ladies joined in the present study

Serum hormonal levels in subfertile ladies joined in the present study were shown in Table (2). In this study, the mean and SD of (FSH, LH, E_2, prolactin, testosterone, and TSH) hormones levels of control and Misoprostol post-IUI groups were investigated, the difference was statistically insignificant.

c. Endometrial thickness in subfertile females joined in the present study

Endometrial thickness in subfertile females joined in the present study was investigated, the mean endometrial thickness of control and Misoprostol post-IUI groups were 8.20 ± 0.63 mm, and 8.26 ± 1.55 mm, respectively; the difference was statistically insignificant (P = 0.825).

d. Biochemical pregnancy outcome

The biochemical pregnancy outcome according to study groups is shown in Table (3). The highest biochemical pregnancy rate was obtained by Misoprostol post-IUI group, followed by the control group, 19.5 % versus 5.0 percentage, respectively; the variance in biochemical Statistically, the pregnancy rate between the study groups significant (P = 0.047). To evaluate factors that may predict positive biochemical pregnancy, all study groups were considered as a single group, and correlations of pregnancy outcome to all other variables were carried out. Pregnancy outcome was insignificantly correlated to any of the demographic characteristics, female age, male age, BMI, the period of infertility, or kind of infertility ($P > 0.05$), as shown in Table (4). Besides, biochemical pregnancy outcome was insignificantly correlated to any of serum hormonal levels, FSH, LH, and E_2, prolactin, testosterone, TSH, or progesterone (P > 0.05). Moreover, it was

Table (1): Demographic characteristics of sub fertile women participating in the present study

Characteristic	Control *n* = 40	Misoprostol post IUI *n* = 41	*P*
Female age (years)	26.95 ±4.75	27.17±5.44	0.846 † NS
Male age (years)	35.00 ±7.54	34.78±7.81	0.898 † NS
BMI (kg/m^2)	27.49 ±4.97	28.01±4.66	0.627 † NS
Duration of infertility (years)	4.28 ±2.20	3.73 ±2.03	0.250 † NS
Type of infertility			
Primary	28 (70.0 %)	28 (68.3 %)	0.868 ¥ NS
Secondary	12 (30.0 %)	13 (31.7 %)	
Previous IUI trials			
1	27 (67.5 %)	33 (80.5 %)	0.392 ¥ NS
2	9 (22.5 %)	5 (12.2 %)	
3	4 (10.0 %)	3 (7.3 %)	

Data were expressed as either mean ±standard deviation or number (%); n: number of cases; IUI: intra uterine insemination; BMI: body mass index; †: independent samples t-test; ¥: Chi-square test; NS: not significant at P ≥ 0.05

Table (2): Serum hormonal levels in sub fertile women enrolled in the current study

Characteristic	Control *n* = 40	Misoprostol post IUI *n* = 41	*P*
FSH (mIU/ml)	7.19 ± 2.97	7.22 ± 3.56	0.970 † NS
LH (mIU/ml)	6.30 ± 4.89	5.87 ± 3.54	0.651 † NS
E_2 (Pg/ml)	33.78 ± 17.94	38.10 ± 11.59	0.201 † NS
Prolactin (ng/ml)	16.47 ± 9.04	15.43 ± 9.14	0.607 † NS
Testosterone (ng/ml)	0.38 ± 0.05	0.45 ± 0.08	0.234 † NS
TSH (mlU/ml)	2.53 ± 1.13	2.74 ±2.05	0.583 † NS

Data were expressed as either mean ± standard deviation; n: number of cases; †: independent samples t-test; NS: not significant at P ≥ 0.05.

Table (3): Biochemical pregnancy outcome according to study groups

Biochemical pregnancy	Control *n* = 40	Misoprostol post IUI *n* = 41	*P*
Positive	2 (5.0 %)	8 (19.5 %)	0.0 47 ¥ S
Negative	38 (95.0 %)	33 (80.5 %)	

Table (4): Relationship among biochemical pregnancy outcome and demographic characteristics

Characteristic	Positive pregnancy *n* = 10	Negative pregnancy *n* = 71	*P*
Age (years)	27.30 ±5.56	27.03 ± 5.05	0.875 † NS
Male age (years)	33.90 ±7.11	35.03 ± 7.74	0.664 † NS
BMI (kg/m²)	30.53 ±4.68	27.36 ± 4.71	0.059 † NS
Duration of infertility (years)	4.20 ±2.15	3.97 ± 2.12	0.752 † NS
Type of infertility			
Primary	5 (50.0 %)	51 (71.8 %)	0.301¥ NS
Secondary	5 (50.0 %)	20 (28.2 %)	

Table (5): Correlation between biochemical pregnancy outcome and hormonal levels and endometrial thickness

Characteristic	Positive pregnancy *n* = 10	Negative pregnancy n = 71	*P*
FSH (mIU/ml)	7.36 ± 2.35	7.19 ± 3.38	0.878 † NS
LH (mIU/ml)	7.60 ± 3.97	5.87 ± 4.26	0.232 † NS
E_2 (Pg/ml)	43.53 ± 23.36	34.90 ± 13.48	0.091 † NS
Prolactin (ng/ml)	11.92 ± 6.79	16.51 ± 9.22	0.134 † NS
Testosterone (ng/ml)	16.29 ± 5.71	14.30 ± 4.45	0.798 † NS
TSH (mlU/ml)	2.40 ± 1.20	2.67 ± 1.71	0.635 † NS
Endometrial thickness	8.70 ± 0.97	8.17 ± 1.2	0.183 † NS

insignificantly correlated to endometrial thickness (P = 0.183), as shown in Table (5).

