Fertivision 2022- Oral Papers Abstracts

NO 1 COMPARISON OF EFFECTS OF AUTOLOGOUS INTRA-OVARIAN PLATELET RICH PLASMA INSTILLATION ON REPRODUCTIVE OUTCOMES IN POSEIDON 3 VERSUS POSEIDON 4 GROUPS: A PROSPECTIVE STUDY

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Objective: With the rising incidence of female patients with poor ovarian reserve, it is the impetus of reproductive physicians to help these couples conceive with their own biological child. With the emergence of regenerative medicine, platelet rich plasma (PRP) has been portrayed gloriously in improving fertility outcomes; however, conclusive data still remain elusive. Consequently, we attempt to compare the effects of autologous intra-ovarian platelet rich plasma instillation on reproductive outcomes in POSEIDON 3 versus POSEIDON 4 groups.

Materials and methods: Eighty five patients ranging in age from 20 to 40 years were prospectively enrolled in the 1-year duration study and categorized into POSEIDON 3 and 4 groups (AMH <1.2 ng/mL; AFC <5) in the beginning of August 2021. All patients received fresh autologous PRP, prepared from 30 mL venous blood, 1.5 mL of which was instilled in each ovarian stroma between Day 7 and Day 10 of menstrual cycle under sedation. Patients were followed-up for 3 consecutive months to assess ovarian reserve parameters including serum FSH (Follicle stimulating Hormone), AMH (Anti mullerian Hormone), and AFC (Antral Follicle count) levels. Patients showing significant improvement in parameters compared to the pre-recruitment cycle were enrolled for fresh IVF cycles using antagonist protocol. These patients were distributed into the two groups of POSEIDON 3 and POSEIDON 4 for comparison. Outcomes were analyzed using linear mix effect model and student's *t*-test was used to compare quantitative variables while qualitative variables were compared using chi-square test.

Results: There was a response rate of 70.5% (60/85) among the enrolled women undergoing PRP instillation. Overall, linear monthly improvement in AFC (3.75 vs. 6.98 vs. 7.97 vs. 6.90, $P < 0.001$) was observed from baseline to 3 consecutive follow-up months with maximal response witnessed in the second month in 62.5% of the responded DOR females. However, the change in serum FSH ($P = 0.11$) and AMH ($P = 0.16$) from the baseline resulted out to be insignificant. Sixty responded patients were categorized into POSEIDON 3 ($n = 40$) and 4 ($n = 20$) groups. The mean age of POSEIDON 3 group was 29.7 years versus 36.4 years in POSEIDON 4 group ($P < 0.001$). After recruiting into the antagonist IVF cycle, 12 out of 60 cycles were cancelled due to inadequate response to stimulation in spite of highest dose of gonadotropins (450 IU). The IVF cycle characteristics were similar between the two groups ($P > 0.05$). The clinical pregnancy rate of the POSEIDON 4 group (26.66%) was similar to POSEIDON 3 group (27.27%) ($P = 0.96$).

Conclusion: Intra-ovarian PRP instillation improves the reproductive outcomes in both POSEIDON 3 and 4 groups of low prognosis patients and is not dependent upon the age of the patient. It holds promising results for the poor ovarian reserve patients, giving them hope of their own biological child. To further validate and establish its role, a large randomized trial with a "no-intervention" arm is required.

Study funding/Competing interest(s): No.

DOI:10.4103/fsr.fsr_2_23-ABS01

NO 2 DOES A LITTLE EXTRA ACTUALLY HELP?

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Study question: Does the repeat dose of gonadotrophin-releasing hormone agonist trigger in polycystic ovarian syndrome improve in vitro fertilization cycle outcome?

What is currently about the subject: Since 1990s, after the introduction of GnRHa for final oocyte maturation as a trigger, it has been a revolutionary tool in ART (Assisted reproductive techniques) procedure in polycystic ovarian syndrome. The gonadotrophin response following GnRHa trigger has a much shorter duration compared to that of an endogenous LH surge in a natural cycle. As a result, the response might be suboptimal. In PCOD (Polycystic Ovarian Disease) cases, with marked increase in the numbers of follicles, there might be insufficient LH receptors. Hence, a single dose might not be sufficient. In this study, we wanted to find out whether a 2nd dose of GnRHa repeated after12 hours following the initial dose optimizes the cycle outcome or not?

Study design, size, duration, material and methods: This study is a prospective, randomized, double-blinded study conducted at a tertiary care Research and Fertility center. A total of 80 women diagnosed with PCOD undergoing IVF with Antagonist protocol from January 2019 to January 2022 were randomized into two groups. Group A: single dose of GnRHa 0.2 mg, 35 hours prior to oocyte retrieval, and Group B: 0.2 mg GnRHa 35 hours prior to oocyte retrieval + repeat dose of 0.1 mg after 12 hours following 1st dose. Pre- and post-trigger lutenizing hormone (LH) and progesterone (P4) were estimated.

Results: A higher number of mature (Metaphase 2) oocytes were obtained in Group B compared to Group A (OR 1.12, CI – 1.13–2.25, $P = 0.71$), but it was not statistically significant. The number of blastocysts was higher in Group B and was statistically significant ($P < 0.05$). No empty follicular syndrome was reported.

Limitations of study: Study number was less.

Conclusion: A repeat dose of GnRHa trigger after12 hours following the first dose does improve the outcome of IVF cycle in terms of more number of M2 and blast rate by maintaining a sustained level of gonadotrophins. The incidence of empty follicle syndrome is nil due to the same reason.

Study funding/Competing interest(s): No.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS02

NO 3 EMERGING ROLE OF SEMINAL PLASMA TESTIS EXPRESSED SEQUENCE (TEX)-101 IN THE QUALITATIVE ASSESSMENT OF MALE FACTOR INFERTILITY: A CASE-CONTROL STUDY

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Study question: Can seminal plasma testis expressed sequence 101 be used as a non-invasive biomarker for male factor infertility?

What is currently about the subject: Infertility is the failure to achieve pregnancy after 12 months or more of regular unprotected sexual intercourse and affects 15% of couples globally. Around 7% of men are affected by infertility and contribute to 50% of all cases. Semen analysis

remains the gold standard for diagnosis, though a crude and inaccurate method. Hence, newer tests are required for better estimation of male infertility and its causes. One such seminal biomarker is Testis Expressed Sequence-101 (TEX-101), glycosyl phosphatidylinositol GPI anchored protein encoded by testis expressed 101 genes on the long arm of chromosome 19 (19q13.31). It is a testicular germ cell-specific protein located on the plasma membrane of germ cells in all stages of spermatogenesis. During epidydimal maturation of sperms, it is cleaved from the sperm surface and released into seminal fluid. This shedding of TEX-101 is essential for sperm binding to zona pellucida, indicating its crucial role in male fertility.

Study design, size, duration, material and methods: Study design, setting: The case-control study was conducted in the Obstetrics and Gynaecology Department in collaboration with Microbiology Department of AIIMS, Bibinagar over 2 years. Study population, size: The study was conducted on male partners of couples reporting to infertility clinic. Men between 20 and 50 years with abnormal semen parameters on semen analysis were included as cases and those with normal parameters as controls. Sample size of 180 was calculated with 90 cases and 90 controls. Exclusion criteria: Men with acute infection, infertility treatment, chronic diseases/malignancy, cryptorchidism and congenital abnormalities of reproductive tract were excluded. Data collection: After a detailed history, physical examination and semen analysis participants were categorized into cases and controls. Semen samples of all were cryopreserved in liquid nitrogen (196 °C) till the desired sample size was collected (180). Biochemical test for TEX-101 was run using human testis-expressed Protein 101 ELISA Kit manufactured by ImmunoTag with the catalog number ITEH04614.

Results: The mean ± SD of age for cases was 30.10 ± 4.75 years and controls 29.79 ± 5.08 years. There was a significant difference between the BMI (Body mass index) of cases (mean ± SD = 26.91 ± 4.8) and controls (mean ± SD = 25.63 ± 4.24), $P = 0.048$. Of 90 cases, 44 (48.9%) had asthenospermia; 22 (24.4%) had oligoasthenospermia; 14 (15.6%) had oligospermia; and 10 (11.1%) had azoospermia. A statistically significant difference was observed in the mean values of TEX-101 between cases (1.45 ± 0.08) and controls (2.26 ± 0.18), $P = 0.001$. A significant correlation was found between TEX-101, semen volume ($P = 0.000$); sperm concentration ($P = 0.000$), sperm progressive motility ($P = 0.000$); total motile sperm count ($P = 0.000$); and morphology ($P = 0.000$) in all the participants. The area under the receiver operating characteristic (ROC) curve of TEX-101 between cases and controls was 1.00 (std. error = 0.000, $P = 0.000$), indicating TEX-101 as a very effective biomarker in distinguishing between men with abnormal semen analysis reports and men with normal semen parameters. Hence, the sensitivity, specificity and negative and positive predictive values of TEX-101 at a 95% confidence interval were 100% for the prediction of male factor infertility. Furthermore, the correlation TEX-101 with less sperm concentration.

Limitations of study: The study included only one seminal plasma biomarker; in the future, we can plan to include other seminal proteins like ECM-1, ACRV1 and correlate their findings with male fertility. Also, we can support the data of biochemical analysis by immunohistochemical studies of seminal plasma to know the exact underlying mechanisms.

Conclusion: Seminal TEX-101 is an effective biomarker for the diagnosis of male infertility and has a strong correlation with sperm concentration, progressive motility, morphology. It has a high sensitivity (100%) and specificity (100%) for the prediction of male infertility, and hence, can be used in the qualitative assessment of male infertility.

Study funding/Competing interest(s): No.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS03

NO 4 MOST EFFECTIVE DURATION OF TRANSDERMAL TESTOSTERONE GEL (TTG) AS THE FIRST LINE PRETREATMENT FOR PATIENTS WITH POOR PROGNOSIS UNDERGOING GNRH ANTAGONIST IVF-ICSI CYCLES

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Study Question: Can the most effective duration of the TTG be considered as the first line treatment for patients with poor prognosis in antagosist cycles?

What is currently about the subject: The management of patients with diminished ovarian reserve (DOR) remains one of the most challenging tasks in IVF clinical practice. There are several reports on possible methods affecting the performance of gonadotropins in the ovaries such as the use of high-dose gonadotropins, treatment with growth hormone, glucocorticoids and low-dose aspirin. Another proven adjuvant treatment is the use of low-dose androgens to improve ovarian response to gonadotropins. Timing and duration of androgen supplementation were thought to be critical in adequate follicle stimulation and total amount of androgen supplementation was also considered to be an important factor.

Study design, size, duration, material and methods: Prospective randomized control study was conducted at Tertiary care infertility center, Akanksha IVF center, Delhi during 1st April 2021–31st March 2022. Hundred patients Age of 21 to 40 years of age, AMH ≤1.1 ng/mL were randomized into four groups of 25 each – Group 1, control received no pretreatment while Group 2, 3 and 4 received 1% TTG one actuation per day (12.5 mg testosterone) for 2, 3 and 4 weeks, respectively. Patients underwent stimulation with antagonist protocol when ≥2 follicles >18 mm, final oocyte maturation trigger – 250 mcg Inj r-hCG oocyte retrievals 35 to 36 hours after trigger. Day 3 fresh embryo transfers for all (2 x 8 cell embryos). The luteal phase support was given and serum beta hCG after 14 days of embryo transfer. Primary outcome measured was clinical pregnancy rate. Secondary outcomes measured were number of mature oocytes retrieved and number of fertilized oocytes and pregnancy outcomes in all the groups.

Results: Total dose of gonadotropins used in groups 2, 3 and 4 was less than control group, though it was significant only for group 4. Days of stimulation were less in groups 3 and 4, although not significant. The number of retrieved, mature and fertilized oocytes was significantly increased in groups 3 and 4. One cycle of control group was cancelled. No. of embryos transferred (2 x 8 cell A) were similar in all groups.

Limitations of the study: The study had a relatively small sample size. Moreover, live-birth rate comparison could not be carried out as the study was of shorter duration.

Conclusion: The TTG-treated patients for 3 to 4 weeks responded to gonadotropins > controls for 2 weeks, with more numbers of growing follicles and oocytes and better clinical pregnancy rate. We concluded that 4 weeks is optimal time duration for prior treatment with TTG in women with poor prognosis.

Study funding/Competing interest(s): Yes.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS04

NO 5 MPA VERSUS GNRH ANTAGONIST FOR LH SUPPRESSION IN OOCYTE DONORS

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Study question: How efficacious is MPA in LH SUPPRESION as compared to GnRH antagonist?

What is currently about the subject: An RCT conducted at the Institute of human reproduction Sir Gangaram hospital, New Delhi in oocyte donors. Progesterone-primed ovarian stimulation (PPOS) using Medroxyprogesterone Acetate (MPA) has been used for LH suppression.

Study design, size, duration, material and methods: Randomized controlled trial was conducted from Dec'21 to June'22. Sixty three oocyte donors were recruited in total. After random allocation using sealed envelopes, 31 donors were assigned in the study group A and 32 donors in group B (control group).

Results: The characteristics of oocyte donors were comparable at baseline. The number of oocytes retrieved, days of stimulation and dose of gonadotropins in both the groups were also comparable. No premature LH surge was detected in either group. Given that PPOS protocol was non-inferior with fertilization and blastocyst formation rates; hence it was a reliable alternative.

Limitation of study: Further investigations, specifically aiming to assess the live-birth as main outcome, is needed in our study.

Conclusion: MPA as an oral agent is an effective alternative for the prevention of premature LH surge in women undergoing COS for IVF higher patient comfort and lower cost of MPA compared to GnRH antagonist makes it an attractive option.

Study funding/Competing interest(s): No.

Is it a clinical trial: Yes.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS05

NO 6 ADVANTAGES OF FETAL REDUCTION IN HIGHER ORDER PREGNANCIES

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Study question: What are the complications following fetal reduction procedure?

What is currently about the subject: The incidence of multifetal pregnancies has increased significantly in recent years due to the increased use of ART. Higher-order multiple pregnancies are associated with increased incidences of pregnancy complications mainly abortions, pre-eclampsia, preterm delivery and fetal death. Multifetal reduction (MFR) during the first trimester and subsequent delivery of twins or singleton can reduce pregnancy-associated morbidities. This study was done to evaluate the complications of trans abdominal ultrasound (TAS) guided fetal reduction technique.

Study design, size, duration, material and methods: It was a retrospective observational study of the past 3 years, that is from January 2019 to January 2022. Multifetal pregnancy reduction was carried out in 109 patients, at 11 to 12 weeks of gestational age after assessment of NT/NB and chorionicity. FR was done using 2 mEq/mL KCl, 0.5 €“ 2 mL solution was injected intracardiac/intra thoracic into fetus under the guidance of TAS.

Results: The study included 109 multi fetal pregnancies which underwent MFR. 97.3% of reduction were done due to higher order pregnancy. Among them 59.6% were reduced from triplet to twin. 2.7% patients underwent fetal reduction for anomaly in co-fetus. 69.7% of patient were primigravida and 62.38% of patients conceived through IVF. Average age of patients was 29 to 30 years. The average time required for the fetal reduction was 4 to 6 minutes. 3.6% of cases had abortion or IUD of cotwin within 2 weeks of procedure. 4.5% of cases had preterm delivery at 22 to 24 weeks of gestation age.

Limitations of study: Single center based study, retrospective study.

Conclusion: Transabdominal ultrasound guided fetal reduction is an effective technique in preventing maternal and fetal complications of higher order pregnancy but with a 4% to 5% risk of abortion and preterm delivery.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS06

NO 7 GENOMICS EVIDENCE BASED CONTROLLED OVARIAN STIMULATION (COS) €“ CASE PRESENTATIONS DEMONSTRATING IMPROVEMENT IN COS OUTCOME USING PHARMACOGENOMIC RECOMMENDATIONS OF GENEFEMINA, A GENOMIC FERTILITY ANALYSIS

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Study question: IVF success depends greatly on the effectiveness of controlled ovarian stimulation. The response to COS varies among women. The study evaluates genetic predictive markers.

What is currently about the subject: Artificial reproductive technologies have drastically improved the infertility treatment but still the success rate of the expected outcome is not as high as desired. IVF success depends greatly on the effectiveness of controlled ovarian stimulation, where exogenous gonadotrophins are used to stimulate folliculogenesis. The response to stimulation varies substantially among women leading to multiple stimulation cycles to achieve optimal response using different protocols and gonadotropin doses. Although there are several predictive markers such as maternal age, AMH value and AFC, none of them can be used as absolute prediction marker. In the era of genomics, research on population based genetic marker based predictors is gaining importance. With the advent of next generation sequencing technologies multiple genotypes of genes such as AMH, AMHR2, CYP19A1, BMP15, ESR1, ESR2, FSHR, KISS1, KISS1R, LHB, LHCGR, MTHFR, PAI, VEGFA, COMT, TNF, etc. are reported to have a role in COS.

Study design, size, duration, material and methods: We present 12 cases of repeated IVF/IUI failures and poor response to COS. Genomic fertility analysis was performed by GeneFemina (TM) on female partner. GeneFemina (TM) is a next generation sequencing-based analysis of risk genotypes designed for Indian population. It identifies genomic variants associated with oogenesis, fertilization, implantation failure, pregnancy loss, premature ovarian insufficiency, oocyte quality, maturation and response to ovarian stimulation including pharmacogenomic implications of infertility treatment. DNA corresponding to targeted genomic regions is amplified using Ion AmpliSeq„¢ library 2.0 and custom-designed primers. Purified library is quantified, sequenced on a next generation sequencing platform and sequences are aligned to hg38. Uniform coverage is ~99% at mean read depth of 150X. Variants are called using Torrent Variant Caller using default parameters and annotated using Ion reporter Software. Analytical sensitivity, specificity and test reproducibility ~99%. Variant analysis and interpretation is done using AI-based Genomic Fertility Analysis software.

Results: GeneFeminaTM showed multiple genes associated with poor ovarian response. Good response was achieved using evidence-based pharmacogenomic recommendations. AMH gene (c.146G > T) reported in three patients is associated with reduced AMH bioactivity, low oocyte numbers and DHEA supplementation is favorable. AMHR2 gene (c.622-6C > T) reported in one patient is associated with poor follicle recruitment, poor response to stimulation and higher gonadotropin dose required. ESR1

gene (c.453-397T > C) reported in three patients is associated with poor reserve, low oocyte retrieval rates, poor oocyte quality and require longer induction and higher doses of rFSH. LHCGR gene (c.161 + 4491T > G) reported in six patients is associated with female infertility, PCOS risk, immature oocytes, slow response to stimula tion, a recognized pharmacogenomic tool in ovarian stimulation with better outcome with exogenous LH stimulation. FSHR gene (c.2039G > A) reported in six patients is associated with poor response to COS requiring stronger stimulus and resistant to clomiphene citrate. In addition, thrombophilia risk genotypes (MTRR and PROZ genes) identified with implantation failure and pregnancy loss risk. The cases will be discussed in detail during the presentation.

Limitation of study: Studies with larger sample size may be required to determine multi-gene effect on ovarian response.

