*IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)*
*e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 17, Issue 6 Ver. 16 (June. 2018), PP 12-18*
*www.iosrjournals.org*

# Comparative Study of Clinical Efficacy of Dinoprostone Sustain Release Vaginal Peccary &Intracervical Gel for Induction of Lab our.

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***Abstract:*** *With the availability of dinoprostone sustained release vaginal pessary in India, for induction of labour (IOL), this study was planned with the aim of studying its clinical efficacy and comparing it with another preparation of dinoprostone which has been available and being used since years for IOL, i.e. instant released intracervical gel. Different study from west has shown the vaginal dinoprostone to be safe and efficacies for IOL, and PGE2 in different forms of tablets, gel and pessary appear to be equally efficacies. The vaginal preparation has an advantage of single application, slow and sustained release of drug over 24 hours, less invasiveness, ease of administration and removal allowing greater dose control. Patients selected for induction were offered sustained release vaginal preparation and intracervical preparation alternatively and relevant data were collected for first 100 patients for each group. There was statistically insignificant difference between the two groups in parity, gestational age and indications for induction for labour and also in induction delivery interval and change in bishop score after 6 hours. However, the rate of caesarean section was more with the use of intracervical gel (37%) as compare to vaginal pessary (29%) and also the need of oxytocin was higher in intracervical gel group (72%) as compared to vaginal pessary group (51%). Adverse effects reported were also found to be the same in both the groups. Therefore, intravaginal sustained release preparation of dinoprostone was found to be more effective than intracervical instant release preparation for IOL.*

***Keywords:*** *Induction of Labour, dinoprostone, vaginal pessary, intracervical gel.*

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Date of Submission: 16-06-2018 Date Of Acceptance: 02-07-2018

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## I. Introduction

Labour is often induced in 15-30% of term pregnancies due to various fetal-maternal conditions, using different methods and drug formulations.[1] Slow release dinoprostone (PGE2) vaginal pessary, has been licensed for use in India, for induction of labour (IOL), since June 2016. There are various other dinoprostone preparations available, which has been used since the 1972's for induction of labour, which differ in their effectiveness and side effects.[2] The most commonly used is intracervical instant release gel, for which the evidence suggests that in females with unfavorable cervix, intracervical PGE2 is more effective than placebo, as an inducing agent, but it is less effective than vaginal PGE2, in achieving vaginal birth within 24 hours. The disadvantages associated with its use is related to the invasive nature of administration, and to the frequency of dose repetition.[3]

Slow release vaginal preparations of PGE2 is being used in various countries for long and has an advantage of sustained physiological release of prostaglandin, resulting in slow and progressive cervical effacement, and it has retrieval system which allows immediate removal if hyperstimulation occurs. Also the application is easier and less invasive, with fewer dose requirement to achieve ripening of cervix and IOL [4]Dinoprostone vaginal delivery system is a controlled release hydrophilic matrix containing 10 mg. of dinoprostone, which provides a gradual release of the drug, releasing 03mg/hr in a controlled manner over 24 hours after single administration. The knitted polyester retrieval system allows easy removal if hyperstimulation occurs.[5]The effects and properties of PGE2 have been studied in various studies, comparing the efficacy of the

different formulations available. To our knowledge, this is the first Indian study for publication comparing commonly used PGE2 intracervical gel to the recently available slow release vaginal insert.

## II. AIM

This prospective randomized comparative study was done to detect the clinical efficacy of newly available preparation of dinoprostone slow release vaginal pessary and to compare it with the dinoprostone immediate release intracervical gel which has been used since long for IOL.

## III. Material & Methods

This prospective randomized comparative study was done at Mahatma Gandhi Medical College & Hospital, Jaipur since the availability of sustain release dinoprostone vaginal insert for induction of labour in India. Patients selected for induction of labour were offered slow release dinoprostone vaginal insert and immediate release intracervical gel alternatively. After admission, detailed history, systemic and obstetric examination, routine investigation and ultrasound was done. Patients selected for induction of labour and those who fulfilled the exclusion and inclusion criteria were divided into 2 groups according to the preparation of dinoprostone used. Informed consent for IOL, and for preparation of PG used was taken. Approval of the ethical committee of the institute was taken before starting the study.

