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Original Research Article

Comparison of clinical pregnancy rates and miscarriage rates in frozen vs selective fresh embryo transfers: a multicentric retrospective analysis

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ABSTRACT

Background: IVF initially involved making of embryos and transferring in same cycle. However, with advanced freezing techniques, most of the clinics now have shifted to freeze all strategy claiming better pregnancy rates. Our study aims to compare clinical outcomes in frozen vs. selective fresh transfers. We also compared clinical outcomes in these groups in subgroups of PCOS, Poor reserve, tubal factor, endometriosis and male factor.
Methods: Multicentric, retrospective study conducted across 65 centers. The IVF cycles were included for a period of 5 years from 1st January 2019 to 31st December 2023. Sub fertile couples between 23 to 43 years of age undergoing self-cycles in antagonist protocol, undergoing embryo transfer with one or two blastocysts. Patients with severe uterine factor infertility (multiple fibroids, unicornuate uterus, Asherman's syndrome, and severe adenomyosis), patient who had history of previous three or more IVF failure (recurrent implantation failure), patients with bad obstetric history (three or more pregnancy losses) were excluded.
Results: Total number of embryo transfers were 38,789. Frozen transfers were 34,407 and 4382 were fresh embryo transfer. Only those patients which had clinically low risk of OHSS and good endometrial thickness with trilaminar appearance were considered for fresh embryo transfers. Clinical pregnancy rates and miscarriage rates were calculated in both the groups. Further, the clinical pregnancy rates and miscarriage rates were also calculated in subgroups like PCOS group (n=3341), tubal factor (n=1929) endometriosis (n=693), low ovarian reserve (n=863) and male factor infertility (n=31963).
Conclusions: Our study showed better pregnancy rates with frozen embryo transfers over fresh embryo transfers, more so in endometriosis and male factor infertility. However, even miscarriage rates are higher in frozen embryo transfer except in endometriosis patients.

Keywords: Fresh, Frozen, Pregnancy rates, Miscarrige

INTRODUCTION

The first baby born through IVF was in 1978. Since then, there have been many advances in IVF techniques. On 28th March 1984, Zoe Leyland was born, the first baby from a frozen embryo.[1] The freezing method used at that time was slow freezing. Later improvements, especially blastocyst vitrification, have significantly increased embryo survival compared to slow freezing. Because vitrification results in higher survival rates, improved pregnancy rates, and healthy neonatal outcomes, most IVF centres now favour frozen embryo transfer (FET) over fresh cycles.[2] In 2011, Devroey et al developed the 'freeze-all' strategy to prevent ovarian hyperstimulation syndrome (OHSS), a potentially

life-threatening condition.[3] Additionally, supraphysiological hormone levels during controlled ovarian stimulation can reduce endometrial receptivity.[4] It is hypothesised that the freeze-all strategy may be linked to higher clinical pregnancy rates; however, further research is needed to determine if it also leads to higher miscarriage rates. Our study aims to compare clinical pregnancy rates and miscarriage rates between fresh embryo transfers (ET) and frozen embryo transfers (FET). Furthermore, when analysing infertility factors, the study seeks to identify which factors show better outcomes with frozen transfers. The primary outcome was to assess the clinical pregnancy rates during FET compared to ET. The secondary outcomes included comparing miscarriage rates between the two techniques and identifying which subsets of infertility would benefit most from FET.

METHODS

It is a multicentric, retrospective study conducted across 65 centres of a private fertility clinic in India and Bangladesh. Ethical committee approval was obtained for the study. Waiver of consent was granted by the Ethics Committee as there was no contact with any of the patient. Data were collected from software records, and patient confidentiality was strictly maintained. The software records of the centre, maintained over a five-year period, were scrutinised to retrieve the data. The IVF cycles included spanned a period of 5 years, from 1st January 2019 to 31st December 2023. Participants comprised subfertile couples aged between 23 and 43 years who underwent IVF/ICSI with their own eggs. Only the antagonist protocol was considered, with one or two blastocyst transfers. Patients with severe uterine factor infertility such as multiple fibroids, unicornuate uterus, Asherman's syndrome, and severe adenomyosis were excluded. Patients with a history of three or more previous IVF failures (recurrent implantation failure) or a poor obstetric history (three or more pregnancy losses) were also excluded. The records with the missing data were excluded. Data from 38,789 embryo transfers were analysed. These were divided into two groups: Fresh ET and frozen ET. When selecting patients for fresh transfer, only those with a clinically low risk of OHSS and good endometrial thickness with a trilaminar appearance were included. Clinical pregnancy rates and miscarriage rates were noted for both groups. Furthermore, each group was divided into five subgroups depending on the factors causing infertility PCOS, tubal factor, endometriosis, low ovarian reserve, and male factor. Clinical pregnancy and miscarriage rates in both ET and FET were further analysed and compared within each of these subgroups.