Conclusion: The cases presented clearly demonstrate clinical utility of genomic markers in not only predicting the response to controlled ovarian stimulation but also in customizing stimulation protocol based on patient's genotype and it's known pharmacogenomic implications.

Study funding/competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS07

NO 8 COMPARISON OF OUTCOMES IN TERMS OF NUMBER AND QUALITY OF OOCYTES, EMBRYOS AND PREGNANCY RATE IN PRETREATMENT AND NON-PRETREATMENT GROUP IN GNRH ANTAGONIST PROTOCOL IN IVF

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Study question: Comparison of outcomes in terms of number and quality of oocytes, embryos and pregnancy rate in pretreatment and non-pretreatment group in GnRH antagonist protocol in IVF.

What is currently about the subject: The GnRH agonist play an important role in the prevention of premature LH surge in controlled ovarian hyperstimulation (COH) through desensitization of pituitary leading to increase in the number of retrieved oocytes and decrease in the number of cancelled cycles. A proper downregulation and synchronization of follicles is very important for improved outcome in a GnRH antagonist cycle in IVF. However, one of the main drawbacks of GnRh antagonist cycle is the absence of cycle programming and lack of synchronization of follicle growth. But both these drawbacks may be minimized and cycle regulation made convenient by pre-treatment with medications like combined OCPs, estradiol, progesterone and GnRH antagonist.

Study design, size, duration, material and methods: This was a prospective study and was conducted in the department of Reproductive Medicine for I year. A total of 148 patients were included in this study. The study participants were recruited from the patients seeking infertility treatment who wanted to undergo and were candidates for IVF-ICSI. The study group (74) was participants with pre-treatment with synthetic progestogens prior to the start of controlled ovarian stimulation with gonadotropins in GnRH antagonist protocol for IVF cycle. The study group was informed to review on day 2 of the cycle for initiation of gonadotropins for GnRH antagonist cycle. The control group (74) did not receive any treatment.

Results: No significant difference was observed in the mean number and quality of the mature oocytes retrieved and embryo quality. The number of oocytes retrieved in the study group was comparable to that of in the control group 12 (7.0–14.8) versus10.5 (8.0–13.0) ($P = 0.469$). The pregnancy rate in pre-treatment group was higher than the control that is, non-pre-treatment group (34.5% vs. 31.6% case and control group, respectively), but the difference was not statistically significant ($P > 0.05$). The cycle cancellation rate, clinical pregnancy and live birth-rate per embryo transfer were similar in both the study group and the control group.

Limitations of study: No significant difference was observed in the mean number and quality of the mature oocytes retrieved and embryo quality. The number of oocytes retrieved in the study group was comparable to that of in the control group 12 (7.0–14.8) versus 10.5 (8.0–13.0) ($P = 0.469$). The pregnancy rate in pre-treatment group was higher than the control, that is, non-pre-treatment group (34.5% vs. 31.6% case and control group, respectively), but the difference was not statistically significant ($P > 0.05$). The cycle cancellation rate, clinical pregnancy and live birth-rate per embryo transfer were similar in both the study group and the control group.

Conclusion: In spite of homogeneous follicular cohort in pre-treatment with synthetic progesterone, pre-treatment before GnRH antagonist protocol for IVF-ICSI cycles does not promise a noticeable benefit in terms of IVF outcome.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS08

NO 9 CAN MORULA SUBSTITUTE CELL STAGE AND BLAST TRANSFERS?

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Study Question: Can morula transfer substitute cell stage and blast transfers and give the best clinical pregnancy rate and live birth rate?

What is currently about the subject: Worldwide frozen embryo transfers are mainly cell stage transfers done on day 3 and blastocyst transfers done on day 5. Morula stage embryo on day 4 when transferred is gaining importance and appears to be a safe, practical alternative with comparable results.

Study design, size, duration, material and methods: Women who came for treatment for subfertility were evaluated. Those who required treatment with IVF were stimulated from second day of cycle, IVF-ICSI done and fertilized embryos were frozen. During embryo transfer cycle, when endometrial thickness was satisfactory, progesterone was started for 3 to 5 days. Accordingly frozen embryos were thawed, cultured and transferred. Luteal support was given with progesterone injections and oral tablets. Pregnancy was confirmed with serum beta hcg done 16 days after embryo transfer. Early pregnancy ultrasound was done after a week after positive beta hcg. Antenatal care was given and they were followed up to delivery. Clinical pregnancy rate and live birth rates were calculated and compared based on the day of transfer. Statistical analysis was done using Stata ver 14 and *P*-value.

Results: Morula transfer appears to give better clinical pregnancy and live birth rate.

Limitations of study: This study is a retrospective study and it shares the disadvantages of any retrospective study.

Conclusion: Morula transfer on day 4 can substitute cell stage and blastocyst transfers.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS09

NO 10 TO STUDY IVF/ICSI OUTCOME ON THE BASIS OF FOLLICULAR OUTPUT RATE (FORT)

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Study Question: What is the IVF/ICSI outcome on the basis of FORT?

What is currently about the subject: In IVF/ICSI, basal FSH, antral follicle count and anti mullerian hormone are used for assessment of basal ovarian reserves. These can predict the ovarian response but not oocyte/embryo quality or IVF outcome. To assess follicular responsiveness to exogenous FSH, FORT has been suggested. FORT is measured as a ratio of preovulatory follicle count (PFC) on day of HCG administration to antral follicle count (FORT = PFC Ã – 100 /AFC). FORT was positively related to IVF outcome, including pregnancy and considered a qualitative marker of follicular responsiveness. Despite many studies demonstrating significant predictive value for antral follicle count in the ovarian response rate and pregnancy rates of IVF, few reports in literature have used FORT as the measure of responsiveness.

Study design, size, duration, material and methods: Study design – Prospective observational study. Study size – 138. Duration – 1 year from October 2021 to September 2022. Materials & methods €": we studied AFC using transvaginal probe on D2/D3 of cycle. Gonadotropins were administered until the day of HCG administration. On the day of HCG administration, transvaginal ultrasound was performed. FORT was calculated as PFC on the day of HCG administration/AFC at baseline. Transvaginal oocytes were retrieved 34 to 36 hours after the administration of HCG. Oocytes were fertilized via IVF/ICSI based on couple's history. Fertilization was assessed 16 to 18 hours after IVF/ICSI. Embryo transfer was done D3 or D5 after oocyte retrieval. Surplus embryos were cryopreserved. Luteal phase support was given from the day of oocyte retrieval. Clinical pregnancy was confirmed by positive urine pregnancy test after 14 days of embryo transfer.

Results: FORT was similar in patient who were pregnant and who were not pregnant (0.66 ± 0.37 vs. 0.64 ± 0.33). Age, BMI, duration of infertility. AFC, AMH, starting FSH dose, duration of gonadotropin, total gonadotropin dose. Number of retrieved oocytes, total embryos and number of embryos transferred were similar between two groups. Only the rates of 2PN fertilization (70.34 ± 27.38 vs. 64.74 ± 28.16, $P = 0.73$), respectively. AFC was highest in medium FORT group (17.76 ± 6.08 vs. 18.75 ± 5.75 vs. 15.75 ± 9.69). PFC (6.33 ± 2.08 vs. 11.25 ± 4.07 vs. 16.15 ± 10.19), number of retrieved oocytes (4.66 ± 2.52 vs. 6.5 ± 3.3 vs. 9.2 ± 5.6), total embryos (2.81 ± 2.13 vs. 3.07 ± 2.47 vs. 3.5 ± 2.68) increased progressively from low to high FORT groups.

Limitations of study: There could be interobserver variations while measuring antral follicle count and preovulatory follicle count by transvaginal probe which affect FORT values. Number of retrieved oocytes may be affected by previous surgeries or any anatomical distortion of ovaries of the patient.

Conclusion: FORT can be used as a predictor of oocyte response in terms of number of numbers of retrieved and fertilized oocytes. FORT can be used to predict clinical pregnancy rate after ICSI. To use FORT as a determinant to cancel IVF/ICSI for poor responders is yet to be searched.

Study funding/Competing interest(s): No.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS10

NO 11 CAN SEMEN REGURGITATION AFTER INTRA UTERINE INSEMINATION ALTERS THE SUCCESS RATE?

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Study question: To investigate pregnancy results in IUI with or without sperm regurgitation

What is currently about the subject: A thin flexible catheter filled with prepared sperm is placed in uterine cavity through the cervix in an IUI procedure. To minimize the sperm reflux from cervical OS after an IUI procedure loading minimum volume (0.5 mL) of prepared sperm is the practice. Still such phenomenon also known as Regurgitation occurs some time.

Study design, size, duration, material and methods: Retrospective study done at Ferty9 Fertility Center, Secunderabad, India for the period of 6 months. One hundred forty one couples undergoing Controlled Ovarian Stimulation -COH for an IUI cycle were studied. Inclusion criteria for women were age below 35 years with functional fallopian tube/s and no other noted uterine or ovarian abnormalities. Men with post-wash total motile sperm count of at least 10 million were included in the study. And the exclusion criteria was double IUI in the same treatment cycle and the details of the IUI procedure were not documented (including regurgitation). Years of infertility, medications and infertility diagnosis were matched for both the groups. All women underwent COH and ovulation tracking was done with ultrasound scan. Insemination were performed once and observed for any leakage of sperm through cervical OS.

Results: A total of 421 IUI cycles were studied. Regurgitation observed in 131 [31.1%] women after an IUI procedure. The overall clinical pregnancy rate was 15.17% [44/290] and 14.50% [19/131] [$P = 0.3424$] for with out and with sperm leakage through cervical OS.

Limitations of study: A large group prospective study with live birth rate will help in concluding our observation.

Conclusion: There is a common belief that sperm leakage or regurgitation after an IUI procedure affects the IUI outcome. Contrary to this statement this study observed comparative pregnancy rate with or without sperm leakage after an IUI procedure.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

Study funding/competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS11

NO 12 COMPARISON OF CLINICAL PREGNANCY RATE FROM FRESH VERSUS FROZEN EMBRYO TRANSFER

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Study question: Is IVF with frozen-thawed blastocyst transfer (freeze-all strategy) more effective than IVF with fresh and frozen-thawed embryo transfer?

What is currently about the subject: To check clinical pregnancy rate between fresh and frozen embryo transfer as IVF without transfer of fresh embryos, thus with frozen-thawed embryo transfer only (freeze-all strategy), is increasingly being used in clinical practice because of a presumed benefit. It is still unknown whether this new IVF strategy increases IVF efficacy.

Study design, size, duration, material and methods: It is cohort retrospective study duration – IVF cycles taken from January 2020 to September 2022. Material and methods – clinical pregnancy rate is compared between fresh and frozen embryo transfer between this duration.

Results : CPR between ages compared – 40–1.4 -*P*-value.

Limitations of study: As this was retrospective study, data were limited and further live birth rate should be evaluated

Conclusion: There is significant CPR from fresh embryo transfer compared to frozen embryo transfer

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS12

NO 13 CLINICAL AND EMBRYOLOGICAL FACTORS EFFECTING OUTCOME OF FROZEN EMBRYO TRANSFER CYCLES

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Study Question: What is the impact of various clinical and embryological factors on pregnancy and live birth in frozen embryo transfer cycle?

What is currently about the subject: In recent years, the freeze-all strategy has been widely adopted and applied. Identifying and influencing the factors that influence FET outcomes can help to increase the "take-home-baby" rate of FET. Hence, the focus of research has recently shifted toward identifying relevant factors that affect FET outcomes. Age is a well-known factor that affects the LBR after FET. However, other factors that could affect the outcome of FET are still unclear

Study design, size, duration, material and methods: Prospective observational study conducted at Milann fertility Centre. Data of 360 frozen-thawed embryo transfer cycles were analyzed over a duration of 2 years Multivariate analysis was done with respect to clinical factors such as maternal age, serum FSH levels prior to stimulation, dose of gonadotropins, endometrial thickness on the day of frozen embryo transfer and embryological factors – D3 versus D5, duration of cryopreservation, use of assisted hatching. Impact of these factors on clinical pregnancy rate and live birth rate were analyzed. Frozen thawed embryos were transferred under USG guidance. Detecting an increased serum (B-HCG) (>50 IU/mL) 14 days post transfer, was considered as positive biochemical pregnancy. Clinical pregnancy was defined by presence of fetal heart activity by USG at 7 weeks. Patients were followed up through their antenatal period till delivery. Statistical analysis was performed using student *t*-test and chi-square test with SPSS software

Results: Eight hundred eighty nine embryos were thawed with a post thaw survival rate of 90%. Implantation rate was 38%. CPR per embryo transfer cycle was 24.8%. CPR 26% and LBR 22% was higher (p 35 yr. The CPR 24% and LBR 21% was higher (P 8 mm had a statistically significant influence on pregnancy outcome.

DOI:10.4103/fsr.fsr_2_23-ABS13

NO 14 EMBRYOGLUE: AID OR FAD TO STUDY THE IMPACT OF EMBRYOGLUE AS A TRANSFER MEDIUM ON IMPLANTATION RATE IN ART CYCLE

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Study question: Our study aims to evaluate the efficacy of embryo glue over standard culture media as a transfer medium in improving ART outcomes.

What is currently about the subject: Embryoglue is a hyaluronan rich medium acts as supplement for embryo transfer. Hyaluronan is a naturally existing macromolecule present in the extracellular matrix of the reproductive tract. It is thought to aid the adhesion of embryos to uterine lining; hence it may improve the implantation and live birth rate in the freeze thaw cycle. According to HEFA embryo glue is an adjuvant and its use is debatable in assisted reproductive technology.

Study design, size, duration, material and methods: A retrospective study conducted in Indira IVF clinic at Delhi Centre over 3 months of period from June 2022 to August 2022. In study group (n = 54), the women undergoing IVF embryos were transferred in pre-equilibrated 0.5 mL of embryoglue. In control group (n = 157) vitromed/sage onestep culture medium was used as transfer medium. Statistical analysis – we compared the standard treatment arm versus embryo glue arm in a propensity score-matched population to reduce the imbalance and potential biases in the study. The matched ratio for the standard treatment arm versus embryo glue arm was 3:1. The propensity scores were calculated using binary logistic regression analyses based on the following variables at baseline: (maternal age, maternal BMI, AMH, endometrial thickness, and the number of transferred embryos). After the propensity match score, there were 157 cycles of standard treatment, and 54 cycles of embryo glue were selected in the final analysis.

Results: In this study, a total of 211 cycles were analyzed. One hundred fifty seven cycles in the standard treatment arm and 54 cycles in the embryo glue arm. The biochemical pregnancy rate in standard treatment versus embryo glue was 117 (74.5%) versus 45 (83.3%); a notable higher biochemical pregnancy rate was observed in the embryo glue arm.

Limitations of study: A prospective study with large sample size may give better understanding of the impact of embryoglue on implantation rate.

Conclusion: Pilot study showed embryo glue arm increased biochemical pregnancy rate compared to standard arm. Current data provide potential proof to carry out a prospective study with preferable large sample size to evince the regular application of embryo glue in ART cycle.

Study funding/Competing interest(s): No.

Is it a clinical trial: Yes.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS14

NO 15 COMPARISON OF ART OUTCOME WITH MINIMAL STIMULATION PROTOCOL VERSUS CONVENTIONAL DOSE ANTAGONIST PROTOCOL

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Study question: Does minimal stimulation protocol have a better ART outcome than conventional dose stimulation protocol?

What is currently about the subject: Many clinicians practised conventional dose/higher dose gonadotropin protocols with good success rate in normal ovarian reserve cases. However, there is dilemma in choosing the best possible protocol in poor ovarian reserve cases. The newer school of thought favors the use of minimal/mild stimulation with remarkable better outcomes and less complication rates.

Study design, size, duration, material and methods: Study design: Retrospective cohort study. Sample size: Data of 9752 women. Study Duration - 2018 to 2022. Material and Methods: The data were retrieved from patient's record sheet archived at the centralized data system of Indira IVF hospital Pvt. Ltd. (all centers). The inclusion criteria was women of age group 25 to 45 years with BMI ranging from 18.5 to 25 kg/m^2 and AMH less than 1.2 ngm/dL. The exclusion criteria were uncontrolled medical illness (diabetes, hypertension, or thyroid disorder), history of regular smoking within last 3 months, any androgen prepa-

rations like DHEA within 3 months of stimulation, congenital uterine anomaly, ovarian cyst, and pelvic or systemic inflammatory disease. Group I was the minimal stimulation (MS) group ($n = 833$) and Group 2 was the conventional stimulation (CS) group receiving conventional dosage as per institutional practice ($n = 8916$).

Results: The propensity score matching was done for the baseline characteristics (wife age, husband age, BMI, AMH, sperm count, motility, morphology, endometrial thickness, and number of embryos transferred) to minimize potential bias and minimize the baseline heterogenicity between two groups. The clinical pregnancy outcomes were better in minimal stimulation as compared to antagonist. There is a significant difference in following parameters in MS gr versus CS group, total gonadotropin used (1888.78 ± 459.42 IU vs. 3101.84 ± 898.99 IU $P < 0.001$), M2 rate (71.86 ± 18.97 vs. 68.68 ± 17.94, $P < 0.001$), OSI (315.93 ± 323.45 vs. 386.42 ± 434.37, $P < 0.001$), oocyte expected (8.9 ± 7.47 vs. 11.07 ± 6.86, $P < 0.001$), oocyte retrieval rate (96.83 ± 29.75 vs. 97.84 ± 27.12, $P < 0.001$), blast rate (57.29 ± 28.97 vs. 50.43 ± 27.26) ($P < 0.001$), good blast rate (41.87 ± 26.89 vs. 35.64 ± 23.68) ($P < 0.001$). However the clinical pregnancy rate, miscarriage rate and live birth rate were comparable in both the groups.

Limitations of study: Retrospective study.

Conclusion: The minimal stimulation protocol is more patient-friendly, physiological and cost-effective and may gain high acceptance in low ovarian reserve cases in coming days with a shorter duration of stimulation with reduced gonadotropin requirements.

Study funding/Competing interest(s): No.

Is it a Clinical Trial: No.

Ethical clearance Done or Not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS15

NO 16 THE EFFECT OF PROFOUND LH SUPPRESSION IN GNRH ANTAGONIST CYCLES STIMULATED WITH GONADOTROPINS ON BLASTULATION RATES–A RETROSPECTIVE OBSERVATIONAL STUDY

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Study question: Does profound LH suppression in GnRH antagonist cycles affect the blastulation rates?

What is currently about the subject: There is conflicting evidence that in GnRH antagonist cycles stimulated with recombinant FSH, may negatively affect the pregnancy outcomes in fresh embryo transfer in patients with low serum LH levels. Whether the observed effect of low LH is on the embryo or on the endometrial receptivity is not clear. (Benmachiche et al., 2019, Doody et al., 2011, Griesenger et al., 2011)

Study design, size, duration, material and methods: It is a retrospective observational study, done in a private hospital, between December 2019 and December 2021 with a sample size of 400. Inclusion criteria – patients undergoing controlled ovarian hyperstimulation in antagonist protocol. Exclusion criteria – patients undergoing – 1. Long protocol; 2. Flare protocols; 3. Donor oocyte cycles; 4. Oocyte cryopreservation cycles; 5. Hypogondotropic hypogonadism.