5. Discussion

Some research found that the uterine contractions vary depending on the uterine status (pregnant, non-pregnant, and postmenopausal women), Retrograde contractions wave are moving from the cervix to the fundus in non- pregnant females. These contractions of the inner myometrial third may be important in sperm transport and for the conservation of early pregnancies within the uterine cavity. While in menstruating women and the case of abortion, the contractions were antegrade (Zhang, et al. [15]). Research work has been directed toward using prostaglandins in assisted reproductive techniques especially when planning to do IUI. Because the proposed factors that have been linked to unexplained infertility is the low level of prostaglandin in seminal fluid in the male and genital tract of a female when compared to control fertile couples (Zhang, et al. [15]). The demographic characteristics of subfertile patients were shown in Table (1). The mean age of subfertile women undergoing IUI who were enrolled in the current study was following many previous studies (Malizia, et al. [16]). The relatively younger age of women in the current study when compared to previous studies may reflect some cultural variation in that women in our community tend to get married at a relatively younger age, therefore, the problem of infertility and subsequent seek for medical advice will be a younger age when compared to other communities (Ahmed, et al. [17]). Female age was described previously by a large number of articles to be the single most important predictor of pregnancy in women undergoing assisted reproduction (Tan, et al. [18], Yavuz, et al. [19]). They stated that advanced females age is associated with less pregnancy outcome, due to the low number of retrieved oocytes, the poor oocyte quality, poor embryo quality, less fertilization rate and less implantation rate

(Yavuz, et al. [19]). In the present study, the mean age of male partners among control and study groups respectively were comparable to that observed by other authors (Isa, et al. [20]). The Mean BMI of females enrolled in the present study showed that the majority of women were within the overweight range of BMI (≥ 25 kg/m^2). No significant difference in BMI was found between successful & non-successful IUI cases. Many studies have evaluated the association between women's BMI and IUI outcome with some contradictory results that BMI may or may not significantly affect pregnancy outcome (Huyghe, et al. [21], Soria, et al. [22], Peivandi, et al. [23]). The duration of infertility in the present study was comparable and nearly similar to that obtained by several other authors who studied pregnancy outcome following IUI cycles (Wadhwa, et al. [24], Ganguly, et al. [25], Thomsen, et al. [26]). The insignificant association between duration of infertility and pregnancy outcome was in agreement with some researchers (Weiss, et al. [27]). But not with the findings of others (Wadhwa, et al. [24]). Who reported that a higher pregnancy rate was found with a shorter duration of infertility. Because of the close range of infertility duration in the present study, it showed no significant association between the duration of infertility and pregnancy outcome. In the present study, primary infertility was more frequent than secondary infertility in control and misoprostol post IUI groups respectively. In one study by (Wadhwa, et al. [24]). Found similar to that of the current study. This is probably because families with secondary infertility are less willing to seek medical advice at fertility centers as they already succeeded to have children. In the present study, primary infertility was more frequent than secondary infertility in control and misoprostol post IUI groups respectively. One study by (Wadhwa, et al. [24]), found similar to that of the current study. This is probably because families with secondary infertility are less willing to seek medical advice at fertility centers as they already succeeded

to have children. Basal testing with cycle day 2 FSH, LH, Testosterone, TSH, Prolactin, and estradiol (E_2) are commonly used to screen women for the response to ovulation induction before enrolling them in IUI. However, the utility of these endocrine markers in predicting ongoing pregnancy from intrauterine insemination (IUI) is less well established (Liu, et al. [28]). In the current study, all these hormones were measured in cycle day 2, these results are in agreement with (Isa, et al. [20]). However, they are inconsistent with (Wadhwa, et al. [24]). Also about basal hormonal level, no significant difference between Misoprostol treated group and the control group because all disturbed hormones usually corrected before starting ovarian stimulation protocols, and the patients randomly distributed into two groups. In the current study, mean endometrial thickness of control and Misoprostol Post IUI groups was in comparison to that obtained by other authors who studied the association between endometrial thickness in subfertile women and pregnancy outcome following IUI (Kolibianakis, et al. [29], Habibzadeh, et al. [30]). In the present study, pregnancy outcome was insignificantly correlated to endometrial thickness. This fact was in agreement with several workers (Richter, et al. [31]). But did not agree to others (Brown, et al. [32], Moslemizadeh, et al. [33]). Stated that, women with endometrial thickness less than 6 mm have a significantly lower pregnancy rate than women with an endometrial thickness higher than 6 mm. Therefore, the lack of a significant effect of endometrial thickness on the rate of pregnancy in this study may be explained by that most of women enrolled in the current study have an endometrial thickness of > 6 mm. In the current study, the use of misoprostol post IUI resulted in a significant elevation in biochemical pregnancy rate, 19.5 % versus 5.0 %, respectively. The use of misoprostol in women undergoing assisted reproduction has been evaluated by many studies (Barroso, et al. [34], Chikkagowdra, et al.