Women were called on day 2 or 3 of the menstrual cycle for a baseline scan, and ovarian stimulation was initiated with gonadotrophins (recombinant FSH, menotropins, or a combination of the drugs). The dose was determined by the antral follicular count on day 2 or 3. The maximum dose of gonadotrophins used was 600 IU per day. An antagonist protocol was employed. A GnRH antagonist (Ganirelix, Cetrorelix) was added when the dominant follicle was above 12 mm and continued until the day of trigger. The trigger was administered when two or more follicles reached 17 mm. The trigger used was either recombinant HCG (250 mcg) or inj. Triptorelin (0.2 mg) subcutaneously. Ovum pick-up was performed between 35 to 36 hours after the trigger. Monitoring of ovarian response, gonadotropin dose adjustments, and the timing of the final oocyte maturation trigger during ovarian stimulation were guided by individual Estradiol (E2) levels and follicular growth assessed by ultrasound.

The embryos were cultured until the blastocyst stage. In patients with a low risk of OHSS (fewer than 15 follicles and serum E2 below 2500) and with good endometrial thickness (8mm or more with trilaminar appearance), one or two blastocysts were transferred on day 5. Luteal phase support was provided through vaginal micronized progesterone 800mg, injectable progesterone 50mg intramuscularly daily, or 8% vaginal progesterone gel daily.

In patients who were candidates for "All freeze" - embryos were frozen on D5 or D6 using vitrification. Only high-quality blastocysts suitable for freezing were selected. During the FET cycle, endometrial preparation was carried out using estrogen premedication (HRT cycle), natural cycle, or modified natural cycle.

Clinical pregnancy was defined by the appearance of gestational sac on ultrasound. The miscarriage was defined as loss of pregnancy within 12 weeks of gestation. The patients were monitored for 12 weeks of pregnancy, and clinical pregnancy rates and miscarriage rates were calculated for both groups. The groups were further divided into subgroups like PCOS, tubal factor, endometriosis, male infertility and poor ovarian reserve. Clinical pregnancy rates and miscarriage rates were determined and compared across various subgroups.

We analysed the data of 38789 embryo transfers across 65 centres of the clinic. The demographic details of the sample population were reported as descriptive data. We used comparison of proportions test for statistical analysis and considered p value as $p=0.05$.

RESULTS

Total number of embryo transfers done were 38789. Frozen transfers were 34,407 and fresh transfers were 4382.

Total number of pregnancies in FET group were 22,467 (65.29%), of which clinical pregnancies were 19735 (57.35%) and miscarriages were 2788 (12.4%).

Total number of pregnancies in fresh ET group were 2186 (49.58%), of which clinical pregnancies were 1885 (43.55%) and miscarriages were 222 (10.34%) (Table 1).

Table 1: Comparison of clinical pregnancy rate and miscarriage rate in fresh vs frozen embryo transfers.

Total	Fresh, N (%)	Frozen, N (%)
Total ET	4382	34407
Pregnancies	2186 (49.58)	22467 (65.29)
Clinical pregnancies	1885 (43.55)	19735 (57.35)
Miscarriages	222 (10.34)	2788 (12.4)

These groups were further divided into 5 subgroups Male factor (Table 2), tubal factor (Table 3) Poor ovarian reserve (Table 4) PCOS (Table 5) and Endometriosis (Table 6). Clinical pregnancy rates and miscarriage rates are calculated in these subgroups.

Table 2: Comparison of clinical pregnancy rate and miscarriage rate in fresh vs frozen embryo transfers in couples with male factor infertility.

