

## Original Article

# Monitoring of Ovulation — By Adopting “Dutta’s New Scoring” Technique & Pregnancy Outcome

Dilip Kumar Dutta<sup>1</sup>, Indranil Dutta<sup>2</sup>, Rumpa Banerjee Dutta<sup>3</sup>

**Background :** Ovulation usually occurs in between 12<sup>th</sup> to 16<sup>th</sup> day of normal menstrual cycle of 28 days, but due to non-synchronization in timing of releasing estrogen, progesterone & LH hormone during ovulation and its subsequent effect on Endometrial Thickening (ET) & Cervical Mucus, it may lead to failure of implantation of fertilized ovum or embryo finally leading to failure of pregnancy outcome.

**Aims and Objectives :** To analyze the efficacy of Dutta’s New Scoring Technique & its impact on exact date of ovulation, timely sex and use of drugs for successful pregnancy outcome.

**Materials and Methods :** This study was conducted at GICE Infertility Clinic, GICE NH, Kalyani, Nadia, WB from April, 2018 to March, 2022. In 800 cases were selected for this study.

Detection of ovulation was done by adopting Dutta’s Scoring technique. The following observations were done on D<sub>13</sub> which includes :-

- (1) Size of Graafian Follicle (GF), (2) Endometrial Thickness (ET), (3) Cervical Mucus (CM)
- (4) Progesterone (P) Level, (5) LH level.

Score of 0,1,2 were given on each observations. Three groups were created depending on scoring such as Group –A (N=418) - 8 to 10, Group B – (N=274) 5 to 7, Group –C (N=108) < 5 for better management as per scoring (Materials & Methods) technique.

**Observation & Result :** Excellent Results were observed in Group A Patients particularly in terms of implantation, biochemical pregnancy and clinical pregnancy as compared to Group B Patients and Group C patients.

### **Treatment Protocol according to Scoring Methods :**

Treatment Group A (Score 8-10 with sample size 418) = N-418, Inj hcG (5000IU) on D 13 and Dydrogesterone 20 mg daily from D14 X 10days.

Treatment Group B (Score 5 to 7 with sample size 274) = Inj FSH (75 IU) on D2& D8, Estradiol Valerate (2mg) from D5 for 10 days, Inj hcG (5000 IU) IM on D13 of cycle and Dydrogesterone – 20mg/daily from D14 for 10 days.

Treatment Group C (Score <5 with sample size 108) = Inj FSH (75 IU IM) on Day 2 and Day 8, Clomiphene Citrate (100mg)- Day 3 to Day 7, Estradiol Valerate (2mg) from Day 5 of Cycle for 10 days, Inj hcG (5000 IU IM) on Day 13 and Dydrogesterone – 20mg/daily from D14 for 10 days were found to have better option for successful pregnancy rate.

**Conclusion :** Dutta’s Scoring technique is done to accurately predict the exact date of ovulation, subsequent timely sex and also help to implement proper drugs for successful implantation thus increasing chances of subsequent pregnancy rate.

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**Key words :** Ovulation study, Dutta’s Scoring, Drugs, Implantation Rate & Pregnancy Outcome.

In normal 28 days of menstrual cycle, ovulation usually occurs in between 12<sup>th</sup> to 16<sup>th</sup> day of cycle but due to non- synchronisation in hormone release<sup>1</sup> and its action at receptor level, the endometrial proliferation and changes of cervical mucus during

### **Editor’s Comment :**

- "Dutta’s Scoring Technique" Helps to find the exact date of ovulation, actual timing of sex in a normal cycle and also proper use of drugs for a successful clinical pregnancy.

pre – ovulation<sup>1,2</sup> or day of ovulation may play some role in causing failure of implantation or pregnancy outcome.

Scoring technique is done to accurately predict the exact date of ovulation<sup>2,3</sup>, subsequent timely sex and also help to implement proper drugs for successful implantation thus increasing chances of subsequent pregnancy rate<sup>4,5</sup>.