The inclusion criteria were those with singleton pregnancy, vertex presentation, gestational age $\geq$ 37 weeks (calculated by LMP and confirmed by first trimester ultrasonography) and bishop score $\leq$ 5. The exclusion criteria were presence of any contraindication to vaginal delivery, any contraindication for labour induction by prostaglandin or oxytocin, history of previous caesarean section or any other uterine surgery, patients with bishop score > 5, presence of uterine activity, fetal presentation other than cephalic and active vaginal bleeding.

Patients selected for intravaginal insert, received a single dose of 10 mg slow release dinoprostone vaginal insert placed transversely in the posterior fornix of the vagina. The insert was removed after 24 hours. Also the insert was removed earlier if a nonreassuring FHS pattern persisted, or if regular painful uterine contractions started. Those selected for intracervical gel, received the instant release gel preparation containing 0.5 mg dinoprostone. A second, or a maximum of three doses of gel were repeated after every 6 hours if there is no response. Continuous electronic fetal heart monitoring was done for 30 minutes after administration of PG, and after that two hourly CTG was done till patient enters in active phase of labour. Labour monitoring was done according to the new FIGO consensus guidelines on intrapartum fetal monitoring. [6] Induction failure was considered when the Bishop score was still less than 6 and in case regular contractions did not start after 24 hours of dinoprostone use.

The relevant data of first 100 patients in each group were collected and tabulated, including demographic data, indications of IOL, changes in bishop score in 6hours, 12hours, and 24 hours, labour details, induction to delivery interval, and neonatal outcome.

The primary outcome measures studied were:-

- Achievement of uncomplicated vaginal delivery
- Induction to delivery interval

The secondary outcome measures studied were:-

- Change in bishop score after 6 hours induction
- Need for oxytocin for acceleration labour
- Fetal and maternal adverse effects

## IV. Observation and Results

The results of the first 200 patients, selected for induction and fulfilling the inclusion/exclusion criteria were analysed. Out of all patients, which were induced by dinoprostone 2 patients demanded LSCS after induction and in 1 patient the pessary was expelled, these 3 patients were excluded from the study.

Table No. 1 - Demographic variables in women in two study groups

| Variables | | Vaginal Passary | Intracervical gel |
|---|---|---|---|
| Age (in years) | | 23.9 ± 3.33 | 24.11 ± 3.20 |
| Parity | Nullipara | 46 (46%) | 59 (59%) |
| | Multipara | 54 (54%) | 41 (41%) |
| Gestational Age (in days) | | 279.85 ± 23.14 | 281.06 ± 26.32 |

Figure 1: Pie chart showing indications for induction of labour in patients with Vaginal Pessary

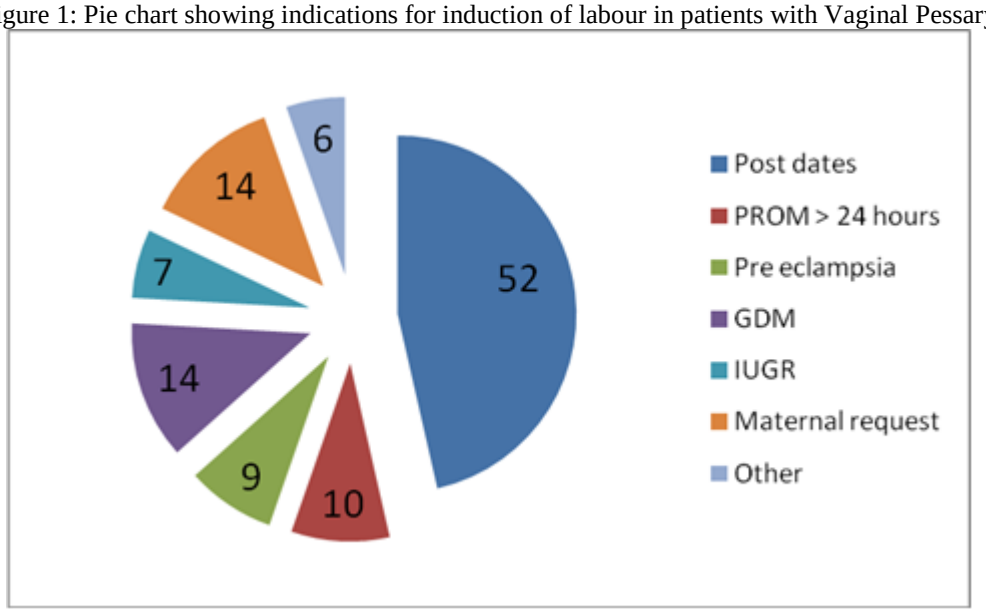


Figure 2: Pie chart showing indications for induction of labour in patients with Intracervical gel