Participants/materials, setting, methods: Controlled ovarian stimulation is done according to the hospital's standard operations of practice in flexible antagonist cycle with human menopausal gonadotropins or recombinant/urinary follicle stimulating hormone. When three or more follicles >17 mm, triggered with HCG or dual trigger. Oocyte pick up scheduled at 35 to 36 hours following the trigger. Serum LH measured at baseline and at the time of trigger. Outcomes are assessed in between low serum LH, that is, <1.5 MIU/ML and normal serum LH ≥ 1.5 MIU/ML.

Results: The two groups are comparable with regards to baseline variables of age, BMI, IVF number, semen analysis parameters, S.AMH, baseline FSH. Baseline serum LH is low in low pre-trigger serum LH group with significant *P*-value ($P = 0.02$). The mean dose of gonadotropins, mean number of oocytes retrieved, mean number of mature oocytes, mean number of fertilized oocytes are not significantly different between the two groups. The mean duration of stimulation is significantly more in low serum LH group (11.67 ± 1.87 vs. 11.09 ± 2, $P \leq 0.01$). The mean number of blastocysts, D5 and D6 blastocysts and good quality blastocysts are comparable but poor quality blastocysts are significantly more in the low serum LH group (2.5 ± 1.91 vs. 2.48 ± 2.01, $P = 0.04$)

Limitations of study: Retrospective study. Relatively smaller sample size. Live births not assessed.

Conclusion: The study provides reassuring data that low serum LH on the day of trigger does not affect the blastulation rates. Further studies assessing the cumulative live birth rates rate in cases of low serum LH are advocated for better predicting the final outcomes in this group of women.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS16

NO 17 SUCCESSFUL PREGNANCY AFTER OOCYTE ACTIVATION BY CALCIUM IONOPHORE FOR A PATIENT WITH PREVIOUS BLASTOCYST DEVELOPMENT PROBLEM – A CASE REPORT

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Study question: To study the effect of artificial oocyte activation (AOA) using calcium ionophore on the rate of blastocyst in patient with history of poor blastocyst development

What is currently about the subject: In animal model it is evident that changes in intracellular free calcium regulate the events of cell division. In human before cell division calcium fluctuations observed with a peak. Hence, calcium ionophore is considered efficient treatment for fertilization failure cases. There is scant evidence where calcium ionophore is used for the cases with embryo development issues.

Study design, size, duration, material and methods: Case report. In this study, out of 14 mature retrieved oocytes – 8 oocytes were treated with pre-incubated calcium ionophore for 10 minutes after an ICSI procedure with couple's consent. Whereas six oocytes were cultured without artificial oocyte activation. Five (62.5%) blastocyst were developed in treatment group where as only one blast observed in control.

Results: Out of eight calcium ionophore treated mature oocytes, five blastocyst grade AA and AB formed. Whereas untreated control group of six oocytes only one blastocyst grade BC formed.

Limitations of study: Larger group study is recommended.

Conclusion: There was significant improvement in development of good quality blastocyst after oocyte activation using calcium ionophore treatment. This case study supports the use of calcium ionophore for specific indicative patients.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS17

NO 18 OUTCOME OF LOW COST MINI IVF PROGRAM PROVIDING ACCESS OF CARE TO NORMO RESPONDER SOCIO ECONOMICALLY DIVERSE RURAL POPULATION

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Ferty9 Fertility Center, India

Study question: To test the efficacy for a novel Clomid based minimal stimulation protocol for normo responder women

What is currently about the subject: The number of women from disadvantaged socio-economic groups' to access IVF treatment is less than women from more advantaged groups. However, women from disadvantaged groups tend to start families younger, making them less likely to suffer from age-related sub fertility and potentially have less need for standard stimulation protocols. Minimal stimulation in vitro fertilization (mini-IVF) consists of a gentle controlled ovarian stimulation that aims to produce a maximum of four to six oocytes. Reduce ovarian hyperstimulation syndrome, multiple pregnancy rates, and cost are the main advantages of Mini IVF

Study design, size, duration, material and methods: Retrospective study done at Ferty9 Fertility Center, Secunderabad for the period of 8 months. Patients from our fertility awareness camp were recruited for Mini IVF program from rural part of Telangana and Andhra Pradesh state. All patients received a free basic infertility evaluation and counseling prior to referral for Mini IVF. In study group a total of 150 women underwent Mini IVF cycles, where as in control group 150 women received standard antagonist protocol. Both the groups were matched for the age, infertility cause, baseline AMH and male factors. The Mini-IVF cycle consisted of 50 mg/day of clomid on day 3 of menstruation and continuing beyond the usual 5 days until the time of ovulation triggering, 150 IU of follicle stimulating hormone (FSH) were administered twice or thrice depending upon follicular growth response. An average of four to six eggs was obtained with mini-IVF and over 12 eggs with standard IVF.

Results: Though the numbers of retrieved oocytes were less in study group, the clinical pregnancy rate per transfer was not significantly different between the two regimens (47.3% vs. 50%, minimally stimulated cycle vs. standard antagonist protocol, respectively).

Limitations of study: Larger group study till live birth is recommended.

Conclusion: Mini IVF is a viable alternative with comparable pregnancy rates to the standard antagonist protocol, and with added advantages of close to zero multiple pregnancy rate, zero risk of ovarian hyper stimulation syndrome, less time consuming, physically and emotionally less demanding for patients and main feature is cost-effective

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABSI8

NO 19 CLINICAL OUTCOMES WITH EXTRA DAY OF PROGESTERONE IN FROZEN EMBRYO TRANSFER (FET) CYCLES: A PILOT STUDY.

Raga Sudha Vennapusa, Lavanya Bommakanti, Vandana Hedge, Akash Agarwal

Study question: To evaluate beta HCG positive, clinical, ongoing pregnancy rates after 6 and 7 days progesterone in Day 5 FETs, 4 and 5 days progesterone in D3FETs in patients with at least one previous failed embryo transfer.

What is currently about the subject: Routine practice in IVF clinics worldwide is to supplement progesterone for 4 days before transferring a day 3 embryo and 6 days before day 5 blastocyst. However, it has been shown that in a natural cycle, some amount of progesterone synthesis begins after the LH surge even before ovulation, and similarly in a fresh IVF cycle the progesterone starts increasing after HCG surge. Therefore, in a FET cycle the endometrium could be lagging in terms of maturity and progesterone exposure compared to natural cycle and hence the concept of Extra day progesterone was studied in few clinical publications with encouraging results. The same is practiced in our clinic as a second option in women with previous failed standard protocol FET cycles. In this study, we tried to analyze these cycles and compare the outcomes.

Study design, size, duration, material and methods: Study design: Retrospective pilot study. Material and methods: Patients who underwent frozen embryo transfer at Hegde hospital between January 2022 and June 2022 were included in the study. Women undergoing FET cycles with routine duration of 4 days (D3) and 6 days (D5) of progesterone were taken as controls. Study cases were women who failed to conceive with standard FET protocol with oral/ vaginal / transdermal estrogen was applied in all women. Once endometrium reached 8 mm, women in the case group received an additional dose of progesterone (100 mg Gestone IM) which was given 12 to 24 hours prior to starting standard luteal support. Patients with known causes of implantation failure were excluded.

Results: Total 303 frozen embryo transfer cycles were performed. We had 200 D5 embryo transfers out of which 183 were standard protocol D5 embryo transfers (group 1) and 17 women received extra day progesterone (group 2). We had 103 D3 embryo transfers out of which 90 were standard protocol embryo transfers (group 3) and 13 women received extra day progesterone (group 4). Between groups 1 and 2 pregnancy rates were 67.7% versus 82.3%, clinical pregnancy rates were 65% versus 70.5%, ongoing pregnancy rates are 55% versus 58.8% and miscarriage rates were 9.2% versus 11.7% respectively. Between groups 3 and 4 pregnancy rates were 53.3% versus 69.2%, clinical pregnancy rates were 48.8% versus 53.8%, ongoing pregnancy rates are 41.1% versus 46.1%, and miscarriage rates were 7.7% versus 7.6% respectively.

Limitations of study: This is a pilot study to analyze the clinical utility of this protocol. Hence, the sample size was too small to detect statistically significant differences. Considering the encouraging trend of results, we intend to continue the study. Live birth rates were not analyzed.

Conclusion: Frozen embryo transfer after an extra day of progesterone supplementation resulted in better pregnancy rates, clinical pregnancy rates and ongoing pregnancy rates in both D3 and D5 groups when compared to standard FET protocol. No difference was noted in miscarriage rates.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABSI9

NO 20 TO STUDY THE EFFECT OF BMI ON SEMEN PARAMETERS OF MALE PARTNER OF INFERTILE COUPLE

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Study question: Is there a correlation between BMI and semen parameters like semen volume, sperm concentration, total sperm count, pH, gross morphology and motility?

What is currently about the subject: It has been proposed that BMI affects the semen parameters of male partner in infertile couple. This study aimed at studying the effect of BMI on semen parameters of male

partner of infertile couple. The fat accumulation in the suprapubic region and around the pampiniform plexus in obese men resulting increase in scrotal temperature enhances oxidative stress and sperm DNA fragmentation (SDF) and reduces sperm concentration and motility and produces more reactive oxygen species beyond the physiological concentration. Currently, there is no literature available on the effect of BMI on semen parameters of male partner of infertile couples among Indian men using Asian BMI cut-offs for public health action.

Study design, size, duration, material and methods: Cross-sectional study was conducted at Department of Obstetrics and Gynaecology, IVF lab at ESI PGIMSR Basaidarapur with sample size of 202 men between December 2020 and April 2022 who met inclusion criteria. Their BMI was calculated after anthropometry and the semen sample was collected and analysis was done and was compared with the BMI and was compared with WHO cutoff values of semen parameters.

Results: The semen volume decreased as the BMI increased but not significant ($P = 0.968$). The sperm concentration and total sperm motility was lower in underweight and obese men but was not significant ($P = 0.740$ and 0.988, respectively). The total sperm count was lower in obese men as compared to men with normal BMI ($P = 0.646$) with negative correlation coefficient of –0.088 ($P = 0.211$). The mean progressive motility was below the WHO lower limit. It was observed that progressive motility decreased as the BMI increased ($P = 0.988$). The gross morphology was lower in underweight as compared to normal BMI but was not statistically significant ($P = 1.387$).

Limitations of study: Single center study with a limited sample size. Cross-sectional, observational study design. The effect of BMI on semen parameters of obesity class 3 couldn't be studied due to none of the cases were in obesity class 3 in our study population Covid pandemic.

Conclusion: As BMI increases, the semen volume, total sperm count and progressive motility decrease and in underweight male, gross morphology, sperm concentration and total motility.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS20

NO 21 IMPACT OF TUBAL PATENCY TEST SELECTION ON THE LIVE BIRTH RATE FOLLOWING INTRAUTERINE INSEMINATION IN COUPLES WITH UNEXPLAINED INFERTILITY: A RETROSPECTIVE COHORT STUDY

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Study question: Does the type of tubal patency test affect live birth rates following ovarian stimulation and intrauterine insemination in couples with unexplained infertility?

What is currently about the subject: The diagnosis of unexplained infertility is made by evidence of ovulatory cycles, documentation of at least unilateral tubal patency and normal semen analysis for the male partner. Among all the tests for fertility evaluation, the tubal patency tests are considered the most invasive. Often in practice, the decision of selecting a tubal patency test is based on various factors including woman's preference, clinical suspicion of pelvic comorbidities and cost. In light of these differences, an important clinical question is whether the choice of tubal test influences the outcome of subsequent fertility treatment such as intrauterine insemination among couples with unexplained infertility.

Study design, size, duration, material and methods: The study comprised a retrospective cohort and included all couples evaluated for infertility at our tertiary level hospital between January 2008 and December 2019. Couples diagnosed with unexplained infertility based on tubal patency test (either HSG or diagnostic laparoscopy) were included in the study. We compared outcomes following ovarian stimulation (OS) and intrauterine insemination (IUI) between women who underwent HSG versus laparoscopy for up to three treatment cycles. The primary outcome was the clinical pregnancy rate per cycle. Secondary outcomes included cumulative live birth rate, cumulative clinical pregnancy rate, miscarriage rate and time to achieve pregnancy.

Results: A total of 7413 women who underwent HSG ($n = 1376$) or laparoscopy ($n = 6037$) were screened. Out of these, 1002 women fulfilled the eligibility criteria and were included in the study. We did not find a significant statistical difference in the clinical pregnancy per IUI cycle (16.7% vs. 11.7%; OR [odds ratio] 1.51; 95% CI [confidence interval] 0.90–2.5) or live birth rate per IUI cycle (15.1% vs. 10.7%; OR 1.51, 95% CI 0.9–2.6) in women who underwent HSG for tubal evaluation as compared to laparoscopy. After further adjustment for potential confounders through multivariate analysis, we found that outcomes were comparable between the HSG and laparoscopy group in terms of live birth per IUI cycle (adjusted odds ratio (aOR) 1.49, 95% CI 0.8–2.7) and clinical pregnancy per IUI cycle (aOR 1.51, 95% CI 0.9–2.6). The cumulative live birth rates following IUI treatment were not statistically different between the women who underwent HSG (26.5% vs. 18.8%; OR 1.63, 95% CI 0.9–2.9) and women who underwent laparoscopy for tubal patency.

Limitations of study: The retrospective design is one of the limitations of the study. A substantial number of participants did not return for follow-up during the 2 years follow-up period leading to the possibility of attrition bias.

Conclusion: The current study findings suggest minimal or no impact of selecting HSG over diagnostic laparoscopy as a tubal patency test for establishing the diagnosis of unexplained infertility on subsequent IUI outcomes. The results support the current ASRM practice committee recommendations on avoiding routine diagnostic laparoscopy for assessing tubal patency.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS21

NO 22 IS OVARIAN RESERVE ASSOCIATED WITH BODY MASS INDEX AND OBESITY IN INFERTILE WOMEN? A CROSS-SECTIONAL STUDY

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Study question: Is there a correlation between BMI and ovarian reserve in infertile women?

What is currently about the subject: Obesity is a recognized chronic disease with increasing prevalence across the world. Increase in incidence and prevalence of reproductive health issues among men and women is also being observed. Various molecular and endocrinological mechanisms elaborate interplay between obesity and reduced fertility. In obesity, higher concentration of reactive oxygen species is generated in tissues and induces early apoptosis. Greater amount of leptin synthesis inhibits ovarian steroidogenesis. Higher circulating insulin levels stimulate ovarian androgen synthesis and inhibits hepatic synthesis of sex-hormone-binding-globulin, leading to hyperandrogenemia. Peripheral aromatase inhibits secretion of gonadotrophins and inhibits ovarian folliculogenesis. Females have limited number of ovarian

follicles at birth, majority of which undergo atresia, resulting in reproductive ageing. Number and quality of remaining oocytes determine ovarian reserve which is further depleted by obesity. This lowers chances of pregnancy which is achieved spontaneously or with ART. Therefore, this study was aimed to find correlation between BMI and ovarian reserve.

Study design, size, duration, material and methods: This cross-sectional study was conducted for 18 months among 202 infertile women between 21 and 45 years attending infertility clinic at Department of Obstetrics and Gynaecology, ESI-PGIMSR, Basaidarapur, New Delhi after excluding diagnosis of tubo-ovarian mass, PCOS, endometrioma or history of ovarian surgery. Ethical clearance was taken from institutional ethical committee. Informed written consent was obtained. Height (centimeter) and weight (kilograms) were measured, BMI was calculated. The patients were classified as underweight/normal/overweight or obese as per Asian BMI reference. For ovarian reserve estimation, bilateral ovarian volume and antral follicular count (AFC) were measured using TVS and blood tests for S.FSH, S.estradiol and S.AMH were performed on day 2–3 of menstrual cycle. AFC.

Results: Mean age of study participants was 30.6 ± 4.66 years (21–39 years). Average duration of infertility was 6.76 ± 4.28 years (1–25 years). 63.9% women attending infertility clinic had primary infertility. Mean BMI of infertile women was 23.8 3.87 kg/m^2 (15.6–39.67 kg/m^2). 58.91% women were overweight or obese, 15 were underweight and 33.7% infertile women had normal BMI. Baseline ovarian reserve testing indicates that study participants had low ovarian reserve according to serum FSH and total AFC. Underweight women had higher serum FSH, lower AMH and lower ovarian volume than normal weight females. Total AFC ($r = -0.158$, $P = 0.025$), volume of right ovary ($r = -0.217$, $P = 0.002$), left ovary ($r = -0.187$, $P = 0.008$) and basal ovarian volume ($r = -0.240$, $P = 0.001$) had significant negative correlation with BMI of female. 50% normal weight, 45.95% overweight, 44% obese and 73.33% underweight infertile women had low ovarian reserve.

Limitations of study: Single-centered study.

Conclusion: Infertile women have low ovarian reserve at a younger age of 30 years. Both increase and decrease in BMI has a negative impact on ovarian reserve of women.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS22

NO 23 EVALUATION OF NECESSITY OF ROUTINE LUTEAL PHASE SUPPORT IN IUI CYCLES STIMULATED WITH ORAL OVULOGENS

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Study question: Routine luteal phase support – a need or a habit? Especially in IUI cycles which aim at mono or bifollicular development.

What is currently about the subject: Luteal phase defect has multiple etiologies. Apart from the known gynaecological or medical conditions, assisted reproductive techniques involving superovulation and subsequent negative feedback on HPO axis with LH inhibition are among the known indications of supporting luteal phase. But whether this holds true for IUI cycles with mild stimulations, is still a debatable issue. Presently, there is a reflex among practitioners to routinely prescribe the luteal phase support. Our study has made an attempt to answer that, unless indicated, luteal support with progesterones not significantly affect the clinical pregnancy in IUI cycles. Till date, with limited literature on the use of letrozole as the oral ovulogen, our study could be a basis for future research and practice development. Due to limited period of study and hence restricted sample size, the observation needs to be extended over a larger population for further interpretation.

Study design, size, duration, material and methods: Prospective observational randomized control trial over a period of 8 months carried over 100 cases and 100 controls, selected as per inclusion exclusion criteria, randomized by computer assisted methods. Patients will be randomly allocated to either of the groups being investigated. After a baseline history, examination and work up, on day 2 of menstrual cycle, baseline transvaginal scan (TVS) will be conducted. This will be followed by ovarian stimulation from day 2 to day 6 by oral ovulogen, letrozole (2.5 mg). Follicular study will be done in clinic from day 8/9 onwards to assess antral follicles and endometrial thickness. When follicle reached a size of 18 to 24 mm with endometrial lining >7 mm, HCG trigger will be given 10,000 IU s/c and IUI is timed at 36 to 44 hours after trigger only after confirmation of rupture on USG. One group

Results: Among cases, 23% had a positive urine pregnancy test. Whereas, in controls 21% had a positive urine pregnancy test, the difference being statistically non-significant with P-value = 0.733. Clinical pregnancy rate as a marker of successful outcome of study was present in 22% of cases and 21% of controls, although difference was statistically non-significant with $P = 0.755$.

Limitations of study: Due to limited duration of study and the restricted sample size, data analysis needs to be revised on a larger group over a long duration of study period.