Scoring helps to identify which patient should be given which drug rather than rampant and irrational use of drugs to induce ovulation. Scoring enables us

<sup>1</sup>MD, PhD, FRCOG, Senior Consultant, Department of Obstetrics and Gynaecology, Gynaecology Institute of Clinical Excellence, Kalyani, West Bengal 741235

<sup>2</sup>MBBS, MS , PGDHHM, PGDMLS, Professor and Unit Head, Department of Obstetrics and Gynaecology, IQ City Medical College Hospital, Durgapur, West Bengal 713206

<sup>3</sup>MBBS, MD (Radiodiagnosis), Assistant Professor, Department of Radiodiagnosis, Gouri Devi Institute of Medical Sciences and Hospital, Durgapur, West Bengal 713212 and Corresponding Author

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to group which patient requires basic treatment or which requires cycle stimulation. This is also beneficial in Rural Population where affordability of basic Drugs is less and compliance is poor.

**MATERIALS AND METHODS**

This study was conducted at GICE Infertility Clinic, Kalyani, from April, 2018 to March, 2022. During this period 800 cases were selected. Patients were selected on Double blinded randomization for only those who had infertility and we are observing them for Natural Cycle monitoring or basic Infertility Treatment to induce Ovulation by Scoring Various Parameters

**Inclusion Criteria :** All women who are being chosen for natural cycle and ovulation monitoring as well as those who require basic induction/stimulation for Ovulation

**Exclusion Criteria :** Anatomical factors, cervical factors and other causes like PID, endometriosis, leiomyoma.

Consent was taken from each participant before they participate, Funding is self, Ethical standards were maintained as *none* of the drugs used are experimental, but are the same medicines approved by Government of India and Drug Controller, Ethical Permission was obtained.

This Study is just using an observational method and grouping patients according to their score and giving established drugs in a planned manner to avoid unnecessary/ rampant use of medicines randomly.

Monitoring of exact time of ovulation were done by USG (TVS), cervical mucus study (per speculum examination) and hormonal analysis on D13 of 28 days normal menstrual cycle, Scoring were done which includes size of Graafian Follicle (GF), Endometrial Thickening (ET), Cervical Mucus(CM), Progesterone (P) and LH hormone (L) levels.

Score of 0,1,2 were given on each Observations on D-13 of cycle			
Criteria of Scoring as per findings in Observations			
	0	1	2
Size of Graafian Follicle (GF)	<15mm	16-20mm	>20mm
Endometrial Thickening (ET)	<5mm	6-8mm	>8mm
Cervical Mucus (CM)	STICKY/ SCANTY <sup>7</sup>	WET/ DRIBBLE <sup>7</sup>	SLIPPERY/ CASCADE <sup>7</sup>
Progesterone (P)	<10pg/ml	10-15pg/ml	>15pg/ml
LH- (L)	<20µ/ml	20-25miu/ml	>25miu/ml

Distribution of Scoring in Group	
Group A	8-10 (GF – 2, ET- 1 or 2, CM – 1or 2, P-2, LH- 2)
Group B	5-7 (GF – 1, ET- 1 or 2, CM – 1, P- 1 or 2, LH- 1 or 2)
Group C	<5 (GF – 0 or 1, ET- 0 or 1, CM – 0-1, P- 0-1, LH- 0-1)

Management Protocols	
Group –A (418)	Inj-hcG (5000 IU) on D13, Dydrogesterone – 20mg/daily from D14 for 10 days.
Group –B (274)	FSH (75 IU) on D2& D8, Estradiol Valerate (2mg) from D5 for 10 days, Inj-hcG (5000 IU) on D13, Dydrogesterone – 20mg/daily from D14 for 10 days.
Group –C (108)	FSH (75 IU)- on D2 and D8, Clomiphene Citrate (100mg)- D3 to D7, Estradiol Valerate (2mg) D5 for 10 days , Inj-hcG (5000 IU) on D13, Dydrogesterone – 20mg/daily from D14 for 10 days.