[35]). In one study, 253 women are given vaginal misoprostol in a dose of 400 µg immediately after completing intrauterine insemination (IUI) procedure; those women achieved significantly higher biochemical pregnancy rate than the control group comprising 241 subfertile women, 17 % versus 9 % (Barroso, et al. [34]). These results are under the finding of the present study; however, a dose of 100 µg rather than 400 µg was used to overcome the pain associated with uterine contraction with higher doses of misoprostol. In another study evaluating the use of 200 µg vaginal misoprostol, the pregnancy rate was significantly higher than that of the control group (Zahiri, et al. [36]). Again, these results are under the findings of the current study. On the contrary, to the finding of the present study and the later mentioned studies, some authors found no significant rise in biochemical pregnancy rate following vaginal administration of 200 µg misoprostol to subfertile women post IUI (Chikkagowdra, et al. [35]). The insignificant effect of vaginal misoprostol when was administered to subfertile women undergoing IUI on biochemical pregnancy outcome was also observed by other authors (Chikkagowdra, et al. [35], Zahiri, et al. [36]). Given the available data from the current study and other previous studies that support the significant effect of using misoprostol in subfertile women undergoing IUI, this observation must have a scientific explanation. Indeed, almost all body fluids contain some amount of prostaglandins and seminal fluid is one of the richest body fluids in its prostaglandin content (Barroso, et al. [34]). The introduction of seminal fluid into the vagina causes a lot of effects that may aid fertilization, such as "increasing myometrial contractility, potential relaxation of the tubal isthmus, improved spermatozoon–oocyte binding/penetration and attenuation of the female immune response to spermatozoa may all facilitate fertilization potential" (Zhang, et al. [15]). However, the existence of literature that does not support the hypothesis of the

beneficial role of misoprostol use in IUI cycles may suggest the need for more research work with the inclusion of larger sample sizes and performing a multicenter study.

6. Conclusion

Misoprostol use after intrauterine insemination has a positive impact on pregnancy outcome in the control group 5.0% and it 19.5% in Misoprostol post-intrauterine insemination group. Smaller doses (100 µg) of misoprostol can decrease side effects without affecting the outcome.

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Author Contribution

Mohan ZH, performed the study, Selman MO, and Al-Hilli NMS supervised the work.

Conflict of Interest

The authors declare no conflict of interest.

Ethical Clearance

The study was approved by the Ethical Approval Committee.

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Biography

Zahraa Hamid Mohan

She was born in Babylon. Iraq in 1992 (BVM) is a graduate from the Al-Qasim Green university college of veterinary medicine, graduated in 2016. she is an M.Sc. student in Applied Embryology at Al Nahrain University, the High Institute of Infertility Diagnosis, and Assisted Reproductive Technologies.

Dr. Nadia Mudher Sulaiman Al-Hilli

She was born in Babylon, Iraq in 1976. She received the M.B.Ch.B. from College of Medicine, the University of Babylon in 1999, the Diploma in Obstetrics & Gynecology in 2005, Iraqi Board in Obstetrics & Gynecology (FIBMS) in 2006, the Part I MRCOG in 2006, and the Certificate of minimal access surgery from the Iraqi Ministry of Health in 2017. Currently, she is an Assistant Professor and the Head of the department in Obstetrics & Gynecology department, College of Medicine, University of Babylon. She is also a lecturer and supervisor of Ph.D. students in the High Institute of Infertility and Assisted Reproductive Technologies since 2016. She is a member of the medical education committee at the University of Babylon, College of Medicine, and a member of the scientific committee of Obs. & Gyne. department at the University of Babylon, College of Medicine. She participated in more than, 25 Symposiums, 3 International Symposiums, 18 National Conferences, 15 International Conferences, 16 Workshops, and 9 Training Courses. She published more than 21

articles both local and international. She has more than 200 diagnostic & operative hysteroscopy operations & More than 200 diagnostic and operative laparoscopies performed for infertility patients.

Dr. Mohammad Oda Selman

He is a professor of Applied Embryology in the High Institute for Infertility Diagnosis and ART, Al-Nahrain University. He has more than 70 published articles both local and international. He supervised many M.Sc. and Ph.D. students

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