Conclusion: Luteal phase support with progesterones makes no significant difference in clinical pregnancy rate oral ovulogen stimulated IUI cycles.

Study funding/competing interest(s): Yes.

Is it a clinical trial: No.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS23

NO 24 A COMPARATIVE STUDY OF EARLY PREGNANCY OUTCOMES FOLLOWING FROZEN THAWED EMBRYO TRANSFER BETWEEN MODIFIED NATURAL AND HORMONAL REPLACEMENT CYCLES.

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Study question: Does the endometrial preparation method, modified natural (MNC) versus hormone replacement cycles (HRC) have an impact on the early pregnancy outcomes?

What is currently about the subject: An important factor that determines success in frozen-thawed embryo transfer is obtaining optimal endometrial receptivity as well as synchronization between embryo and endometrium. This can be achieved by different endometrial preparation methods. There is no agreement on optimal endometrial preparation in terms of pregnancy outcomes. While certain studies report a higher pregnancy loss in hormone replacement cycles compared with natural cycles or stimulated cycles, other studies have shown no significant difference. Most of the previous studies are retrospective in nature with scarce evidence from prospective studies.

Study design, size, duration, material and methods: It is a prospective observational study with the desired sample size of 440 participants with 220 in each arm. We have done an interim analysis of 315 cycles. Duration is from Jan 2021 to June 2022. Women aged 23 to 38 years

planned for frozen embryo transfer were included. Those women who had recurrent pregnancy loss history, known diabetes (DM), and hypertension were excluded. In MNC the follicle is tracked from day 8 of the menstrual cycle and once the follicle diameter reaches 14 to 15mm, the serum LH and progesterone are checked and wait till the follicle reaches 17mm if there is no endogenous LH surge. If LH surge is absent, hCG trigger is given and luteal support is started on hCG + 2 days. If the endogenous surge is positive, luteal support is started on LH + 1 day. In HRT cycle incremental doses of estradiol tablets are given with or without GnRH agonist suppression for

Results: A total 315 women have been included. Fifty three women were excluded in view of age, hypertension, DM and RPL history. Twenty seven (10.3%) women were included the MNC group and 235 (89.7%) women in the HRC group. The clinical pregnancy rate in MNC group was 48.1%, while in the HRC group it was 44.7% with no significant difference among the two groups ($P = 0.334$). The miscarriage rate in the MNC was 15.3% compared to in the HRC group 21.9% ($P = 0.58$). The biochemical pregnancy loss rate in the MNC group was 7.1% compared to 15.4% in the HRC group ($P = 0.40$).

Limitations of study: Small sample size of the modified natural cycle group.

Conclusion: There was no statistically significant difference in the first trimester pregnancy outcomes amongst the MNC and HRC groups. However, in view of smaller sample size in the MNC group the results need to be interpreted cautiously.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS24

NO 25 FEASIBILITY OF LIFESTYLE INTERVENTION IN POLYCYSTIC OVARIAN SYNDROME WOMEN WHO DESIRE FERTILITY

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Study question: How feasible is following the lifestyle intervention, for polycystic ovarian syndrome (PCOS) women who are trying to conceive?

What is currently about the subject: Lifestyle interventions are recommended as first line management in PCOS. These include mainly dietary modification and exercise. These interventions are beneficial in overweight or obese PCOS women and help in improving the menstrual irregularities and the metabolic profile. But the main problem associated is the poor adherence and compliance of the women to these interventions. Previous studies have shown high drop-out rates. Hence it is useful to conduct a pilot study to explore the feasibility of lifestyle modifications as an intervention in polycystic ovarian syndrome women seeking fertility treatment.

Study design, size, duration, material and methods: It's a randomized controlled trial with sample size 60 with 30 women in each arm. Women aged 18 to 40 years diagnosed with PCOS (Rotterdam criteria 2003) with body mass index >23 kg/m^2 trying to conceive were recruited. Women with endometriosis, male factor infertility, tubal pathology, diabetes mellitus, gastrointestinal absorption disorders, musculoskeletal disorders which limits the physical activity were excluded. Randomization was done with consecutive, opaque, sealed envelopes. In intervention group structured diet and exercise advice was given at first visit and advised to follow up at 3rd and 6th month. In control group general diet advice given and advised to follow up at 6th month. The primary outcome is to see the number of participants not completing the intervention (dropout rate) and the secondary outcomes are weight loss, improvement in menstrual regularity, improvement in anthropometric parameters, clinical pregnancy rates, miscarriage rates, quality of life specific to PCOS were measured.

Results: This is an interim analysis. We recruited 30 women in each study arm. The dropout rate at first visit was 26.6% (8/30) in intervention group versus 10% (3/30) in control group. Total 22 women were analyzed after 6months of study duration till date. The dropout rate at 3rd month is 66.6% (10/15) in intervention arm so far. The dropout rate at 6th month is 60% (6/10) in intervention arm versus 41% (5/12) in control arm so far

Limitations of study: It is a feasibility study. The results of this study cannot be extrapolated, but it will be useful in conducting larger randomized control trials in future.

Conclusion: Adherence to the lifestyle interventions is a challenge in the PCOS women with a high dropout rate of 60% (6/10).

Study funding/Competing interest(s): No.

Is it a clinical trial: Yes.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS25

NO 26 EFFICACY AND SAFETY OF PERGOVERIS IN ART – A PILOT STUDY

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Study question/Objective: To study the efficacy and safety of fixed ratio combination of r-FSH plus r-LH (PERGOVERIS) in ART in IVF patients.

Introduction: Adding LH supplementation to COH protocols can improve outcomes of IVF cycle in poor responders as shown in recent publications. LH increases FSH receptor expression and growth, improves follicular recruitment, lowers cumulus cell apoptosis, enhances oocyte competence, stimulates CYP.
Seventeen leading the conversion of progesterone to androgens and estrogens, and also reduces premature progesterone rise prior to trigger. Thus, addition of LH results in high estradiol levels, increased oocyte yield and better quality embryos. LH supplementation also improves response to controlled ovarian stimulation, increases implantation rate and lowers miscarriage rate independent of maternal age. Adding LH in patients with LHCGR gene mutation also has shown to effectively improve all cycle parameters. Known adverse events are OHSS, thromboembolic events and hypersensitivity reactions.

Study design, size and duration: Retrospective study of 31 IVF cycles in patients who underwent ovarian stimulation at Hegde hospitals in the year 2021-2022 using PERGOVERIS completely or partially were analyzed. Internal comparison with the patients previous cycle where available was done. Outcomes of Pergoveris use results are analyzed in three groups. Exclusive PERGOVERIS group (22), cross over from other drugs to PERGOVERIS (6) and viceversa (3). Primary outcomes analyzed were FOR, FOI, number of M2 oocytes and number of good quality embryos. Secondary outcomes analyzed were pregnancy rates and clinical pregnancy rates. Safety assessed by noting the incidence of adverse reactions if any.

Results: Mean dose of gonadotropins ($n = 5550$) and mean days of stimulation ($n = 11.66$) were highest in the group crossed over from Pergoveris to other Gonadotropins and least in the exclusive Pergoveris group ($n = 2904.5, 9.68$), respectively. Mean Pre trigger E2 levels ($n = 5539.5$) were highest in the group crossed over to Pergoveris reflecting in mean number of expected oocytes ($n = 12.33$) and M2 oocytesretrieved (14.6). Moderate to

good quality oocytes were obtained in all groups except cross over to other gonadotropins group. Mean FOR (n = 1.01) and mean FOI (n = 1.09) were highest in the exclusive Pergoveris group. Clinical pregnancy rates were 50% in exclusive pergoveris group and 100% in cross over to pergoveris group. Internal comparison was done between previous IVF cycles and pergoveris groups (exclusive + cross over to pergoveris), we found that mean number of oocytes retrieved (9.39 vs. 12.67) and the pregnancy rates (27% vs. 64%) and clinical pregnancy rates (9% vs. 64%) were less in previous IVF cycles. P-values for each comparison group are statistically significant.

Limitations: Sample size of the study was small. However, as the results show promising trend, we intend to continue the study further. Clinical pregnancy outcomes are pending in women who did not yet have their embryo transfer cycles. Cost effectiveness was not studied.

Conclusion: In our pilot study, results showed that, ovarian stimulation with Pergoveris resulted in higher oocyte yield, more M2 oocytes and good quality embryos especially in poor responders and in patients with LHCGR gene mutation. No significant adverse effects were noted.

DOI:10.4103/fsr.fsr_2_23-ABS26

NO 27 A RANDOMIZED CONTROLLED STUDY ON THE EFFECT OF PREOPERATIVE RECTAL MISOPROSTOL ON INTRA AND POSTOPERATIVE BLOOD LOSS IN ELECTIVE CAESAREAN DELIVERY

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Study question: Does preoperative rectal misoprostol administration reduces intraoperative and postoperative blood loss in caesarean delivery?

What is currently about the subject: The increase in caesarean delivery adds up to increase in obstetric hemorrhage which is the leading cause of maternal mortality. Oxytocin is the gold standard to prevent blood loss, however, 10% to 40% of them end up in the usage of additional uterotonic agents like prostaglandins like misoprostol, which is affordable and widely available, easily administered through different routes (vaginal, rectal, sublingual, oral), and is having a good safety profile. As compared to oxytocin which needs to maintain its cold chain, misoprostol on the other hand does not require the same have shelf life of several years and hence does not require specific condition for storage thus making it the standard treatment option for PPH in low-resource settings. Less is known about the role of misoprostol in reducing intraoperative blood loss. Synergistic effect of oxytocin misoprostol would allow a reduction in dose for both agents and therefore limit the side effects while improving efficacy.

Study design, size, duration, material and methods: It was a randomized controlled study including 60 women posted for elective LSCS (Lower segment caesarean Section) during December 2020 to April 2022. Allotted in to two groups, case group received preoperative rectal misoprostol 400 mcg after spinal anaesthesia and intravenous oxytocin infusion post-delivery as standard of care, other control group received only intravenous oxytocin infusion post-delivery. Outcome measures where change in preoperative and postoperative Hb and Hct in both the groups, amount of intraoperative blood loss in both the groups and side effects of misoprostol along with duration of surgery and number of days in hospital, use of additional uterotonic agents.

Results: In our study intraoperative blood loss ingroup which received preoperative rectal misoprostol was significantly lower as compared to control group (433 ± 92.23 mL vs. 511.67 ± 92.55 mL, P = 0.003). The blood loss during first 24 hours post-delivery was not statistically significant, although they showed mean difference in both case and control groups, 102 ± 16.69 mL versus 106.33 ± 14.50 mL, P = 0.0113 respectively, probably due to the decreased sample size in our study. The mean Hb difference was 0.32 ± 0.05 in cases group and 0.99 ± 0.1 in control group with a P-value of <0.001 which was significant. The hematocrit values showed a mean difference of 1.21 ± 0.11 in controls versus 0.23 ± 0.05 in cases with P-value of <0.001 which was significant. There were no serious side effect of the drug. No additional uterotonics were used in both the groups. The mean duration of LSCS was 33.33 minutes in case group versus 37.33 minutes in the control group, P-value <0.002 which was significant.

Limitations of study: Only elective cesarean deliveries were studied. Sample size was small.

Conclusion: Preoperative misoprostol insertion significantly reduces the risk of PPH and use of additional uterotonic agents. With nil to less side effects, preoperative rectal misoprostol can be advised in women where other additional uterotonics are contraindicated, in periphery settings where cold chain for Inj oxytocin is difficulty to maintain also.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS27

NO 28 PREGNANCY RATES WITH ERA BASED FET IN RIF

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Study question: To compare the pregnancy rates between patients with RIF who undergo personalized (PET) after endometrial receptivity array versus frozen embryo transfer with standard timing

What is currently about the subject: The human endometrium is receptive to the embryo for a specific period of time known as the window of implantation (WOI). During this period, the endometrium shows a specific gene expression profile suitable for endometrial function evaluation. Endometrial receptivity array is novel diagnostic test that measures the endometrial expression of 248 genes and categorizes a patient's endometrium as prereceptive, receptive and postreceptive.

Study design, size, duration, material and methods: Design: This is a retrospective study. Study period: from January 2021 to September 2022. Materials and methods: Patients with recurrent implantation failure (two or three failed previous embryo transfers) with either fresh or frozen embryo transfer, both PGT untested good quality embryos and PGTA tested euploid blastocysts were considered. After excluding all known causes of RIF, seventy three participants those who met the inclusion criteria were analyzed in two groups – 50 in study group and 23 in control group. ERA was performed by igenomix protocol. ERA predicted receptive (R) endometrium at P + 5 in 33/50 (66%) patients and NR in 17/50 (33%) patients (13/17 – prereceptive and 4/17 – postreceptive). Timing of subsequent FET cycles were modified based on ERA report (prereceptive, receptive and postreceptive).

Results: Pregnancy rate (PR) in study versus control group are – 38/50 (76%) versus 10/23 (43.4%), clinical PR – 34/50 (68%) versus 10/23 (43.4%), abortion rate (AR) – 8/50 (16%) and ongoing pregnancy rate (OPR) – 30/50 (60%) versus 10/23 (43.4%), respectively. Sub group analysis done of PGT A tested euploid embryo transferred with ERA versus PGT A non-tested ERA based FET – pregnancy rate – 7/10 (70%) versus 28/40 (70%), abortion rate – 2/10 (20%) versus 5/40 (12.5%), ongoing pregnancy rate – 5/10 (50%) versus 23/40 (57.5%), respectively.

Limitations of study: Live birth rates are being followed as a separate study.

Conclusion: Our data demonstrates a high rate of both clinical pregnancy and ongoing PR after ERA based FET, using both PGT-A tested and PGT untested good grade embryos in patients with RIF.

Study funding/competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS28

NO 29 IMPACT OF DFI ON CUMULATIVE LIVE BIRTH RATE IN ICSI CYCLE IN SOUTH INDIAN POPULATION

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Study question: Does DFI impact the cumulative live birth rate in ICSI (Pont 40) cycle with freeze all strategy

What is currently about the subject: Current research says DNA fragmentation index (DFI) plays a role in recurrent miscarriage, DFI reduces live birth rate in IVF cycles but has no effect in ICSI cycle. The role of DFI in recurrent implantation failure is unknown.

Study design, size, duration, material and methods: An observational study of 4 years duration conducted in Craft Hospital and Research Centre, Trissur. Couples who satisfied the inclusion criteria were divided into two groups. Group A ($N = 153$) with normal DFI and group B ($N = 63$) with high DFI after controlling female factor. All patients underwent ICSI. Patients with high DFI underwent magnetic-activated cell sorting (MACS) as a sperm selection process as per institutional protocol to select non-apoptotic sperms. All patients underwent frozen embryo transfer cycle and cumulative live birth calculated at the end of the ICSI cycle.

Results: Group B had lower cumulative live birth rate (57% vs. 41%, $P < 0.032$), lower cumulative clinical pregnancy rate (69% vs. 46%, $P < 0.01$) and higher miscarriage rate MR (18% vs. 43%, $P < 0.004$) which is statistically significant.

Limitations of study: The study was not randomized so selection bias cannot be avoided.

Conclusion: Men with high DFI have reduced cumulative live birth rate when compared to men with low DFI because of reduced clinical pregnancy rate (recurrent implantation failure) and also high miscarriage rate.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS29

NO 30 OUTCOME OF ENDOMETRIAL COMPACTION IN FROZEN THAWED EMBRYO TRANSFER (FET) CYCLE

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Study question: Does progesterone cause compaction of endometrium and does compaction affect pregnancy rate in frozen thawed embryo transfer cycle?

What is currently about the subject: There is paucity of data on the subject and the result on the compaction of endometrium is variable in various studies.

Study design, size, duration, material and methods: Prospective observational cohort study, size – 75, duration – 15 months. Inclusion criteria: 1. Age <40 years undergoing FET cycle. 2. Artificial hormonal replacement therapy (HRT) cycle. Exclusion criteria: 1. Endometrial thickness 7 mm, Inj progesterone was started according to the Department protocol. Endometrial thickness (transabdominal ultrasound) was measured on the day of starting progesterone and compared to the endometrial thickness (transabdominal ultrasound) on the day of embryo transfer and difference was noted. In all patients D5 embryo (Gardner classification) was transferred. The study population was divided into groups according to the decrease and increase in the EMT. Primary outcome : clinical pregnancy rate. Secondary outcome: ongoing pregnancy rate and miscarriage rate.

Results: We calculated clinical pregnancy rate in different compaction groups and it came to be 66% in the group with compaction 20%, 62% with compaction of 10%, 35% of clinical pregnancy rate in 5% and 33% in <5% compaction group, respectively. While clinical pregnancy rate was 16% when endometrial thickness increased on the day of Embryo transfer.

Limitations of study: Number of patients included in the study was less.

Conclusion: There is inverse correlation between compaction and clinical pregnancy.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS30

NO 31 A DECADES EXPERIENCE OF MICRO-DISSECTION TESTICULAR SPERM EXTRACTION FOR NON-OBSTRUCTIVE AZOOSPERMIA – AN INDIAN PERSPECTIVE

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OASIS Fertility, India

Study question: To evaluate the results of microtese and ICSI for treatment of non-obstructive azoospermia

What is currently about the subject: Microtese is an effective method for the treatment of non-obstructive azoospermia (NOA) and its combination with ICSI can help NOA patients obtain their own genetic offspring.

Study design, size, duration, material and methods: This is a retrospective study conducted at a tertiary level fertility clinic. The study population comprised of 79 patients with non-obstructive azoospermia who underwent microtese between June 2020 and June 2022. Upon successful sperm retrieval, sperm was either used fresh for ICSI, frozen for future use or both. Outcome measures were sperm retrieval rate (SRR) and ICSI results.

Results: Mean age of the patient in the mTESE positive group is 35.43 years. Age range (25–56). Serum FSH in the positive group is 17.88 mIU/mL and in negative group is 15.55 mIU/mL (*P*-value 0.4). Range (63–0.3). Serum testosterone in the positive group is 3.98 ng/mL and in the negative group is 3.49 ng/mL (*P*-value 0.2). Range (9.4–0.7). Sperm retrieval rate – 57% in the current study. Of the 45 men with positive mTESE 34 (75%) underwent ICSI giving good quality blastocyst in 48%. In 11 men (25%) ICSI could not be done owing to poor sperm viability. Incidence of genetic abnormalities noted in the study where three patients with klinefelter syndrome and one with AZFc deletion. Hypospermatogenesis men had maximum chances of sperm retrieval 67% while maturation arrest had 20% chance and least chances of sperm retrieval with sertoli cell only syndrome 13%. Reproductive outcomes fertilization rate – 75%, blastocyst rate – 48%, implantation rate 42%, clinical pregnancy rate 33%, live birth rate 31%, miscarriage occurred in three patients and four patients delivered twins.

Limitations of study: Retrospective study small sample size.

Conclusion: Neither serum FSH nor serum testosterone is a positive predictor of sperm retrieval. Histopathology results to considerable extent can predict sperm retrieval probabilities. Considering Mtese sperm has

given encouraging results patients with NOA should undergo Mtese as the chance of outcome is better.