**OBSERVATIONS**

Duration of infertility more than 4 years were found to be 15.6% (n-125) of the patients, 37.6% (n-300) of patients in between 2-4 years & 46.8% (n-375) patients in between 1-2 years respectively (Table 1).

On 5<sup>th</sup> day of missed period and with/without a history of light bleeding, nausea & mood swings, USG (TVS) was done. It is interesting to observe that Implantation rate in Group A – (N-418) were found to be better (71.7%) as compared to Group B (N-274) – 45.6% & Group C (N-108) 37% respectively (Table 2).

After Implantation (Table 3) the embryo usually produces sufficient amount of hCG to be detected in the initial pregnancy test which is either conducted in blood or urine in the absence of an definite identifiable pregnancy (foetal pole) on USG.

It was observed that Group A – 64.6% (N-418) had more percentage of biochemical pregnancy as compared to Group B – 38.3% (N-274) & Group C – 32.4% (N-108).

It is also seen that in Group A In spite of 71.7% Implantation Rates, Biochemical Pregnancy rates have reduced to 64.6% as compared to in Group B (Implantation to Biochemical Conversion Rate) of

Years	Number	Percentage
1-2 years	375	(46.8%)
2-4 years	300	(37.6%)
>4 years	125	(15.6%)

Group	Number	Percentage
Group A (418)	300	(71.7%)
Group B (274)	125	(45.6%)
Group C (108)	40	(37%)

Group	Number	Percentage
Group A (418)	270	(64.6%)
Group B (274)	105	(38.3%)
Group C (108)	35	(32.4%)

45.6% to 38.3% and in Group C - 40% to 32.4% respectively indicating that further study like biochemical, immunological, molecular and genetic study may require for better diagnosis & treatment.

During follow-up (Table 4) of 375 pregnancy cases with proper history and physical examination,  $\beta$ -hCG in serum & Urine and USG(TVS) were done on 6 weeks of pregnancy.

It was interesting to note that in Group -A approx 62.3% (N-418) had successful clinical pregnancy (ie, Presence of Foetal pole) as compared to Group B – 36.1% (N-274) and Group C – 28.7% (n-108) clinical pregnancy.

Hence it is important to note that dydrogesterone were found to be better result to have clinical pregnancy rate as per scoring 8-10 ( Group A) through it reduces from 64.6% (Bio-chemical pregnancy) to 62.3% (Clinical pregnancy) as compared to Group B 38.3% (Bio-chemical) to 36.1% ( Clinical) & Group-C -32.4% (Bio-chemical) to 28.7% (clinical) pregnancy respectively which also require further study of maternal & foetal immunological and genetic factors etc.

### DISCUSSION

Ovulation usually occurs in between 12th to 16th days of normal 28 days menstruation cycle. Every woman had ovulation about 14th days before her next period. Normal timing of sex is also paramount important for successful pregnancy outcomes<sup>1</sup>.

Exclusion of PCOS, Hypothyroid, Hyperprolactinemia, POF and obesity is very much important, ( Who had the history of irregular menstrual cycle) to diagnose exact date of Ovulation.

Hence, detection of ovulation and timely sex/IUI/ IVF & ET is found to be very important for the successful pregnancy outcome<sup>7</sup>.

To have a successful Implantation Rate as well as viable clinical pregnancy - there should be excellent endometrial receptivity and synchronization in between size & shape of Graafian follicle (>20mm), Oestrogen level >600 pg, Endometrial Thickening (ET) >8 mm , cervical mucus (cascade) as well as good vascularisation of endometrial wall.

Level of LH (>25 mIU/ml) is very much significant as regards rupture of mature Graafian follicle and excellent nutritional environment at endometrium (good receptivity by progesterone) for embryo implantation<sup>2</sup>.

Although in practical reality it is not found to occur (non-synchronization) in between size of Graafian Follicle with Estrogen secretion<sup>3,4</sup> endometrial thickening, cervical mucus changes and exact timing

Table 4 — Clinical Pregnancy

Group	Number	Percentage
Group A (418)	245	(62.3%)
Group B (274)	99	(36.1%)
Group C (108)	31	(28.7%)

of sex which may be the important causes of failure of pregnancy<sup>5,6</sup>.