Male factor	Fresh, N (%)	Frozen, N (%)
Total ETS	3389	28574
Pregnancies	1707 (50.33)	18467 (64.7)
Clinical pregnancies	1471 (43.37)	16189 (56.76)
Miscarriages	166 (9.72)	2183 (11.82)

Table 3: Comparison of clinical pregnancy rate and miscarriage rate in fresh vs frozen embryo transfers in couples with tubal factor infertility.

Tubal factor	Fresh, N (%)	Frozen, N (%)
Total ET	6	1923
Pregnancies	2 (33.33)	1224 (63.65)
Clinical pregnancies	2 (33.33)	1080 (56.16)
Miscarriages	0	185 (15.11)

Table 4: Comparison of clinical pregnancy rate and miscarriage rate in fresh vs frozen embryo transfers in patients with poor ovarian reserve (POR).

POR	Fresh, N (%)	Frozen, N (%)
Total ET	777	86
Pregnancies	396 (50.9)	55 (63.91)
Clinical pregnancies	342 (44.08)	45 (52.32)
Miscarriages	48 (12.12)	7 (12.72)

Our observations indicated that the overall clinical pregnancy rate of FET was significantly higher than in the ET group (57.35% vs. 43.55%) [p=0.0001]. However, the miscarriage rate was also notably higher in frozen cycles compared to fresh cycles (12.34% vs. 10.34%) [p=0.007]. When we analysed the subgroups, we found that in the endometriosis group, the clinical pregnancy rate of frozen embryo transfer was significantly higher than that of fresh transfer (52.8% vs. 38.55%) [p=0.0146], while the miscarriage rate was significantly higher in the fresh transfers compared to frozen transfers (15% vs. 13.1%) [p=0.0418]. Similarly, in the male subfertility group, the clinical pregnancy rate was significantly higher in the frozen group than in the fresh group (56.76% vs. 43.37%) [p=0.0001], and miscarriage rates were also elevated in the frozen group compared to the fresh group (11.82% vs. 9.72%) [p=0.017]. The difference in miscarriage rate was likewise statistically significant.

Table 5: Comparison of clinical pregnancy rate and miscarriage rate in fresh vs frozen embryo transfers in patients with PCOS.

PCOS	Fresh, N (%)	Frozen, N (%)
Total ET	71	3270
Pregnancies	41 (57.7)	2349 (71.8)
Clinical pregnancies	38 (53.52)	2099 (64.2)
Miscarriages	2 (4.87)	364 (17.3)

Table 6: Comparison of clinical pregnancy rate and miscarriage rate in fresh vs frozen embryo transfers in patients with endometriosis.

Endometriosis	Fresh, N (%)	Frozen, N (%)
Total ETs	83	610
Pregnancies	40 (48.19)	372 (60.98)
Clinical pregnancies	32 (38.55)	322 (52.8)
Miscarriages	6 (15)	49 (13.1)

DISCUSSION

Our study results showed that clinical pregnancy rates were higher in frozen cycles compared to fresh transfers. However, we also observed that the miscarriage rate was higher in frozen transfer patients than in those with fresh cycles.

In recent years, the number of frozen embryo transfers has gradually increased due to improved laboratory conditions and enhanced embryo survival following thawing after vitrification. The practice of elective freezing of all embryos has also risen. Recently, there have been multiple studies on pregnancy rates and clinical outcomes in both fresh and frozen transfers.

In a retrospective study of 128 patients by Gullo et al, the cumulative live births following fresh and frozen transfers were calculated, and they found no significant difference between the two groups.[5]

In a single-centred, randomised, open-labelled trial by Wong et al, 205 cycles were studied. Their results indicated that there might be no benefit of a freeze-all strategy in terms of cumulative ongoing pregnancy rates. They suggested that the effectiveness of the freeze-all approach in different patient subgroups, various stages of

embryo development, and multiple freezing protocols needs further investigation and should be weighed against potential benefits and harms for mothers and children.[6]

The Cochrane review (2021) included a study of eight randomised controlled trials involving a total of 4712 women. The findings of this review showed a cumulative live birth rate of 58% for fresh embryo transfers, while in frozen cycles, the live birth rates ranged from 57% to 63%. The OHSS risk in fresh cycles was 3% compared to 1% in the freeze-all group.