Study funding/competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS31

NO 32 PROMISING REPRODUCTIVE OUTCOMES IN PATIENTS WITH REFRACTORY THIN ENDOMETRIUM AFTER AUTOLOGOUS BONE MARROW REGENERATIVE CELL THERAPY (ABM-RCT): A CASE SERIES

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Study question: Could regenerative therapy using autologous bone marrow derived cells suspended in platelet derived growth factors offer safe and efficient therapeutic approach for refractory thin endometrium?

What is currently about the subject: Refractory thin endometrium is one of the most difficult challenges faced by clinician in the field of infertility. Many therapies have been attempted to improve this condition, but none have proved effective. Impaired endometrial function can limit implantation due to insufficient tissue regeneration. Clinical investigation has proved that the stem cells existing in endometrium might originate from bone marrow. Hence, the bone marrow stem cells (BMSCs) might play an important role in endometrial tissue remodelling, in terms of cell signalling, immune modulation and stimulation of dormant endogenous cells with regeneration potential. A recent study by Tal *et al*., provides evidence that BMSCs have a nonhematopoietic physiologic contribution to the decidual stroma and play a vital role in implantation and pregnancy maintenance and nonhematopoietic BMSCs are able to impact decidual molecular milieu and overcome implantation defects. Bone marrow stem cell therapy is most commonly used cell.

Study design, size, duration, material and methods: This was a prospective, experimental, self-controlled case series. Eleven patients with refractory thin endometrium resistant to conventional treatment modalities were recruited. Five patients had asherman's syndrome, two patients had genital tuberculosis, two patients had thin endometrium hypo-responsive/unresponsive to estrogens with RIF and two patients underwent chemo and radiotherapy as part of gynec-oncology treatment. After obtaining informed consent, BM aspiration was performed under local anaesthesia from iliac crest using a disposable BM aspiration needle (Jamshidi, 11 G) and collected in heparinized syringes. Progenitor cell enrichment was done by Seragen's team. Peripheral blood was collected to enrich Endo-SERA-Seragen's proprietary growth factor concentrate. The same day, all patients were taken up for regenerative cell therapy. A 2.9 mm hysteroscope was used with operating channel and egg pickup needle attached to it and cells were implanted in sub-endometrial zone in all four walls of uterine cavity.

Results: Post ABM-RCT, endometrial thickness showed increase 100% (11/11) of more than 8 mm in all cases on day of embryo transfer with average endometrial thickness improvement was 1.8 mm than previous cycles, with uniform triple layer pattern. Ten out of 11 (91%) patients conceived after autologous stem cell injection. Nine out of 10 (90%) patients conceived had delivered healthy babies and one patient (9%) had a miscarriage at 12th week of pregnancy. One patient did not conceive will be assessed for immunoprofiling and one more rejuvenation cycle. Results of our study are consistent with several previous studies and feasibility of treatment at an IVF set up and encouraging results have motivated us to plan for a well-planned study with more patients. More research is warranted to evaluate safety, effectiveness and cost of this modality before it becomes integrated in treatment of this frustrating condition during IVF procedures.

Limitations of study: Limitations of this pilot study include the small sample size and the lack of control group.

Conclusion: Our results indicate key role of ABM-RCT in enhanced thickness of endometrium, tissue remodelling, uneventful gestation, improved pregnancy and live birth rate. This novel autologous regenerative therapy is a promising therapeutic option for patients with refractory thin endometrium and a wish to conceive.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS32

NO 33 DETERMINANTS OF SUCCESS IN INTRAUTERINE INSEMINATION

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Study question: To determine the clinical pregnancy rate after IUI and the optimum endometrial thickness at time of ovulation trigger

What is currently about the subject: Barring a few cases like bilateral tubal block, most cases of severe endometriosis and severe male factor infertility, intrauterine insemination (IUI) must be attempted in all cases of infertility as a first line of treatment. However, the success rate of this procedure continues to remain low and is reported to vary from 10% to 20%. Little progress has been made over the years to improve the success rate of the IUI. The principle and technique of the procedure has essentially remained the same over the years. However, a number of advances have come up in the types of stimulation protocols, gonadotropins, sperm preparation techniques and ultrasound monitoring which have resulted in promising pregnancy rates with an IUI. If the IUI results are optimized by a careful selection of patients and treatment regimes, several million couples worldwide will benefit from this simple procedure and will not need to undergo the elaborate and expensive ART procedures.

Study design, size, duration, material and methods: Study design: prospective study. Study set up: Level II ART clinic, at a tertiary care hospital. Study duration: 1 year 2 months. Material and methods: All the couples undergoing IUI/controlled ovarian stimulation with an IUI for the treatment of unexplained infertility, male factor, anovulation, minimal and mild endometriosis, tubal factor with at least one tube patent and serodiscordant couples were included in the study. A baseline transvaginal scan was done using 8 MHz transducer. A note was made of the follicle count per ovary and endometrial thickness. Ovulation induction with clomiphene citrate (100 mg once a day for 5 days) or letrozole (2.5 mg once a day for 5 days) was initiated. They were called for a follow up 5 to 6 days later. If the follicles were not recruited, urinary gonadotropins (HmG) were added in dose varying from 37.5 to 150 mg and 75 to 150 mg per day depending upon the patient profile.

Results: There was a decline in clinical pregnancy rate (CPR), with increasing age of the women (age >29 yrs) however, the difference did not reach statistical significance. The mean duration of infertility was 6 years. No correlation was observed between duration of infertility and success in an IUI cycle. A total of 403 (60.5)% of women presented with primary infertility. The common causes of infertility identified were PCOS (14.9%), unexplained (52.8%), tubal factor (16.4%), male factor (7.4%), tuberculosis (4.8%), poor ovarian reserve (4.05%) and endometriosis (3.75%). The total clinical pregnancy rate (CPR) per cycle was 10.4%. The highest clinical pregnancy rate was observed in women with PCOS (16.16%, *P*-value 0.04) followed by couples with different male factor infertility (14.3%,

P-value 0.349). However, the success rate of different groups did not show statistical significance as compared to former. Endometrial thickness on the day of trigger <8.9 mm significantly decreased the chance of pregnancy. The lowest total motile sperm count (TMSC) pre-wash at which pregnancy was achieved after an IUI was 8 million. Protocol used for ovarian stimulation affected the success rate of the cycle. It was highest with human menopausal gonadotropin used alone (33.33%) followed by letrozole with human menopausal gonadotropin (14.29%).

Limitations of study: It is a prospective study. There is no control group.

Conclusion: PCOS, ovulation induction with human menopausal gonadotropin with or without clomiphene or letrozole and endometrial thickness >8.9 mm are associated with better clinical pregnancy rates. IUI can be offered as a first-line option to women <40 years, with no other contraindication to IUI.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS33

NO 34 EVALUATION OF THE EFFECTIVENESS OF CONCEIVE – AN ARTIFICIAL INTELLIGENCE POWERED PERSONALIZED REGENERATIVE MEDICINE STRATEGIES FOR IMPROVING ENDOMETRIAL THICKNESS

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Study question: Could personalized regenerative medicine based strategies promote endometrial growth and receptivity in women with refractory thin endometrium resulting in successful implantation and live births?

Study design, size, duration, material and methods: In this self-controlled (each patient served as their own control) study, 22 women with history of more than three failed IVF cycles due to persistent thin endometrium

Results: Clinical pregnancy rate was 79% (15/19); no pregnancy in four patients accounted for 21%. 26.3% (5/19) delivered healthy babies and 47.3% (9/19) of uneventful pregnancies were progressing. One patient (5%) had miscarriage at 20th week due to cervical incompetence. Improvement in endometrium thickness (EMT) was 96%, with a mean difference of 1.9 mm improvement in 24 patients, and the EMT (1.1 mm) of one patient decreased. No adverse effects were reported. Eleven patients out of 21 conceived; 4 out of 21 patients did not conceive; and 6 out of 21 patients are yet to undergo embryo transfer in the intra-uterine group. All four patients from the sub-endometrial group conceived. Live birth rate and on-going pregnancies are indicators of overall endometrial quality (thickness and receptivity) improvement which validates that personalization helps to achieve a maximum success rate. Eleven out of 22 patients who were referred to surrogacy have conceived. The cumulative 95% (18/19 ET) pregnancy rate has motivated us to plan further for well-planned randomized trials to confirm the results and provides the opportunity for the women with refractory thin endometrium to conceive without surrogacy.

Limitations of study: This is a prospective self-control study, contains a small sample size and lacks a randomized control group.

Conclusion: In women with a history of cycle cancellations due to thin endometrium, the CONCEIVF-AI platform recommended personalized ABCD dosages that resulted in improved endometrial thickness, clinical pregnancy and live birth. Personalization is the key to this phenomenal outcome because no two patients are alike!

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS34

NO 35 HIGH LIVE BIRTH RATES AFTER LOW DOSE IMMUNIZATION THERAPY WITH PARTNER LYMPHOCYTES IN PATIENTS WITH RECURRENT MISCARRIAGE – A MULTICENTRIC ANALYSIS

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Study question: Could low dose immunotherapy improve live birth rates in unexplained recurrent miscarriage patients?

What is currently about the subject: Recurrent miscarriage (RM) affects 1.2% of couples who attempt to conceive and has been defined as three consecutive pregnancy losses prior to 20 weeks of gestation from the last menstrual period. Although many potential causes have been established for recurrent implantation failure (RIF) and recurrent miscarriage (RM), about 50% of these remain idiopathic and unexplained owing to immunology factors. Recently, meta-analyses have observed better effectiveness and safety of low-dose lymphocyte immunotherapy (LIT) in treating couples with RM in vitro fertilization (IVF) cycles. In majority of studies, the use of LIT for unexplained RM couples has shown an improvement in pregnancy outcomes. Still, the results are conflicting due to different screening criteria and therapeutic protocols. The objective of the present study is to evaluate the effectiveness of immunotherapy and live birth rates using low-dose lymphocytes in patients with uRM and Th1/Th2/Treg paradigm disorders.

Study design, size, duration, material and methods: After obtaining informed consent, 108 RM patients underwent immunization with lymphocytes of their respective partners from November 2020 to June 2022, received low-dose lymphocytes immunotherapy. Patients had to fulfill following criteria in order to be approved for immunization: at least three clinical pregnancies that culminated in abortion before 20 weeks of gestation or at least three cycles of IVF or intracytoplasmic sperm injection with at least two good quality embryos (PGT +) and endometrium (>8 mm) in each transfer without pregnancy (implantation failure), normal results for coagulation tests, autoimmune diseases (antiphospholipid antibodies, antinuclear antibodies, thyroid antibodies), hysteroscopy, glucose tolerance test, and karyotyping of both partners. Maternal BMI of 30 (kg/m^2) and age of 45 was upper limit with abnormal proportions of peripheral blood Th1 cells, Th2 cells and Treg cells; and elevated concentrations of TNF-a, IFN-g and low TGF-Î²1, blocking antibody (BA) in serum which were detected by flow cytometry and ELISA, respectively.

Results: The proportion of Th1 cells was significantly decreased while the proportions of Th2 cells and Treg cells were significantly increased in immunotherapy patients after treatment. In addition, the concentration of TGF-Î²1 in serum was significantly higher after immunotherapy than before. The concentrations of TNF-a and IFN-g were significantly high before therapy was significantly decreased after therapy. LIT effectively induced the production of blocking antibodies in all the patients. The pregnancy rate significantly increased in patients who undertook LIT than in those who did not (75.0% vs. 51.92%, p€‰ < €‰.05). Patients in the LIT group had a significantly higher live birth rate (66.6% vs. 37.03%, p€‰ < €‰.05), as well as a lower abortion rate in comparison with those in the control group (10.19% vs. 26.92%, p€‰ < €‰.0001). LIT was associated with high live birth rates, especially in women with RM. It not only ameliorates the patient's cellular immune function but also further increases the patient's pregnancy success rate with high safety, which is worthy of clinical application and promotion.

Limitations of study: This is a multi-centric, prospective study that is well-developed with follow-ups and procedures. This study lacks a randomized control group.

Conclusion: Our findings supported LIT as a beneficial treatment for RM in IVF patients. However, it may be considered safe and effective therapy in individual cases and based on their immune profiling (Th1/Th2/Treg paradigm dis- orders), after all, other potential causes of RM or RIF have been ruled out.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS35

NO 36 EVALUATION OF THE EFFECTIVENESS OF OVA-SERA-PERSONALIZED OVARIAN REJUVENATION PROTOCOLS POWERED BY CONCEIVF-AI ENGINE TO IMPROVE LOW OVARIAN RESERVE IN INFERTILE WOMEN

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Study question: Could personalized ovarian rejuvenation protocols offer safe and efficient therapeutic approach for patients with low ovarian reserve who wish to conceive with their own oocytes?

What is currently about the subject: Patients with a low ovarian reserve will have low quality and quantity of their oocytes and, therefore, when starting a hormonal stimulation cycle for an in vitro fertilization treatment with the patient's eggs, the result will be: a few eggs of low quality with difficulty in reaching the blastocyst stage. This is a challenge for fertility experts and patients. Data-intensive biomedical technologies applied in clinical research reveal that humans vary widely at genetic, biochemical, physiological, exposure, and behavioral levels, especially with respect to disease processes and treatment responsiveness. Hence there is need to deeply personalize interventional strategies at clinical and dosage levels for every individual patient. Our objective is to evaluate artificial intelligence (Conceivf) powered regenerative medicine based personalized therapeutics (Ova-SERA) for improving parameters like AMH, AFC, number of oocytes and embryos in patients with low ovarian reserve aimed to improve the chances of achieving pregnancy with their own eggs.

Study design, size, duration, material and methods: This is a non-randomized study and the study population ($n = 30$) was recruited from inpatient hospital settings or outpatient clinics in various infertility centers across India. The patients recruited (June 2021–June 2022) had a poor ovarian response (3 oocytes with a conventional stimulation protocol), and an abnormal ovarian reserve test [i.e. antral follicular count (AFC)].

Results: Following intraovarian administration of Ova-SERA, when baseline data were compared, mean serum FSH was significantly reduced after treatment for all the patients. The increased serum AMH difference was not very significant. Oocyte yield in this group ranged from 2.8 ± 1.5 eggs/patient after intraovarian injection of Ova-SERA. ICSI was used in all cases; 2pn status was confirmed in 4.2 ± 0.84 zygotes within 24 hours of oocyte retrieval. None of the patients experienced any complications from controlled ovarian hyperstimulation, trigger or oocyte retrieval. Following Ova-SERA treatment, four participants (13.3%) achieved a natural conception, leading to live birth in all four participants and following a complication-free pregnancy in the term. Eleven (36.67%) pregnancies were recorded in the remaining patients who underwent IVF procedures. Out of 11, one participant had a miscarriage before 8 weeks, four patients delivered healthy babies and six complication-free pregnancies are ongoing. Normal first- and second-trimester prenatal screening tests were recorded.

Limitations of study: This study is limited by several factors, including the small sample size, the absence of a placebo control group and the variance in gonadotropin regimes used for IVF after Ova-SERA dosing due to multiple clinical settings.

Conclusion: The efficacy of Ova-SERA is demonstrated as an adjunct for women with poor ovarian reserve, premature ovarian insufficiency, and even early menopause who are trying to conceive using their own oocytes. Given its low-risk profile, the benefits of this personalized therapeutic approach need to be studied in larger randomized controlled studies.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS36

NO 37 PROGESTERONE PRIMED OVARIAN STIMULATION (PPOS) PROTOCOL IN OOCYTE DONATION PROGRAM: SUCCESS, SAFETY AND COST-EFFECTIVENESS

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Study question: Comparison of PPOS with antagonist protocol with respect to following: 1. Dose of gonadotropins during ovarian stimulation; 2. Length of ovarian stimulation; 3. Estradiol values.

What is currently about the subject: Antagonist protocols is almost universally used in donor egg program. With the introduction of progesterone primed ovarian stimulation protocol, a lot of interest was generated about its safety and effectiveness. Most of the research work provided comparable results with PPOS in terms of similar dose and duration of stimulation along with similar oocyte retrieval, maturity rate, implantation rates and incidence of OHSS.

Study design, size, duration, material and methods: This is a retrospective study carried out during the year 2021 to 2022 in a privately owned ART Level 2 clinic. A total of 160 oocyte donors were recruited, out of which 32 oocyte donors were selected whose parameters were duly matched which could potentially interfere in the end results. Out of 36 selected subjects, 16 were stimulated using PPOS Protocol and 16 subjects were stimulated with antagonist protocol. The above-mentioned study questions were compared and statistically analyzed.

Results: A higher dose of gonadotropins was needed in PPOS group compared to antagonist group (3035.94 ± 349.9 and 2611.25 ± 280.2; $P = 0.001$) which was statiscally significant. Similarly, significantly lower estradiol values were observed on the trigger days in PPOS group (5047.63 ± 571.38 vs. 7033.38 ± 409.48; $P = 0.008$). The duration of stimulation, oocyte retrieval and maturity rates were similar in both groups (10.13 ± 0.20 and 9.94 ± 0.193; $P = 0.507$, 19.75 ± 2.0 and 18.50 ± 1.08; $P = 0.6$, 14.69 ± 1.42 and 13.63 ± 0.58; $P = 0.49$, respectively). Although an increased trend was noted about cost in antagonist group, this was not statistically significant (INR 38,518 ± 1081.53 in PPOS vs INR 41,025 ± 872.24; $P = 0.081$). No significant difference was observed in implantation rates (11/16 in PPOS vs. 12/16 in antagonist; $P = 0.694$) and none of the subjects in both groups developed OHSS beyond mild (ovarian size <8 cm^3 with mild pain and occasional nausea).

Limitations of study: It is a retrospective study with a small number of subjects. The study was conducted in a privately owned Level 2 clinic and hence established protocols are always favored.

Conclusion: PPOS seems to provide equal oocyte retrieval and oocyte maturity along with similar implantation rates compared to antagonist protocol. Although it needed a higher dose of gonadotropins, the cost of the

treatment remained low compared to antagonist protocol. The safety profile of PPOS was similar to antagonist protocol.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS37

NO 38 IMPACT OF FOCUSED COUNSELLING IN IVF TREATMENT : PSYCHOLOGICAL WELL-BEING AND COGNITIVE EMOTIONAL QUOTIENT

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Study question: What is the impact of the focused counselling method on aspects of psychological well-being and cognitive emotional quotient amongst patients undergoing IVF self-cycle treatment?

What is currently about the subject: Besides having enough literature creating awareness regarding the importance of psychological counselling in medical treatments, few discuss it specially in IVF treatment procedures. This study aims to understand the counselling effect on two major psychological aspects, which are psychological well-being and cognitive emotional quotient amongst patients undergoing IVF self-cycle treatment. This study throws light on understanding the importance of creating specific counselling sessions to maximize the well-being of the patients and their treatment outcomes.

Study design, size, duration, material and methods: This study used the quantitative method approach to analyze the psychological well-being and cognitive emotional quotient of the patients undergoing IVF self-cycle treatment post the counselling sessions. A total of 60 patients who met the inclusion criteria (first IVF self-cycle) were chosen. The data were collected using the Ryff's psychological well-being scale and cognitive emotional regulation questionnaire. The collected data were analyzed using the non €" parametric statistics methods.