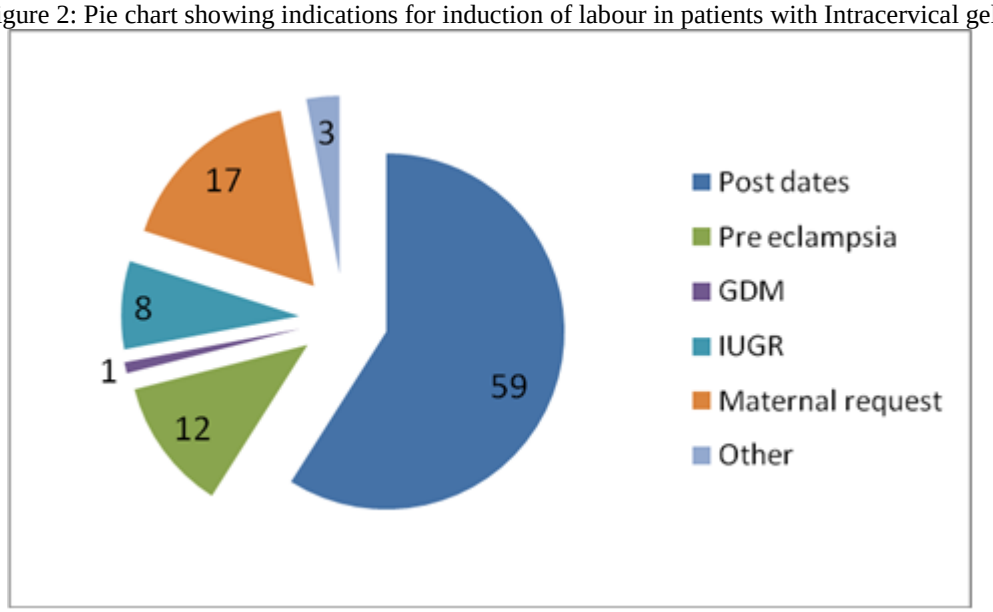


Table no. 1 shows age of the patients, parity, the mean gestational age and indication of induction was comparable in both the groups. Postdated pregnancy was the major indication in both the groups and the rest were preeclampsia GDM, IUGR and others like oligohydramnios, Rh isoimmuniation etc. There were ten cases of PROM in vaginal pessary group, no case of PROM was offered intracervical gel. A few patients (14 in vaginal pessary group + 17 in intracervical gel group) who requested induction, were also included in the study. The indications were equally distributed in the two groups as per figure no. 1 & 2.

Table No. 2 - Delivery outcome

| Variables | | SVD/ Instrumental delivery N(%) | LSCS N(%) | Chi square (df) | p value |
|---|---|---|---|---|---|
| Primigravida | Vaginal pessary | 30 | 16 | 0.929 (1) | 0.335 |
| | Intracervical gel | 33 | 26 | | |
| Multigravida | Vaginal pessary | 41 | 13 | 0.973 (1) | 0.760 |
| | Intracervical gel | 30 | 11 | | |
| All women | Vaginal pessary | 71 | 29 | 1.45 (1) | 0.229 |
| | Intracervical gel | 63 | 37 | | |

Table no. 2 shows that out of total 46 nulliparous patients, in which vaginal pessary was inserted, 30 patients delivered vaginally and 16 had LSCS, and out of 59 nulliparous patients selected for intracervical gel, 33 delivered vaginally and 26 had LSCS. The difference in LSCS rate among nulliparous patients using vaginal pessary of intracervical gel was statistically insignificant. In multigravida, 54 patients had vaginal pessary, 41 patients delivered vaginally and 13 had LSCS, and in intracervical groups. Out of total 41 multigravida, 30 delivered vaginally and 11 had LSCS. This difference was also insignificant statistically. So the gravidity has no influence on induction according to the preparation of dinoprostone use.