Cochrane review found moderate quality evidence that one strategy is not superior to another in terms of cumulative live birth rates and ongoing pregnancy rates. The risk of OHSS is low in the freeze-all group. They could not draw conclusions regarding miscarriage rates and multiple pregnancy rates in both groups. The risk of maternal hypertensive disorders, large for gestational age babies, and higher birth weight is greater in frozen transfers than in fresh transfers.[7]

In a multicentric, retrospective study by Wang et al, 2990 cycles were analysed, comparing 1445 fresh transfers with 1445 frozen embryo transfer cycles. It was observed that in freeze-only transfer protocols, ongoing pregnancy and implantation rates were statistically significantly higher compared to fresh transfer cycles. This effect was most pronounced in cycles with progesterone >1.0 ng/mL at trigger and was also stronger for patients in higher age groups. The study found that the difference in ongoing pregnancy rates was not statistically significant when serum progesterone was less than 1 ng/ml on the day of trigger, whereas it was statistically significant when progesterone levels exceeded 1 ng/ml on the day of trigger. Additionally, the study demonstrated a trend towards increasing benefit of freeze-only cycles with advancing maternal age; for the same progesterone level, the OR for achieving an ongoing pregnancy in a freeze-only versus a fresh cycle increased with maternal age.[8]

Zuo et al analysed factors associated with early miscarriages in IVF-ET pregnancies. They examined 2591 pregnancies, including 544 fresh and 2047 frozen cycles. The early miscarriage rate in frozen embryo transfer was 1.48 times higher than in fresh embryo transfer. In the fresh cycle, the risk of early miscarriage was halved when using top-quality embryos compared to non-top-quality ones. In the frozen cycle, comparing natural and hormone replacement cycles, the miscarriage risk was 0.73 times lower in natural cycles versus HRT cycles.[9] In our study, we observed that clinical pregnancy rates in the frozen group were significantly higher than those in the selected fresh transfers. The selective fresh embryo transfers involved patients with appropriate endometrial thickness and minimal clinical risk of OHSS. Supraphysiological levels of oestradiol and progesterone following ovarian stimulation are known to accelerate endometrial development and impair its receptivity, thereby reducing implantation rates in fresh transfer cycles. Additionally, when opting to freeze all embryos, a gonadotropin-releasing hormone agonist can be used for final oocyte maturation, enabling the avoidance of an HCG trigger altogether, which significantly lowers the risk of early and late ovarian hyperstimulation syndrome.[13]

When we compared clinical outcomes in different patient subgroups, a statistically significant difference was observed in the endometriosis and malefactor groups. In a systematic review and meta-analysis by Chang et al, it was found that cryopreserved embryo transfer results in better reproductive outcomes compared to fresh embryo transfer in patients with endometriosis; however, the evidence is not yet conclusive.[10] In a study by Justin et al, IVF outcomes were compared in fresh and frozen transfers in 728 women with endometriosis. The results showed that the deferred ET “freeze-all” IVF strategy does not improve early pregnancy outcomes among women with endometriosis.[11]

In our study, we did not find any statistically significant difference in pregnancy rates between fresh and frozen cycles in the PCOS group. However, when selecting patients for fresh transfer, only those with very minimal risk of OHSS were chosen; consequently, the number of PCOS patients undergoing fresh cycles was lower compared to those undergoing frozen transfer. In a multicentric trial by Cheng et al, 1508 PCOS women with fresh and frozen transfers were studied. They concluded that frozen-embryo transfer was associated with a higher rate of live birth and a lower risk of ovarian hyperstimulation syndrome.[12]

The strength of the study is the number of the cases. Study involves huge number of transfers done in multiple centres. Study also tries to find out in which subgroup of patients frozen transfer will be more beneficial than fresh transfer.

We must also acknowledge the study's limitations. Firstly, it is a retrospective analysis. Hence, missing data may affect the study's results. Also, if we could include serum progesterone levels on the day of trigger to decide whether to transfer fresh or go ahead with freeze all, it will have more value as some studies have observed that difference in pregnancy rates was more pronounced when serum progesterone was higher on the day of trigger.

CONCLUSION

In conclusion, our study shows better pregnancy rates with frozen embryo transfers over fresh embryo transfers, more so in endometriosis and male factor infertility. However, even miscarriage rates are higher in frozen embryo transfer.

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