Results : The quantitative data analysis performed and the obtained results show that the patients underwent counselling sessions mainly focusing on the aspects on psychological well-being and cognitive emotional quotient at three stages of treatment, that is, pre, during and post the stimulation process of IVF treatment projected better PWB levels (medium and high) and EQ levels and also there was seen a good outcome that highlighted the aspects of self blame, rumination, acceptance, catastrophizing, positive refocusing, autonomy and personal growth amongst the patients.

Limitations of study: The current study was conducted at one center, and the sample size can defy its generalizability. Another limitation of the study could be the short span of time, which could have had an influence on the session timings.

Conclusion: The analysis of the results and the supporting literature helps us to conclude that the specific focused psychological counselling shows countable effects on the patient's overall well-being as a person and obviously the treatment, as the study involved the majorly two focused aspects of individual's psychology PWB and EQ, which highlighted the aspects of self blame, rumination, acceptance, catastrophizing, positive refocusing, autonomy and personal growth. Further, more research could be helpful in the design of better intervention plans and implementation, which can double the benefits of psychological counselling in IVF treatment.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: No.

DOI:10.4103/fsr.fsr_2_23-ABS38

NO 39 FROZEN – THAWED DAY 6 BLASTOCYST TRANSFER FOR SLOW GROWING GOOD QUALITY EMBRYOS HAVE SIGNIFICANT IMPROVEMENT IN IMPLANTATION POTENTIAL AND PREGNANCY OUTCOME IN HUMAN IVF-ET

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Study question: Will extended culture till Day 6 (D6) for slow growing good quality embryos and embryo transfers (ET) have an improved implantation potential in in vitro fertilization (IVF) cycles?

What is currently about the subject: There is conflicting evidence regarding Day 5 blastocyst transfer having higher clinical pregnancy rate (CPR) and live birth rate (LBR) in comparison to D6 ET in both frozen and fresh cycles regardless to embryo quality. The Day 5 priority during fresh cycles can be explained by endometrial asynchrony or embryo quality. In FETs, the endometrial factor is supposedly eliminated. In programmed thawed blastocyst transfer cycles, the same clinical outcome should be expected when transferring day 5 or day 6 blastocyst because of endometrial synchronization due to hormonal priming of endometrial receptors. Slow growing blastocysts have lower implantation potential when transferred in fresh cycles. A meta-analysis from 2010 demonstrated that Day 6 embryos that were at same stage of development at cryopreservation as Day 5 cryopreserved embryos had similar CPR and LBR.

Study design, size, duration, material and methods: A 2-year retrospective analysis of FET results from I January 2020 to 31 December 2021 at Nova IVF fertility, Banjarahills, Hyderabad, Telangana, India was compared. A total of 205 (156 self and 49 donor) Day-6 and 852 (568 self and 284 donor) Day-5 frozen thaw cycles were compared. Self-stimulation and donor cycles were included. Gestational Surrogates were excluded from this study. Controlled ovarian stimulation is done according to standard operations of practice in antagonist cycle. Blastocyst culture was performed on all IVF cases. Intracytoplasmic sperm injection (ICSI) performed for all oocytes. All cultures were performed in bench-top incubators at 37„*f* with 6% carbon dioxide till D6. Cryopreservation and thawing were done using vitrification and warming media with standard protocol. A total of 205 D6 and 852 D5 frozen ETs were performed in hormone replacement cycle with good grade blastocysts. The outcomes were assessed for pregnancy rate and clinical pregnancy rate.

Results: Baseline variable of patients were compared between both arms. Pregnancy rates (PR), biochemical pregnancy rate (BPR), early pregnancy loss (EPL), clinical pregnancy rates (CPR) are the primary outcomes studied during the same period between self and donor cycles. Out of 205 D6 frozen cycles, 156 were self with 51.91% (81/156) PR and 49 were donor cycles with 61.22% (30/49). BPR were 10.9% (17/156) for self and 10.20% (5/49) for donor cycles. EPL were 2.50% (4/156) and 8.10% (4/19) for self and donor cycles respectively. CPR were 38.46% (60/156) for self and 42.8% (21/49) for donor cycles. Out of 852 D5 frozen cycles, 568 were self with 68.6% (390/568) PR and 284 were donor with 69.3% (197/284). BPR were 9.80% (56/568) for self and 8% (23/284) for donor. EPL were 6.10% (35/568) and 4.90% (14/284) for self and donor respectively. CPR were 52.60% (299/568) for self and 56.33% (160/284) for donor cycles. The day 6 FET-Self resulted in significant difference in pregnancy rates ($P = 0.0001$) compared with the day 5 transfers, but the day 6 transfer of FET-Donor is statistically insignificant ($P = 0.2631$) compared with the day 5 transfers. Statistical analysis of the data were performed using chi-square test.

Limitations of study: Retrospective study small size of the sample.

Conclusion: This study concludes that D6 FET has significant implantation potential and would increase PR by improving the efficacy of embryo selection. Extended culture till D6 for slow growing good quality embryos and ET has an improved PR in FET cycles. Thus reducing cycle cancellation with increased cumulative PR.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS39

NO 40 COMPARISON OF EFFECT OF CLOMIPHENE CITRATE WITH ESTRADIOL VALARATE V/S CLOMIPHENE CITRATE ALONE ON PREGNANCY RATE IN INFERTILE WOMEN

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Study question: Is effect of clomiphene citrate better with adding estradiol valarate on pregnancy rate in infertile women?

What is currently about the subject: Anovulatory cycle in young women is the common cause of infertility and PCOS remains the common endocrinopathy and cause infertility. 10% to 14% of Indian population suffers from infertility out of which 25% to 30% is occupied by PCOS.

Study design, size, duration, material and methods: Is this prospective study enrolled 100 infertile women with PCOS age 21 to 35 years which has taken one cycle of clomiphene citrate 100 mg ET 18 mm. 50% patients were treated with clomiphene citrate 100 mg alone and 50% patients were treated with clomiphene citrate 100 mg along with estradiol valerate.

Results: In group A patients treated with clomiphene citrate 100 mg alone, 18% of patients conceived, and in group B patients treated with clomiphene citrate 100 mg along with estradiol valerate, 38% of patients conceived.

Limitations of study: Clomiphene citrate alone cause endometrial thinning.

Conclusion: The pregnancy rate is higher in the group treated with clomiphene citrate and estradiol valerate in comparison with clomiphene citrate alone.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS40

NO 41 A NEW APPROACH FOR DEALING WITH TYPE 4 CERVICAL STENOSIS/ASHERMANN"S SYNDROME SECONDARY TO GENITAL TUBERCULOSIS

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Study question: Genital tuberculosis has a high incidence in chronic infertility patients of Garhwal region, many times it devastates inside female pelvis without making a hissing sound

What is currently about the subject: Many times, when these patients are taken for IVF or ICSI, only hysteroscopy is usually done, and too is unsuccessful. This is because of severe grade 4 cervical stenosis.

Study design, size, duration, material and methods: Herein lies the role of combined laparoscopy and hysteroscopy. In this patient, when the lap was inserted, it was seen that the uterus was retroverted and severely adhered to the thickened uterosacral ligament and bowel. Normal anatomy was restored, then a new innovation was done by a team using a 3 mm ureteroscope for dilating this severe grade stenosed cervix through which a Terumo Guide wire was sent through a pin hole cervix, then over it gradually increasing diameter PCNL dilators used, finally due to the combined effects of the direction of uterine alignment via lap. and gradual dilation via terumo guide wire use, Asherman's uterus was dilated and all adhesions inside the uterus were cut via bipolar forceps.

Results : In the last 2 years five such cases of Grade 4 cervical stenosis with genital tuberculosis done at our center, where a combined laparo-hysteroscope approach was used with successful dilatation of grade 4 cervical stenosis via use of a 3 mm ureteroscope along with Terumo Guide wire and PCNL dilators. No false track or cervico-uterine perforation occurred in any of the cases.

Limitations of study: It was a small group study design, which was not funded by any institution.

Conclusion: We suggest a new approach of dilatation of Grade 4 cervical stenosis which is for benefit of many needy genital tuberculosis patients of Garwhal Hilly Region.

Study funding/Competing interest(s): No.

Is it a clinical trial: Yes.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS41

NO 42 OVULATION INDUCTION IN PCOS PATIENT (BEYOND BASICS)

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Study question: Retrospective case series study of 136 PCOS women attending tertiary care fertility center for a period of 6 months

What is currently about the subject: Polycystic ovarian syndrome is the most common endocrine disorder in women of reproductive age. Infertility is a common feature, with about 75% women suffering from anovulation. Lifestyle modification is first-line treatment, and it is associated with an improved endocrine profile. There number of protocols for ovulation induction in PCOS patients, but our case study is to minimize high cycle cancellation rates to get high pregnancy rates by using the protocol of ovulation induction with letrozole and very minimal injections of gonadotrophins along with advice of lifestyle changes. This stimulation protocol also reduces the chance of developing a lutinized unruptured follicle and also provides a better response in clomiphene-resistant cases and equal pregnancy rates in obese women. With use of less gonadotrophin injections, there is less chance of ovarian hyperstimulation syndrome.

Study design, size, duration, material and methods: Retrospective case series study of 136 women attending our t infertility center for period of 6 months from 1st March 22 to 1st Aug 22. All the patients are in age group 18 to 35 years. All the patients advised to take letrozole 2.5 mg bd from d2 of cycle for 5 days. Follicular study started on d7th of the cycle. If dominant follicle (DF) noticed then patient asked to come for follow up scan for every 2 days. If there is no DF noticed then advised single dose ufsh 75u and advised follow up on day 10th. If on day10th DF noticed then advised them for follow up scan on day 14th. If there is no DF noticed then advised them ufsh 150u. We offered RPT scan on day 18th. If no DF on day 18th we would cancel the cycle. At the size of follicle 16 to 18 mm REC HCG 250 ug given advised timed intercourse or IUI after 36 to 48 hours.

Results: We aimed to evaluate the effects of gonadotrophin in patients with PCOS. Data showed that adding gonadotrophins to PCOS patients along with letrozole improved their life birth rate (CI 95%), showed a sig-

nificant reduction in cancellation rates (CI 95%), reduced rates of OHSS, and reduced the rate of lutinized unruptured follicles.

Limitations of study: Small sample size, women discontinued treatment, severe male factors and morbid obesity.

Conclusion: Beyond basic concepts in stimulation of PCOS is minimum cycle cancellation by waiting up to dI8th of cycle and adding gonadotrophins prevents lagging of maturity of follicle and decreases occurrence of LUF. Along with better pre-treatment plan and lifestyle changes, it will reduce insulin resistance and improve the outcome.

Study funding/Competing interest(s): Yes.

Is it a clinical trial?: Yes.

Ethical clearance done or not: Yes.

DOI:I0.4I03/fsr.fsr_2_23-ABS42

NO 43 EFFICACY OF LASER ASSISTED HATCHING IN FROZEN-THAWED EMBRYO TRANSFER (FET) CYCLES

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Study question: Does application of laser assisted zona drilling – hatching before embryo transfer in frozen-thawed (FET) cycle improves the implantation rate of the embryo?

What is currently about the subject: Zona pellucida (ZP) hardening has been proposed as a causative factor in an unsuccessful IVF cycle in advanced maternal age (AMA) and unexplained recurrent implantation failures. In vitro conditions esp. cryopreservation can further aggravate hardening by bringing various biochemical changes. Thinning or drilling of ZP by various mechanical, chemical and laser guided method has been adopted as a method to improve the implantation of the embryo.

Study design, size, duration, material and methods: This is a retrospective study carried out during the year 2018 to 2022 in a privately owned ART Level 2 clinic. Laser assisted hatching procedures (LAHp) were carried out for various indications like unexplained recurrent implantation (u-RIF), advanced maternal age (AMA), thick ZP, frozen-thawed embryo transfer (FET), or at the choice of the patient. A total of 354 LAHp were carried for FET cycles just prior to Day 3 embryo transfer. Out of these, I00 FET–LAHp were identified whose parameters were duly matched which could potentially interfere in the end results. Out of I00 selected subjects, in 50 subjects (Group I), LAHp was done prior to FET whereas in other 50 subjects (Group 2), embryos were transferred without LAH p. The outcome (implantation rate) was compared and statistically analyzed.

Results: Both the groups had subjects with similar age (group I = 33.19 ± 4.47 years and group 2 = 33.22 ± 5.57 years; $P = 0.98$) and duration of infertility (6.33 ± 2.7I years and 6.46 ± 3.3 years; $P = 0.9I$, in Group I and 2, respectively). No significant difference in the endometrial thickness (I0.03 ± I.54 mm and 9.88 ± I.54 mm; $P = 0.6I$) and progesterone values (0.55 ± 0.26 ng/mL and 0.57 ± 0.23 ng/mL; $P = 0.74$) were noted on the day of start of luteal phase. The implantation rates were similar in both the groups (group I = 35/50, 70% and group 2 = 33/50, 68%; $P = 0.16$). No significant difference in implantation rates were observed in age subgroups of less than 35 years and advanced women age ($P = 0.67$).

Limitations of study: It's a retrospective study with a small number of subjects. The study was conducted in a privately owned Level 2 clinic and hence established protocols are always favored.

Conclusion: Laser assisted hatching doesn't seem to provide additional benefit in frozen-thawed embryo transfer cycles. Considering the cost of the laser equipment and expertise, its use should be restricted in FET cycles.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

DOI:I0.4I03/fsr.fsr_2_23-ABS43

NO 44 LAPAROSCOPY VERSES ART (IVF) IN ADVANCED ENDOMETRIOSIS

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Study question: Study on I00 pts.

What is currently about the subject: For grades 3 and 4 endometriosis cases, options were given to patients for surgery, medical treatment, or an artificial reproductive technique. Laparoscopy was of no extra advantage except in cases of severe pain or if there was difficulty in ovum pick up. The patients who opted for IVF showed a higher pregnancy rate as compared to those who opted for laparoscopy. Surgery further diminished the ovarian reserve.

Study design, size, duration, material and methods: Study design – I00 patients between the age group of 30 to 35 years of age duration I year. Material – laparoscopy and ART.

Results: IVF treatment showed better results as compared to laparoscopy in terms of clinical pregnancy rate and live birth rate.

Limitations of study: Many patients left the treatment in between.

Conclusion: No doubt, in vitro fertilization brought better hope for grades 3 and 4 endometriosis cases.

Study funding/Competing interest(s): No.

Is it a clinical trial: Yes.

Ethical clearance done or not: Yes.

DOI:I0.4I03/fsr.fsr_2_23-ABS44

NO 45 ROLE OF BASELINE LUTEINIZING HORMONE LEVELS ON ASSISTED REPRODUCTIVE TREATMENT OUTCOMES IN PCOS PATIENTS UNDERGOING IN VITRO FERTILIZATION BY ANTAGONIST PROTOCOL

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Study question: To compare the ART outcomes in women with high basal LH levels against those with normal LH in PCOS women undergoing GnRH antagonist cycle.

What is currently about the subject: Women with PCOS are usually accompanied by higher basal LH levels and an increased probability of early LH elevation. Early LH peak can cause premature ovulation and luteinization of follicles. Studies have shown that sustained LH stimulation impairs folliculogenesis by hampering FSH-dependent follicular growth and FSH receptor expression. This altered endocrine milieu also results in poor oocyte maturation, fertilization rates and embryo quality, poor pregnancy rates, and high miscarriage rates. Various strategies have been employed for the control of premature LH surges during controlled ovarian stimulation (COS). GnRH antagonist protocol as well as medroxyprogesterone acetate (MPA) administration during stimulation has been preferred for clamping LH surge in PCOS patients. In non-PCOS patients, studies have described poor pregnancy rates with high basal LH in the antagonist protocol. However, there are limited studies on the effect of high basal LH in the PCOS patients undergoing IVF-ET by the antagonist protocol.

Study design, size, duration, material and methods: This is a retrospective study conducted in 111 PCOS patients with infertility who underwent IVF treatment at AIIMS, New Delhi. This was conducted over a period of 2 years. Subjects were divided into two groups based on the serum LH levels on the day 2 of the menstrual cycle. Group A included 63 patients whose baseline LH level was 8 mIU/mL whereas group B included 48 subjects whose baseline LH was >8 mIU/mL. All the patients underwent controlled ovarian stimulation by standard antagonist protocol followed by fresh or frozen thawed embryo transfer. The primary outcome of the study was the clinical pregnancy rate. The secondary outcomes were the total dose of gonadotropin requirement, duration of stimulation, follicular output rate (FORT), serum estradiol on the day of trigger, number of oocytes retrieved, number of embryos, fertilization rate, cleavage rate, implantation rate, miscarriage rate, and live birth rate.

Results : Out of 153 PCOS patients, 111 met the eligibility criteria. Out of these, 63 patients had baseline LH levels 8 mIU/mL whereas 48 subjects had high baseline LH >8 mIU/mL. The total dose of gonadotropin requirement, duration of stimulation, FORT, serum estradiol on the day of trigger, number of oocytes retrieved, number of embryos, fertilization rate, cleavage rate, implantation rate, clinical pregnancy rate per cycle and transfer, miscarriage rate, and live birth rate were comparable between the two groups.

Limitations of study: The limitations of the study are the retrospective nature of the study and small number of cases especially a smaller number of frozen embryo transfer cycles.

Conclusion: The present study has shown that PCOS with high basal LH levels gives comparable ART outcomes to those with normal basal LH with strict LH monitoring and proper timing of starting antagonist. High basal LH levels should not be considered a hindrance for starting COS in PCOS.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS45

NO 46 COACTION OF GNRH AGONIST AND AROMATASE INHIBITOR DEFIES HUGE ADENOMYOSIS AND ACHIEVES PREGNANCY

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Study question: Study two successful cases of GnRH agonist + aromatase inhibitor prior to FET in women with adenomyosis avoiding surgery

What is currently about the subject: Adenomyosis seems to be rise in the women of reproductive age women and it poses a challenge to achieve a pregnancy in them. Adenomyosis is associated with altered endocrine and inflammatory milieu resulting in impaired implantation, reduced fertility potential, and obstetric complications. Adenomyosis is perpetuated by the vicious cycle involving local hyper-estrogenism, increased peristalsis, micro-trauma, activation of the tissue repair mechanism which once again increases estrogen. This cycle is interrupted by GnRH agonist leading to shrinking of adenomyosis and reducing its activity. However, in women with gross adenomyosis having large uterine volume, use of GnRH agonist alone seems not to produce the desired response in these women before FET. However, when we add a aromatase inhibitor, we see desired outcomes with successful pregnancy.

Study design, size, duration, material and methods: Case report—first case is 31-year–old woman who presented with severe dysmenorrhoea. She was diagnosed with adenomyosis (uterus volume—216 cc) and endometriosis and given leuprolide depot 11.25 + 3.75 mg. After good reduction of pain and uterine volume, controlled ovarian stimulation was done and six day-3 embryos were vitrified. Downregulated FET was done after two doses of Inj leuprolide 3.75 mg. Beta-HCG was negative. To prevent symptom recurrence and achieve further uterine volume reduction, FET was planned after combined down-regulation with GnRHa and Letrozole for 8 weeks. Two day-4 embryos (ut.vol.: 105 cc) transferred with ease and she had a 3.1 kg singleton delivered at 38 weeks. Second case is a 35-year-old woman with history of two miscarriages who presented to us desiring pregnancy. Her ultrasound showed diffuse adenomyosis (ut. vol: 344 cc). She underwent antagonist protocol and four embryos were frozen. She had Leuprolide 11.25 + 11.25 + 3.75 mg and Letrozole 2.5 mg once daily for 18 weeks. FET (ut. vol: 204 cc) done which resulted in a singleton of 2.9 kg delivered at 38 weeks.