Table No. 3 - Efficacy and maternal/fetal outcome

| Variables | | Vaginal Passary | Intracervical gel | Chi square (df) | p value |
|---|---|---|---|---|---|
| Induction delivery interval | < 12 hours | 42 (42%) | 37 (37%) | 2.42 (2) | 0.299 |
| | 12-24 hours | 46 (46%) | 43 (43%) | | |
| | > 24 hours | 12 (12%) | 20 (20%) | | |
| LSCS | Yes | 29 (29%) | 37 (37%) | 1.45 (1) | 0.229 |
| | No | 71 (71%) | 63 (63%) | | |
| Oxytocin augmentation rate | Yes | 51 (51%) | 72 (72%) | 9.31 (1) | 0.002 |
| | No | 49 (49%) | 28 (28%) | | |
| Variables | | Vaginal Passary | Intracervical gel | t value | p value |
| Bishop score | At admission | 4.58 ± 0.912 | 4.56 ± 0.902 | 0.156 | 0.876 |
| | After 6 hours | 5.91 ± 2.238 | 5.52 ± 1.654 | 1.401 | 0.163 |

According to table no. 3 the induction delivery interval was found to be the same in both the groups of vaginal pessary and intracervical gel. In vaginal pessary group, out of 100 patients, 42 delivered within 12 hours and 12 patients took > 24 hrs., rest of 46 patients had delivered within 12-24 hours. In 100 patients of intracervical group, 37 delivered within 12 hours, 43 within 12-24 hours and 20 patients took > 24 patients to deliver. The p value was calculated as 0.299 and therefore statistically insignificant.

The difference in LSCS rate was also statistically insignificant, being 29% in vaginal pessary group and 37% in intracervical gel group. The only significant difference found in both the groups was the use of oxytocin for augmentation of labour, 51 patients of vaginal pessary group and 72 patients of intracervical group required oxytocin for labour augmentation, and the p value was found to be 0.002. The change in bishop score after 6 hours of induction was also same in both the groups.

Table No. 4 - Adverse effects observed

| Adverse event reported | Vaginal Passary | Intracervical gel | Chi square (df) | p value |
|---|---|---|---|---|
| Yes | 23 | 22 | 0.287 (1) | 0.866 |
| No | 77 | 78 | | |
| Adverse effects observed | | | Vaginal Passary | Intracervical gel |
| Fetal distress (FD) | | | 03 | 03 |
| Meconium stained liquor (MSL) | | | 03 | 06 |
| FD + MSL | | | 04 | 07 |
| Non progress of labour (NPOL) | | | 09 | 04 |
| FD + NPOL | | | 04 | 02 |

Table no. 4 depicts the maternal and foetal adverse effects, which were fetal distress, meconium stained liquor and non-progress of labour. These were present in 23 patients of vaginal pessary patient group and 22 patients of intracervical group. Therefore, no difference observed in no. of patients with adverse effects in both the groups. None of these patients, who had their labour induce, developed hyperstimulation.

## V. Discussion

Induction implies stimulation of contraction before the spontaneous onset of labor, with or without ruptured membranes.[7] It is indicated when the benefit to either mother or fetus overweigh those of continuation of pregnancy e.g., premature rupture of membrane, hypertensive disorder of pregnancy, oligohydramnios, post term pregnancy etc. & is contraindicated in most conditions that preclude spontaneous labor or delivery.[8] There are various methods available for induction, like oxytocin, prostaglandins, such as misoprostol &dinoprostone and mechanical methods like membranes stripping, artificial rupture of membrane, extra amniotic saline infusion & hygroscopic cervical dilations. The risk of induction includes caesarean delivery, chorioamnionitis, uterus scar rupture & postpartum hemorrhage because of uterine atony. [7] Because of these side effects the guidelines for perinatal care recommends that each obstetrical department should have its own written protocol for labor induction & augmentation. [9]

Local application of dinoprostone is commonly used for cervical ripening. [8]Dinoprostone is available in 3 forms worldwide, a gel, a time release vaginal insert and a 10 ml. suppository. In India, only the gel form was available is being used commonly. A 10-mg dinoprostone vaginal insert was introduced, and was licensed to use in Indian market since June, 2016. (Govt. of India, central drugs standardized control, registration certificate no RC/FF - 002002). Various studies have been done to compare different formulation of prostaglandin for IOL& the available evidence show conflicting result.