Due to above facts “Dutta’s Scoring” were undertaken at GICE Infertility clinic. 800 cases were selected for a randomized trial. Monitoring of exact time of ovulation were done by USG (TVS), as well as hormone assays on D13 of 28 days normal menstruation cycle.

Depending on findings – scoring were done which included the size of Graafian Follicle (GF), Endometrial Thickening (ET), Cervical Mucus (CM) as well progesterone (P) & LH (L) hormone level. Score of 0,1,2 were given an each observations.

Criteria of scoring were given as per finding on observations. Accordingly, distribution of scoring were done in different groups – Group A – 8-10 (N-418), Group B – 5-7(N-274) & Group C - <5(N-108) as well as management protocols – which include Group A – (N-418) =Inj-hcG (5000 IU) on D13, Dydrogesterone -10mg - twice daily from D14 for 10 days. In Group B – (N-274)- FSH (75mg) in D2 & D8, Estradiol Valerate (2mg) from D5 to D15 and Inj-hcG (5000 IU) on D13, Dydrogesterone 10 mg twice daily from D14 for 10 days & in Group C – (N-108) – FSH (75 IU) or D2 and D8 , Clomiphene citrate (CC) 100mg from D3 to D7, Estradiol Valerate (2mg) from D5 to D15 and Inj-hcG (5000 IU) on D13, Dydrogesterone 10 mg twice daily from D14 for 10 days .

Once pregnancy is confirmed by  $\beta$ -hCG in both blood and urine – continuation of Dydrogesterone were advised till clinical pregnancy and to be continue upto 28 weeks of pregnancy.

From our randomized study – it is very much important to observe that following “ Dutta’s Scoring” and management protocols - Implantation Rate (IR) were found to be better in Group A – (418) - 71.7% as compare to Group B (N-274) – 45.6% and Group C – (N-108)- 37% respectively.

On follow-up study it was also interesting to note that Group A –64.6% (N-418) had biochemical pregnancy as compare to Group B – 38.3 % (N-274) and Group C –32.4 (N-108) cases. On further analysis it is also seen that in Group A in spite of 71.7% Implantation Rate (gestational sac) has reduced to 64.6% (biochemical pregnancy) as compare to Group B – from 45.6% to 38.3% and Group C- from 37% to 32.4% respectively, require further study to know

exact causes of failure which may be due to biochemical, molecular, or maternal and foetal immunological, or genetic problem.

It is very much significant to observe that – during routine check-up of 6 weeks of pregnancy which includes history, physical examination,  $\beta$ -HcG in blood & urine and USG – it was noted that in Group A – 62.6% (N-418) had successful clinical pregnancy (presence of foetal heart rate) as compare to Group B – 36.1% (N-274) and Group C – 28.7% (N-108) respectively.

It is also showed from this study that Dydrogesterone therapy were found to be better to have successful clinical pregnancy rate in Group A, – where scoring is in between 8-10 as compare to Group B and Group C. On further analysis, it was also observe that in Group A – 64.6% (BP) has reduced to 62.3% (CP) as compare to Group B – 38.3% (BP) to 36.1% (CP) pregnancy, Group C – 32.4% (BP) to 28.7% (CP) which indicates that through investigations is to be undertaken to know the exact causes of failure.

#### CONCLUSION

It is concluded from this study that “Dutta’s Scoring Technique” helps to find the exact date of ovulation in 28 days of normal menstrual cycle and also helps to know actual timing of sex as well as implementation of proper drugs for a successful clinical pregnancy rate, but further study is to be undertaken in future whether Dutta’s Scoring Technique is really a good method to know exact date & time of ovulation, timely sex and implementation of different drugs or not.

#### Compliance with Ethical Standards

**Conflict of Interest :** Dilip Kumar Dutta, Indranil Dutta, Dr Rumpa Banerjee Dutta declare that they have no conflicts of interest.

**Informed consent :** All procedure followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008. Informed consent was obtained from all patients for being included in the study.

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