Results: The uterine volume reduction in the first case was 52% and in the second case was 41% when they resulted in the positive pregnancy outcome. In the first case, when the uterine volume reduction was only 31%, it resulted in a failed FET. Also, the ultrasound markers of adenomyosis like the myometrial cysts, altered myometrial echoes were reduced in intensity before embryo transfer. Combined downregulation also helps in reducing obstetric complications. Both cases were given nor-ethisterone acetate for add-back therapy.

Limitations of study: More clinical trials with increased numbers are needed to confirm the data.

Conclusion: GnRHa blocks the ovarian estrogen production and letrozole blocks the abnormally high aromatase activity in the ectopic endometrium of endometriosis and adenomyosis. So in women with advanced disease, the reduction of adenomyotic volume is greater in combined treatment leading to better implantation and successful pregnancy.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS46

NO 47 TRIAL OF AUTOLOGOUS MARROW-DERIVED STEM CELL OVARIAN TRANSPLANTATION (TAMSCOT) FOR OVARIAN REVITALIZATION IN YOUNG INFERTILE WOMEN WITH DIMINISHED OVARIAN RESERVE: AN OPTIMISTIC APPROACH

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Study question: Does autologous bone marrow derived stem cell (BMDSC) ovarian transplantation boost ovarian reserve parameters in young infertile women with diminished ovarian reserve (DOR)?

What is currently about the subject: When individuals with premature ovarian ageing want to conceive, oocyte donation is the most viable treatment option. Not being able to have their own biological offspring imposes a major psychological strain. Through its positive impact on ovarian reserve and IVF results, ASCOT has opened new opportunities for patients with poor response and precocious ovarian failure. However, recent studies have revealed mixed data about its effectiveness. No prior research has been considered for the DOR group.

Study design, size, duration, material and methods: An open label non-randomized controlled trial was conducted at Division of Reproductive Medicine in collaboration with stem cell facility of a tertiary care institute. Forty-two infertile women less than 35 years age with DOR (AFC8IU/l) were enrolled in the study during a period from January 2020 to December 2020. Twenty women who did not opt for the intervention were treated as control group whereas 22 women received the intervention. All patients had a baseline hormonal profile (Day 2 FSH, estradiol, AMH, and AFC). Women having an atypical uterine cavity, endometriosis, past ovarian surgery, or an aberrant karyotype were barred from participating.

A bone marrow aspiration was followed by the isolation of mesenchymal stem cells. On the same day, stem cells were implanted into both ovaries through transvaginal method. Follow-up visits at 1 and 6 months were scheduled to monitor ovarian reserve metrics.

Results: Age, BMI, and duration of infertility were comparable across the control and study groups (29.5 ± 3.34 vs. 29.36 ± 2.95 years, 21.51 ± 1.40 vs. 21.87 ± 1.93 kg/m^2, 6.9 ± 1.94 vs. 7.04 ± 3.67 years, respectively). Positive AMH and AFC responses were seen in 68% (15/22) of the patients. These women were injected with a mean of 77.71 ± 25.33 million stem cells. At the initial follow-up, there was no significant difference between the mean FSH, estradiol, and right and left ovarian volumes (9.23 ± 3.95 vs. 9.02 ± 3.92 mIU/l, 61.46 ± 29.25 vs. 68.12 ± 62.52 pg/mL, 2.82 ± 2.18 vs. 2.44 ± 1.25 cc, 2.02 ± 1.54 vs. 2.72 ± 1.6 cc, $P < 0.05$). AMH and AFC levels increased significantly from baseline (0.79 ± 0.43 vs. 1.26 ± 0.82 ng/mL, $P = 0.03$; 3.47 ± 1.30 vs. 6.40 ± 2.23, $P < 0.001$). At the second follow-up visit, the considerable increase in ovarian reserve for AMH and AFC was maintained (0.79 ± 0.43 ng/mL vs. 1.22 ± 0.76 ng/mL, $P = 0.02$; 3.47 ± 1.30 vs. 6.93 ± 1.71, $P < 0.001$). Serum FSH, estradiol, and ovarian volume did not change significantly. During a 10-month follow-up period, no patients suffered any complications, and the improvement in AFC and AMH sustained.

Limitations of study: The present study has certain flaws, such as a limited number of participants and no randomization.

Conclusion: The present study establishes favorable role of stem cells in improving ovarian reserve parameters in women with DOR and with no acquired cause. If supported by future randomized clinical trials, it could represent a paradigm shift for fertility treatment in these women providing an opportunity to have their own biological child.

Study funding/Competing interest(s): No.

Is it a clinical trial: Yes.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS47

NO 48 AUTOLOGUS PRP IN THE MANAGEMENT OF THIN ENDOMETRIUM

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Study question: Does PRP instillation intrauterine increase endometrium blood flow and endometrial receptivity?

What is currently about the subject: Autologus platelet rich plasma (PRP) has emerged as a newer modality of treatment to improve endometrial thickness in case of thin endometrium. Platelet activation would release growth factors from the alpha granules such as VEGF (Vascular endothelial growth factor), EGF (epidermal growth factor), PDGF (platelet derived Growth factor), TGF (Transforming growth factor), and other cytokines, which may facilitate endometrial development. The present study was aimed to study the effect of autologous PRP on endometrial development in cases of thin endometrium in frozen transfer cycle.

Study design, size, duration, material and methods: It is a cross-sectional study. This study was conducted between Sep 2020 and Sep 2022 at KJIVF and Laparoscopy Centre Delhi. We had taken 100 patients in this duration. All women of age between 20 and 40 years were included who were presenting with thin endometrium.

Results: In my study 100 patients were recruited. All patients were between 29 and 34 years of age with mean age being 32.5 years. In 45 patients endometrial thickness increased from 6.1 to 6.5 mm. In 55 patients endometrial thickness increased from 6.5 to 6.9 mm. Blood flow in uterus on Doppler increased in 40 patients out of 100 patients. Hysteroscopy as performed in all patients out of which 10 patients had grade 1 and grade 2 Ashermanns syndrome and four patients had grade 3 Ashermann syndrome. Out of these 10 patients, four patients conceived with PRP. Out of these four patients, two conceived with PRP. Out of 100 total patients, 38 patients had positive pregnancies. Two out of 38 patients had miscarriage. So as seen from study PRP did increase pregnancy rate and endometrial blood flow along with receptivity.

Limitations of study: Short duration of study and more number of cases to be required to help in diagnosis.

Conclusion: Autologous PRP significantly improves endometrial receptivity in patients with thin endometrium in FET (frozen embryo transfer) cycle.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: No.

DOI:10.4103/fsr.fsr_2_23-ABS48

NO 49 ORAL VERSUS INJECTABLE OVARIAN STIMULATION AGENTS FOR IUI IN WOMEN ≥35 YEARS OF AGE WITH DECREASED OVARIAN RESERVE

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Study question: Do oral ovulation induction agents offer benefits in women more than equal to 35 years of age undergoing insemination cycles?

What is currently about the subject: Given the trend, now over multiple decades, of increasing birth in the older reproductive age group, and given this group's decreased fecundity, there is widespread use of IUI (Intrauterine Insemination) in this population. However, there is paucity of research evaluating stimulation agents in the older maternal age population. Moreover, there is an absence of research comparing the route of administration of this drug in this population. Thus, the goal of the study is to compare ovarian stimulation agents based on pregnancy outcomes, among women of older reproductive age undergoing IUI with decreased ovarian reserve.

Study design, size, duration, material and methods: Study Design: Retrospective cohort study from a university health center. Size: 125 IUI cycles. Duration: May to October (6 months). Material and methods: A database was created of all women aged 35 to 42 years old who underwent IUI with stimulation at our center till October 2022. The database contains 597 IUIs from 450 women. A comparison of outcomes of oral (clomiphene citrate or letrozole) versus injectable (gonadotropins) agents was performed for those with antral follicle count (AFC) less than equal to 6. ANOVA, chi-squared test, stepwise multivariate logistic regression were performed. The primary outcome was clinical pregnancy rate per cycle (intrauterine sac with fetal pole and heartbeat), and secondary outcomes were rate of multiple gestation. Data presented are mean ± SD. Power analysis required 125 cycles for an effect size of 0.2, alpha 0.05, and power 0.80.

Results: Three hundred thirty five IUI cycles in 145 patients met inclusion criteria. Stimulation was with clomiphene citrate in 38 (11.3%), letrozole in 33 (9.8%), and gonadotropins in 264 (78.8%) of cycles. Most common coetiologies of infertility (excluding age and decreased ovarian reserve as factors) were male factor (34.3%) and tubal factor (8.4%). Among the three stimulation agents group, there was no significant difference in mean: age of females ($P = 0.41$) or of males ($P = 0.28$), gravidity ($P = 0.11$), parity ($P = 0.55$), or AFC ($P = 0.98$). No. of stimulated follicles ($P = 0.21$) and follicles (R14mm) ($P = 0.10$) at trigger also did not differ. The clinical pregnancy rates per cycle were similar (p = 0.86), but highest in the letrozole group. A clinical pregnancy was observed in 7.5% of all IUI cycles. There was one multiple gestation total obtained with gonadotropins. Analysis controlling for demographic confounders ($P = 0.20$) (including FSH, estradiol, prolactin, TSH, and total motile sperm count) demonstrated no difference in clinical pregnancy rates ($P = 0.84$).

Limitations of study: retrospective study smaller sample size

Conclusion: Letrozole may be the medication of choice for ovarian stimulation in IUI in older women with decreased ovarian reserve, demonstrating the highest pregnancy rate (although not statically so). The overall clinical pregnancy rate of 7.5% remains notable in the study population. Gonadotrophin offered no benefits over oral medication in our study.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS49

NO 50 COMPARISON OF LETRAZOLE AND CLOMIPHENE CITRATE VERSUS LETRAZOLE ALONE IN WOMEN WITH POLYCYSTIC OVARIES UNDERGOING OVARIAN STIMULATION

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Study question: To compare clinical pregnancy rate during ovulation induction using combination of letrozole and clomiphene versus letrozole alone in infertile women with PCOS.

What is currently about the subject: Letrozole is the drug of choice in PCOS infertile women undergoing ovulation induction.

Study design, size, duration, material and methods: Materials and methods: Prospective randomized controlled trial conducted from July 2019 to December 2020 at tertiary care center in Uttarakhand. Sixty eight infertile patients with PCOS and patent tubes and normal male partner were randomized in two groups. Group I ($n = 34$) received a combination of Letrozole (2.5 mg) and Clomiphene citrate (50 mg) once a day for 5 days starting from day 2 to 3 of cycle. Group II ($n = 34$) received Letrozole 2.5 mg once a day for 5 days starting from day 2 to 3 of cycle for a total four cycles. After induction follicular monitoring was done and trigger with Injection HCG 5000 IU IM was given when dominant follicle reached a size of ≥18 mm with ET ≥8 mm and this was followed by timed intercourse. Pregnancy was confirmed by UPT after 2 weeks.

Results: No statistically significant difference was seen between the two groups while comparing baseline characteristics. Pregnancy rate in Group I was 9.3% ($n = 3$) and 6.3% ($n = 2$) in Group 2 after first cycle of ovulation induction (OVI), after 2nd cycle it was 7.1% ($n = 2$) in Group I and 13.8% ($n = 4$) in Group 2. After three cycles of OVI, pregnancy rate achieved was 11.5% ($n = 3$) in Group I and 8.0% ($n = 2$) in Group 2 and 21.7% ($n = 5$) in Group I and 8.7% ($n = 2$) in Group 2 became pregnant after 4th cycle of OVI. Thus the pregnancy rate was statistically not significant in all the four cycles ($P < 0.615$, 0.413, 0.671, 0.218, respectively). The median number of cycles required for conception in Group I was 3 and that of Group 2 was 2.

Limitations of study: Small sample size. Need for large multicentric studies.

Conclusion: Pregnancy rate was higher if ovulation induction done with combination of clomiphene and letrozole but the difference was not statistically significant in infertile PCOS women. The present study showed that the combination drugs had no added advantage over Letrozole alone in terms of ovulation induction.

Study funding/Competing interest(s): No.

Is it a clinical trial: Yes.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS50

NO 51 PROLACTIN AND ENDOMETRIOSIS

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Study question: Is there any association between hyperprolctinemia and endometriosis

What is currently about the subject: Endometriosis is a benign progressive disease which is estrogen dependent affecting women during their reproductive years. It is the presence of endometrial glands and stroma outside the uterus and is associated with pain and infertility.

Study design, size, duration, material and methods: The aim of the present study is to determine the frequency of endometriosis and to assess it's association with prolactin levels. This retrospective study was conducted at Galaxy Test Tube Baby Center. Fifty infertile women who underwent laparoscopy for evaluation of infertile were included from January 21 to December 21. The presence of endometriosis was evaluated. The patients without any evidence of endometriosis were included in controlled group. Serum prolactin levels were measured in both the groups to assess any association of endometriosis with hyperprolactinemia.

Results: The prevalence of endometriosis was found to be 34%. Prolactin levels were found significantly higher in infertile women with endometriosis versus the infertile women without endometriosis (28 ng/mL vs. 17.5 ng/mL). There was a significant prolactin levels difference between stage I/2 versus stage 3/4 of endometriosis.

Limitations of study: The sample size is small.

Conclusion: Prolactin levels can be used as a biomarker to detect endometriosis. Higher prolactin levels were found in stage 3/4 endometriosis as compared to stage I/2 patients or patients with no endometriosis.

Study funding/Competing interest(s): No.

Is it a Clinical Trial: Yes.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS51

NO 52 DAY 3 VERSUS DAY 5 QUARTER LASER ZONA THINNING-ASSISTED HATCHING (QLZT-AH) IN FROZEN EMBRYO-TRANSFER

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Study question: 1. Advantage of qLZT-AH over other traditional assisted hatching procedures. 2. When to use qLZT-AH?

What is currently about the subject: · To check efficacy of qLZT-AH in FET cycles. To compare PR and IR of day 3 and 5 qLZT-AH.

Study design, size, duration, material and methods: Material and methods: The study was carried out in NIF Raipur from Dec 21, 2020 to Aug 27, 2022. It is a retrospective-study in which patients were randomly divided into two groups: test (patient received qLZT-AH before ET, $n = 60$) and control (transfer was done without qLZT-AH, n = 79), in both day 3 and 5 FET. Study design: Inclusion criteria: One hundred thirty nine women aged between 23 and 38 years were included in this study with BMI ranging between 20 and 38. Patients with good ovarian reserve ICSI Normo-responders. Previous failure of ART (recurrent implantation-failure) Patients with good endometrial thickness (>7 mm) Exclusion criteria: First ART cycle poor responders poor ovarian reserve (low-AMH) Patients with un-corrected Asherman syndrome, submucosal-polyp or fibroid, and congenital-uterine anomaly.

Results: In day 3 control versus test group, significant difference (P = 0.02) was observed on day 3 PR. No significant difference was observed in IR (P = 0.15). Similarly, in day 5 control versus test group, significant difference (P = 0.03) was observed in PR. No significant difference was observed in IR (P = 0.38). No significant difference was observed in either PR (P = 0.25) or IR (P = 0.63) when day 3 and 5 test groups were compared.

Limitations of study: The study size was not large enough to assess the actual effect of quarter laser zona thinning assisted hatching on implantation rate of embryos.

Conclusion: From the above results, it can be concluded that qLZT-AH improves PR in patients receiving day 3 and 5 FET, while the IR remains similar, whether qLZT-AH was performed or not. On comparing day 3 and 5, no significant difference was observed in patients receiving qLZT-AH.

Study funding/Competing interest(s): No.

Is it a clinical trial: Yes.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS52

NO 53 PREVALENCE, RISK FACTORS AND OUTCOME OF PRETERM PREMATURE RUPTURE OF MEMBRANE

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Study question: Objective: The objective of this study was to determine the prevalence of PPROM, to identify its associated factors and to evaluate the maternal and

What is currently about the subject: Background: Premature rupture of membranes (PROM) refers to the spontaneous rupture of the fetal membranes any time beyond the 28th week of pregnancy but before the onset of labor. When rupture of membranes occurs beyond the 37th week but before the onset of labor, it is called term PROM (TPROM) and when it occurs before 37 completed weeks; it is called preterm PROM (PPROM). Preterm premature rupture of membranes (PPROM) is one of the most common complications of pregnancy. It is one of the leading identifiable cause of preterm deliveries, and an important cause of maternal and perinatal morbidity and mortality.

Study design, size, duration, material and methods: Methods: A retrospective observational study was done from March 1, 2022 to August 31, 2022. Total no of deliveries both vaginal and caesarean that occurred at our hospital during the study period was obtained from hospital record section and among that prevalence of preterm premature rupture of membrane was elicited. Data were retrieved from antenatal ward admission register, case files, and theater records of 260 women who were admitted with PPROM over the study period. Information sort were socio demographic characteristics of mother, birth weight, Apgar score at 5 minutes, need for neonatal resuscitation and admission to NICU, fetal outcome, and maternal complication due to PPROM.

Results: Result: During the study period, total 10,410 deliveries were recorded. Among them there was 260 cases of premature rupture of membrane leading to prevalence of 2.4%. It was seen to be common among patient with low socio-economic status and women who have history of abnormal vaginal discharge, urinary tract infection, and previous history of PPROM. Five thousand five hundred fifty six cases underwent normal vaginal delivery (53.3%) and 4854 cases underwent caesarean section (46.6%). Only 0.3% of women presented with PPROM developed chorioamnionitis. 1.1% of women had postpartum complications, which lead to prolong hospital stay including endometritis, retained bits of product in surgical sites infection. Regarding neonatal outcome, 37.6% of babies born to patients with PPROM were low birth weight less than 2.5 kg, 33.8% of infants has unfavorable outcome (either born alive but admitted in neonatal ward, still birth, low birth weight, Apgar score less than 6. 66.1% of infants had good fetal outcome (alive and well).

Limitations of study: The diagnosis of PROM was made based on clinical evaluation, and no other confirmatory test were done except for ultrasound in some cases. We had no control over method used in measuring birth weight and determining the Apgar score of neonates. This research might be subjected to recall bias.

Conclusion: PPROM is an important cause of preterm birth, resulting in large number of babies with low birth weight, requiring neonatal intensive care. It is associated with increased neonatal morbidity and mortality. Demographic variables can be applied to develop risk scoring so as to identify high risk cases.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS53

NO 54 RESPECTFUL MATERNITY CARE: THE NEED OF THE HOUR AT A TERTIARY CARE CENTER

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Study question: Was modern Government maternity hospital able to deliver moderate to good degree of respectful maternal care to mothers admitted for labor?