According to NICE clinical guidelines for IOL, July 2008, for women with an unfavorable cervix, intracervical $PGE_2$ is less effective than vaginal $PGE_2$& confers no benefit, and for women with a favorable cervix, it achieves similar maternal outcome. As intracervical administration is invasive, IC $PGE_2$ is not commonly used in the UK. [3]Another study done at walsall hospitals NHS Trust, UK, suggest that intracervical & intravaginal preparations of PGE2 are equally effective in inducing labor. There was no significant difference between the two as regards to vaginal delivery rate in 24 hours, bishop's score change of > 3 in 24 hours & induction to delivery time. [10]

In a study done to investigate the effect of parity on cervical ripening and labour induction with intra vaginal slow release dinoprostone it was concluded that considering the good performance of dinoprostone slow-release vaginal insert, the choice toward elective induction of labor in high risk pregnancies seems to be certainly facilitated, in both nulliparous and multiparous patients with an unfavorable cervix.[1]

One systematic review (56 RCTs involving 7738 women) assessed the effects of intracervical PGE2 versus placebo/no treatment, versus vaginal PGE2, and of different doses of intracervical PGE2. In women with an unfavorable cervix, intracervical PGE2 was significantly associated with vaginal birth within 24 hours and no difference in caesarean birth when compared with placebo/no treatment. Intracervical PGE2 was significantly more likely not to achieve vaginal birth within 24 hours compared with vaginal PGE2. In women with a favorable cervix, no significant differences were found between intracervical PGE2 and vaginal PGE2 in caesarean and instrumental vaginal birth rates.[11]

There havebeen several meta-analyses and systematic reviewsevaluating the use of PGE2 and suggesting that it iseffective for cervical ripening and labor induction,without distinguishing between dinoprostone insertand gel, RCTs involving 1779 women have showndinoprostone insertcould greatly contribute to vaginal delivery within 24 h compared with dinoprostonegel and the researchers found obvious statisticallysignificant difference ($p = 0.003$). Dinoprostone insert showed a distinct superiority in terms of vaginal delivery within24 h and had an advantage of a shorter hospital stay and less postpartum hemorrhage incontrast to gel.[12]

Another study reconfirms, in agreement with the published data, that both prostaglandin preparations – intracervical gel and intravaginal insert are equally effective in inducing labour. They did not find significant differences between the two preparations as regards to vaginal delivery rate in 24 h, Bishop's score change of 43 in 24 h and induction to delivery time interval. Intravaginal insert was associated with a significantly less number of vaginal examinations as compared with intracervical gel. This amounts to less invasiveness and increased patient comfort and satisfaction.[9] In a study done to investigate the efficacy and safety of vaginal propess as a methodology for cervical ripening and labour induction in full-term pregnant patients, it was found that the bishop score and the rate of vaginal delivery were significantly higher while the induction to delivery interval and total delivery time were much shorter, as compared with oxytocin. There were no significant differences in fetal and maternal outcome and they concluded that propess is an effective and safe approach to promote cervical ripening and be successfully used in IOL.[13]

Hatice et al. has done a study in 2017 to evaluate the efficacy and safety of dinoprostone for cervical ripening and labor induction in patients with term oligohydramnios and bishop score $\leq 5$, and they found that dinoprostone appears to be a safe alternative for IOL. IOL with dinoprostone in term pregnancies with isolated oligohydramnios is associated with increased rate of CS but there is no higher risk of perinatal complications.[14]

One Cochrane review of 2014, which included 70 randomized controlled trials, focusing on prostaglandins given per vaginum, evaluating these in comparison with placebo and with each other; prostaglandins (PGE2 and PGF2a); different formulations (gels, tablets, pessaries) and doses. Overall vaginal prostaglandin E2 compared with placebo or no treatment probably reduces the likelihood vaginal delivery not being achieved within 24 hours. The risk of uterine hyperstimulation with fetal heart rate changes in increased. The caesarean section rate is probably reduced by about 10%. PGE2 tablets, gels and pessaries appear to be as effective as each other.[15]

A study done in Frankfurt, Germany in 2014 comparing an efficacy safety and patients perception of two prostaglandin E2 application methods for IOL concluded that there was no statistical significance difference between the two groups in regard to perceptions of induction. No statistically difference between the groups was detected in regard to parity, gestational age, cervical bishop score, number of fetal blood samples, rate of oxytocin augmentation and mode of delivery.[16]

## VI. Conclusion

Though the dinoprostone show release vaginal insert seems to be easy to use, effective and safe for the mother's and fetus's health, the data obtained by this study suggest that there is no statistically significant difference in the number of vaginal birth or induction delivery interval in using both the preparation of dinoprostone for induction of labour. The only difference found was the use of oxytocin for labour acceleration, which was significantly more with intracervical gel. The Limitations of the study is that the patients satisfaction level related to the route of administration and cost effectiveness of use of both the preparations of dinoprostone needs to be studied, as intracervical route is supposed to be more difficult and uncomfortable for the patients, and there is a difference in the cost and number of doses required for both the preparations.

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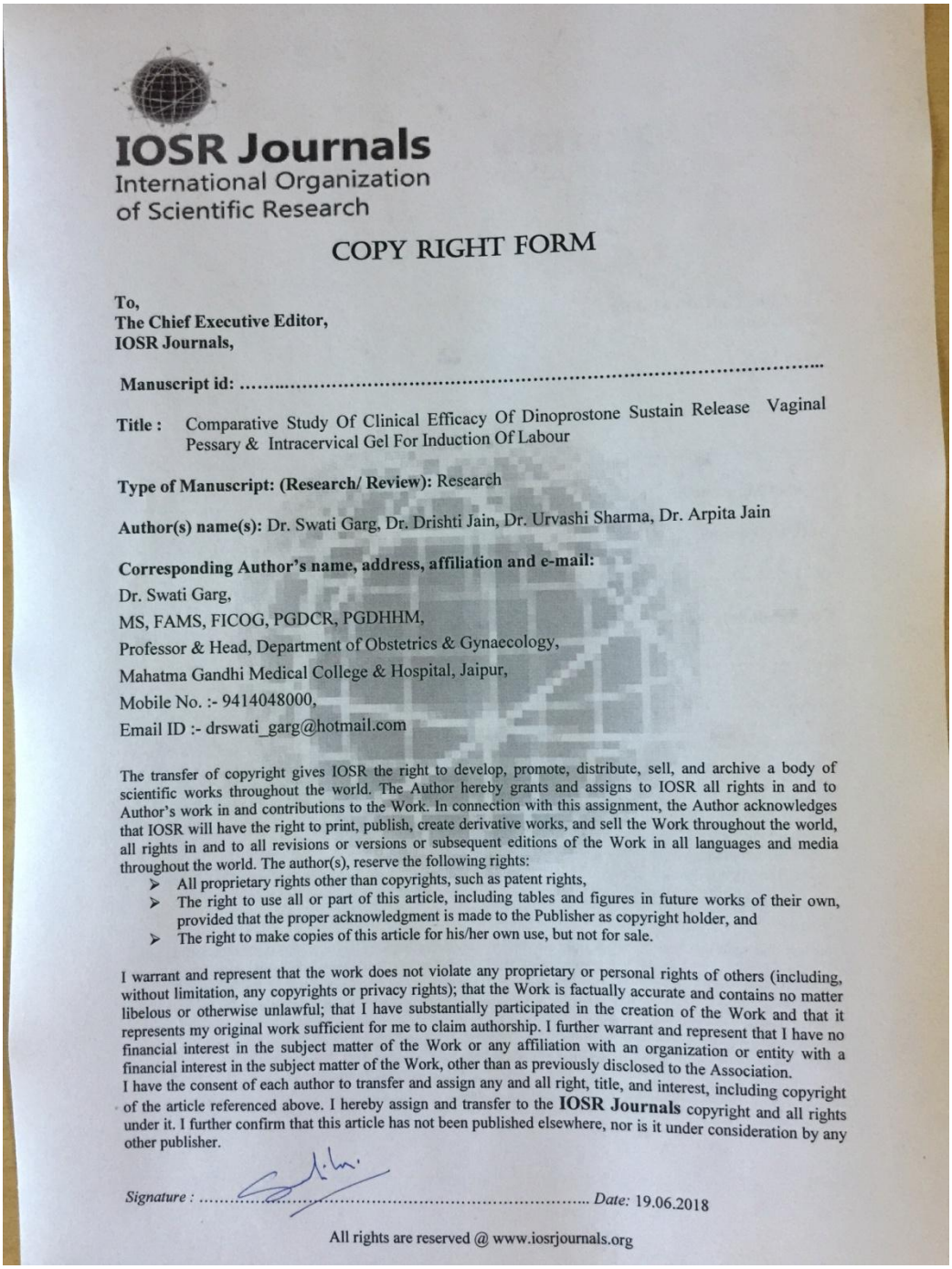

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**Type of Manuscript: (Research/ Review):** Research

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