What is currently about the subject: Compared to access to healthcare, respectful and dignified treatment in healthcare is a topic that has not yet been adequately studied in India. The studies that have been conducted so far show a high prevalence of mistreatment in mothers admitted to the hospital for delivery. One systemic review that analyzed seven studies conducted in various centers across India including a total of 4959 subjects, showed a prevalence of disrespectful maternity care of 71.3%. The highest reported form of ill-treatment was not obtaining consent prior to interventions (49.8%); followed by verbal abuse (25%); threats (21.2%); physical abuse (16.9%); and discrimination (14.7%).

Study design, size, duration, material and methods: Study design: cross-sectional study. Size: 500 cases. Duration: 3 months. Materials and methods: A cross-sectional study was conducted at MGMH, Petlaburj, using the 15-item respectful maternal care (RMC) scale. The questionnaire was given to 500 postpartum women who delivered in our hospital, and the results were collected over 3 months. The final RMC scale with 15 items was loaded on four components which are friendly care, abuse-free care, timely care, and discrimination-free care.

Results: 11% of women in the study reported experiencing some form of physical abuse during care; 93% reported being provided with information about breastfeeding; 1% reported that the table they delivered on not being cleaned prior to delivery; and 5.2% reported being unattended during their care. The study found that on a scale of 0–5, with 0 being €˜very unhappy' and 5 being €˜very happy', the patients involved in the study rated friendly care at 4; abuse free care at 4; timely care at 4.3, and discrimination-free care at 4.5. Overall, the mothers in this study who delivered at our hospital experienced moderate to good degrees of respectful maternity care during childbirth.

Limitations of study: (i) External validity may be limited due to the study being conducted in a single institution. (ii) Internal validity may be limited, given that only mothers between the ages of 20 and 30 were included in the study.

Conclusion: Every woman has a right to dignified and respectful maternity care. This study will provide a descriptive overview of the care provided in the

delivery room focused on respectful maternity care as perceived by women during antenatal care, labor, and delivery in MGMH.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS54

NO 55 TO STUDY THE PREVALENCE OF VAGINAL MICROBIOTA DYSBIOSIS IN INFERTILE WOMEN OF UTTARAKHAND REGION – AN OBSERVATIONAL STUDY

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Study question: To evaluate prevalence vaginal microbiota dysbiosis in infertile women.

What is currently about the subject: As it is known that the presence of certain strains of beneficial bacteria in the female genital tract is a key to resolve many infertility issues. Number of studies have suggested that the vagina is dominated by *Lactobacillus* species. The probiotics influence on female fertility could be understood by the effect of probiotics in maintaining the bacterial balance of the vagina, treatment of bacterial vaginosis, and subsequent amelioration of inflammation. A better understanding of the vaginal microbiome is therefore mandatory to further boost our understanding of natural fertility and reproductive technology. The aim of this work is to explore the prevalence of vaginal dysbiosis in the infertile females and hence utilize this knowledge in clinical practice of female infertility evaluation and treatment. Bacterial therapies, such as probiotics, can be used in a targeted population to replenish depleted microbiota and consequently help treat infections, and restore fertility and improve pregnancy success.

Study design, size, duration, material and methods: We present the preliminary results (6 months) of a prospective observational study, which is being conducted at the Department of Reproductive Medicine in collaboration with the Department of Microbiology at SGRR Hospital and research center Dehradun, Uttarakhand. All eligible women with female factor infertility were enrolled in the study. One high vaginal swab (HVS) was collected from each individual with a sterile swab stick from the posterior vaginal fornix after following all precautions. The swab laden with vaginal secretions was immediately transported to Microbiology Lab before it got desiccated and gram staining was done. Interpretation of the smear – at least five oil immersion field (OIF) were examined to determine the average of each morphotype. If Lactobacilli-like rods were seen in 30%/HPF, it shall be considered as predominant/abundant lactobacilli flora, 5 to 30 rods/HPF reported as few lactobacilli and

Results: A total of 85 women who came for evaluation of infertility were included in the study after obtaining consent and were screened for vaginal microbiome dysbiosis. Out of 85 women, 50 women had predominant *Lactobacillus* flora and 35 women had non *Lactobacilli* flora as evaluated by above methodology. Hence, we found that the current prevalence of non *Lactobacilli* flora in vagina of infertile women is 43.75%. A study conducted by Rasheed *et al*. has shown a prevalence of BV (bacterial vaginosis) is significantly higher in infertile than fertile women as 45.5% versus 15.4%, respectively. Our study is in accordance with the previous published data on vaginal dysbiosis in infertile women.

Limitations of study: A small sample size at present and large numbers are required for further results.

Conclusion: As it already known that the vaginal microbiota composition can show large ethnic differences. *Lactobacillus* and non *Lactobacillus* species are present predominantly in vaginal microbiota of infertile women. Henceforth, we must encourage vaginal dysbiosis screening as a part of routine female infertility evaluation and treatment.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS55

NO 56 THE USE OF ANTI-MULLERIAN HORMONE LEVELS AND ANTRAL FOLLICLE COUNT TO PREDICT THE NUMBER OF OOCYTES COLLECTED AND AVAILABILITY OF EMBRYOS FOR CRYOPRESERVATION IN

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Study question: To identify the reliable the ovarian reserve

What is currently about the subject: As maternal age increases, ovarian reserve decreases and the chances of pregnancy reduces. This study was aimed at identifying the exact predictors of ovarian reserve in patients undergoing IVF. AFC and AMH were correlated with the final number of mature oocytes, fertilization rate till clinical pregnancy rate.

Study design, size, duration, material and methods: AIM: To predict the use of antiMullerian hormone (AMH) and antral follicular count (AFC) on the final number of oocytes retrieved and available embryos for cryopreservation in in vitro fertilization (IVF) cycle in 30 to 35 years age group. Materials and Methods: Fifty patients between age group of 30 and 35 years who have been enrolled for IVF cycle are included in the study. Anti-mullerian hormone taken during the previous cycle and Day 2 antral follicular count measured just before starting ovarian stimulation.

Results: Total number of participants in our study was 50 among 30 to 35 years age. Mean BMI for our study group was 26 (overweight). Majority of patients had AFC between 11 and 15. The mean AMH level measured for the study sample was 3.5 ± 2 between 30 and 35 age group. Average mean number of oocytes obtained after oocyte retrieval procedure was 10, correlates with AFC. Total oocytes correlates with M2 and embryos. Fertilization rate was 64%. Positive clinical pregnancy rate was 70%.

Limitations of study: There are no limitations for the study.

Conclusion: AFC and AMH have their best predictive value for ovarian reserve compared to all other markers. In our study, AFC was superior in predicting ovarian response to stimulation in IVF than AMH. AMH can also be used with AFC as a screening tool for ovarian reserve.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS56

NO 57 TRANSDERMAL ESTROGEN VERSUS ORAL ESTROGEN IN FROZEN THAWED BLASTOCYST TRANSFER CYCLES: PROSPECTIVE RANDOMIZED CONTROLLED TRIAL

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Study question: Is transdermal estrogen better than oral estrogen for achieving endometrial thickness >7 mm in frozen thawed cycles?

What is currently about the subject: Advances in cryopreservation techniques through vitrification have resulted in an increase in the frozen embryo transfer (FET) cycles as it almost eliminates the risk of ovarian hyper stimulation syndrome (OHSS) and gives us a higher number of embryos after thawing. Hormone prepared cycles gives us the advantage of practicality of patient's cycle monitoring and is a good option in anovulatory cycles. Exogenous estrogen is started from day 2/3 of menses in an incremental dose as per the ultrasound findings of endometrial thickness and progesterone is added 4/5 days prior to transfer. Estrogen can be given through various routes. An international survey in 2014 showed that 86% of participants used the oral route and 8% used the transdermal route. Compared to oral route, transdermal route has a better bioavailability as it bypasses the intestine and hepatic metabolism and achieves a better plasma concentration of active form of estrogen (estradiol).

Study design, size, duration, material and methods: Prospective randomized controlled trial done at tertiary hospital in Delhi from May 2021 to April 2022. One hundred twenty patients undergoing hormone replacement (HR)FET were randomized into two groups of 60 each by computer based program. Group I received transdermal estradiol gel, three actuations per day (one actuation containing 1.25 g gel containing 0.75 mg estradiol) and Group 2 received oral estradiol tablet 2 mg thrice a day starting from day 2. Transvaginal ultrasound was done on day 2, 7, 11, and 14 to monitor the endometrial thickness and the dose of estradiol gel/tablet was adjusted accordingly going maximum up to six applications/day in case of transdermal gel and 12 mg per day in case of oral tablets. On day 5 of progesterone, a single blastocyst was transferred. Primary outcome was to compare endometrial thickness on the day of starting progesterone. Secondary outcomes were to compare clinical pregnancy rate, miscarriage rate, and adverse effects between the two groups.

Results: There was no difference in the demographic parameters of both the groups, with average age in group 1 being 32.7 years and in group 2 being 31.8 years. Between the two groups, there was a significant difference in the endometrial thickness on the day of the start of the progesterone. It was higher in the transdermal group as compared to the oral group (9.91 ± 0.761 vs. 9.39 ± 0.712 ; *P*-value = 0.02). The clinical pregnancy rate was higher in the transdermal route but it was not statistically significant (54% vs. 51%; *P*-value = 0.67). Miscarriage rates were lower in the gel group (3.7% vs. 10.5%; *P*-value = 0.30), but it was not statistically significant. The overall patient satisfaction was significantly higher in transdermal group as compared to the oral group (8.4 ± 2 vs. 6.6 ± 1.7, *P*-value = 0.02). The major side effect in the oral group was nausea 71.66% versus 25% in transdermal group (*P*-value < 0.001). The major side effect with the transdermal gel was itching and redness at the site of the application which occurred in 33.3% of the women and no itching was reported in the oral group (*P*-value < 0.001).

Limitations of study: We need large randomized controlled trials to strengthen our results. It is difficult to determine the other confounding factors leading to clinical pregnancy. A comparison between transdermal and vaginal estrogen should also be done.

Conclusion: The study concluded that there was a significant increase in the endometrial thickness in the transdermal group with a higher overall satisfaction rate. There was no significant difference in clinical pregnancy rate and miscarriage rate. Transdermal gel is a good alternative in the women who are unable to tolerate oral.

Study funding/Competing interest(s): No.

Is it a clinical trial: Yes.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS57

NO 58 IS POLYCYSTIC OVARIAN SYNDROME RELATED TO A POOR OOCYTE QUALITY AFTER CONTROLLED OVARIAN STIMULATION FOR INTRACYTOPLASMIC SPERM INJECTION?

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Study question: To compare the different phenotypes of PCOS and control group in reference to oocyte quality.

What is currently about the subject: According to Rotterdam criteria, a woman has at least two of these three characteristics: clinical and/or biochemical hyperandrogenism, ovarian dysfunction, and polycystic ovary morphology to be diagnosed as polycystic ovarian syndrome (PCOS). The excessive number of follicles is associated with folliculogenesis. It should be mentioned that most of these oocytes are not mature, which leads to a decrease in pregnancy rates and an increase in abortion. The oocyte quality is defined by factors such as ability to undergo meiotic maturation, fertilization, proper embryonic development, and successful pregnancy. These qualities are obtained thorough the follicular growth by the interaction of theca and granulose cells. Since follicular growth is disrupted in PCOS patients, especially during IVF, a decreased number of good oocytes/embryos in ART cycles are widespread problem. Therefore, we decided to evaluate the quality of oocytes/embryos in PCOS patients undergoing ART cycles in the region.

Study design, size, duration, material and methods: It is a prospective comparative study that is performed at Genea Fertility Centre, Bengaluru, between September 2021 and September 2022. All women, aged 21€"37 years, undergoing their intracytoplasmic sperm injection attempt at Genea fertility Center, will be prospectively recruited. A total of 70 patients with PCOS and 70 control group will be recruited. Controls will be selected randomly with age group matching (±2 years). A total of 140 patients (70 patients with PCOS and 70 patients in control group) will be recruited. PCOS patients will be categorized into separate phenotypes. PCOS patients will be categorized into separate phenotypes. Recruited patients will undergo baseline, scan, AMH, D2 hormonal assay – E2, LH, and progesterone. Patients received either flexible antagonist protocol or PPOS (progesterone primed ovarian stimulation). Routine monitoring of ovarian stimulation will be done with transvaginal ultrasonography and hormonal tests. Approximately, after 2 hours of OPU (Oocyte pick up) oocyte morphology will be evaluated and Oocyte abnormalities will be noted.

Results: AMH levels and follicle number per ovary (FNPO) were significantly higher in PCOS patients. There was no statistical difference between the two protocols regarding the primary and secondary endpoints in both groups. There were significantly more intermediate follicles (i.e., 10€"15 mm) during COH (Controlled ovarian hyperstimulation) in the PCOS group. The ratio between MII (metaphase II) oocytes and each size category of follicles did not differ between the 2 groups. A higher number of total and MII oocytes was retrieved in the PCOS group. There was no difference between the 2 groups regarding the number of immature and atretic oocytes. We obtained significantly more embryos in the PCOS group. The fertilization rate did not differ in patients with PCOS compared with controls. The mean number of top-quality embryos was significantly higher in the PCOS group. Implantation, ongoing pregnancy, and delivery rates were significantly higher in the PCOS group. Analysis of the oocyte cohort showed that the number of MII oocytes exhibiting a normal morphology was equivalent between the PCOS and control groups. No significant difference was observed regarding extracytoplasmic abnormalities. Incidence of cytoplasmic abnormalities such as presence of vacuoles or an abnormal granularity was similar between the two groups.

Limitations of study: Small sample size observational study

Conclusion: From the results of this prospective comparative study, it seems that PCOS is not related to adverse oocyte quality, at least regarding the rate of nuclear maturation and the rate of morphologic abnormalities.

Study funding/Competing interest(s): No.

Is it a clinical trial: Yes.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS58

NO 59 TO ASSESS THE INTRA- AND POSTOPERATIVE ASSOCIATION IN NDVH IN BENIGN GYNECOLOGICAL CONDITIONS

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Study question: To study the intra- and postoperative outcomes of non-descent vaginal hysterectomy in benign gynecological conditions.

What is currently about the subject: Vaginal hysterectomy has lower morbidity and cost benefitting. Vaginal hysterectomy for larger size uterus is facilitated by debulking, myomectomy, bisection, and morcellation. LH (Lapaoscopic Hysterectomy) was significantly associated statistically with longer duration of operation time and higher operation costs. Because of limited data, NDVH (Non decent vaginal Hysterectomy) are not done much in India.

Study design, size, duration, material and methods: Methods: This prospective observational study was done between November 2020 and September 2022 consisting of 50 patients. The study proceeded after ethical clearance. Details were noted and in detail history was also noted. A complete clinical examination was done. A written informed consent from all the patients were obtained after explaining the procedure and special consent for conversion to abdominal hysterectomy were taken from the patients. Study area: The study was conducted among patients attending Department of Obstetrics and Gynecology, Modern Maternity hospital, Osmania Medical college, Hyderabad. Study design: Prospective observational study. Study period: November 2020 to September 2022. Study population: All cases with benign gynecological conditions as per the inclusion and exclusion criteria, attending the outpatient department (OPD) or admitted under OBG (obstetrics and gynaecology) department, Modern Maternity hospital, Osmania Medical college, Hyderabad.

Results: The mean age was 46.05 ± 5.413 years. On comparison the association between uterus size and debulking procedure, a significant value of $P < 0.001$ was obtained where size of the uterus plays a role. No debulking significance was seen in normal size and <8 weeks uterus size. The association between time taken for the procedure and the amount of blood loss showed a significant value of $P < 0.001$ was obtained and concluded that procedures done within an hour had lesser blood loss. The association between procedure done and hospital stay suggested that irrespective of the procedure done, a hospital stay between 4 and 5 days was ideal and also showed significant value of $P = 0.03$.

Limitations of study: Uterus with restricted mobility, PID changes, association with adnexal mass made difference, so were taken as exclusion criteria.

Conclusion: Patients with Normal size and less adhesions non decent vaginal hysterectomy would be a preferred route of surgery.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS59

NO 60 CIRCULATORY MIRNA AS A POTENTIAL NON-INVASIVE MARKER FOR ENDOMETRIOSIS

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Study question: To evaluate a non-invasive diagnostic approach using oncomiR expression analysis in patients with mild and severe endometriosis to improve the quality of life

What is currently about the subject: Several studies have reported a direct link between oncomiR with several crucial signaling pathways such as TGF-Î², KRAS, and PTEN in endometriosis. These pathways are mostly related to cellular proliferation, apoptosis, cell cycle regulation, and the development of different forms of endometrial cancers. A preclinical study by Dinulescu et al. (2005) reported that activation of the KRAS oncogene and loss of the PTEN is required for the transformation of endometriosis to endometrioid carcinoma. Pan et al. (2007) demonstrated that downregulation of oncomiR-21 expression levels in endometriosis represents tumor suppressor activity of PTEN. Subsequently, Meng et al. (2007) reported that PTEN is a confirmed target of oncomiR, and high expression levels of oncomiR-21 demise the activity of PTEN in ovarian and endometrial cancers. The above findings are well supported by our study results in both tissue and plasma samples of different grades of endometriosis patients.

Study design, size, duration, material and methods: A total of 255 women were enrolled in this study, of which 210 were controls and 45 were endometriosis patients. The Control group included women who underwent sterilization for family planning and tubectomy, totally parous free of any pathology. All women included in the study underwent laparoscopy for various indications, including pelvic masses, pelvic pain, infertility, and uterine leiomyoma. Women were assigned to different endometriosis groups (I, II, III, IV, and Chocolate Cyst) or endometriosis-free control group based on pathological reports. We established an in vitro culture system to conduct a transfection experiment for establishing the relationship between oncomiR- and PTEN. Further, we evaluated differential expression levels of an oncomiR- in histologically graded endometrial biopsy tissues and validated in plasma samples of respective women with mild, severe, and chocolate cysts in the South Indian population using SYBR Green-based RT-qPCR analysis.

Results: Transfection results showed a negative correlation between oncomiR- and PTEN expression levels specifically in severe forms of the disease. Similar to findings in tissue samples for oncomiR-21 expression levels, significantly higher values for endometriosis Grade I and II (8.23 ± 0.76, $P < 0.01$), endometriosis Grade III and IV (11.51 ± 3.47, $P < 0.001$), and Chocolate Cyst (13.37 ± 3.68, $P < 0.001$) was observed. Correlation analysis showed that the best outcome can be measured using oncomiR-21 expression analysis almost equally in tissue as well as plasma samples to distinguish all three categories of endometriosis patients from controls.

Limitations of study: Although Oncomir has been shown to act as a potential biomarker for endometrial pathology, further studies need to be performed with greater sample size to predict its role as a biomarker for malignancy development.

Conclusion: This study revealed that quantitative analysis of circulating oncomiR in plasma samples can be used as a non-invasive tool for early detection and discrimination of mild and severe forms of endometriosis and the risk of malignant transformation for timely diagnosis and improved management of endometriosis patients.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: No.

DOI:10.4103/fsr.fsr_2_23-ABS60

NO 61 AN INDIAN EVIDENCE-BASED STUDY OF PREVALENCE, PHENOTYPIC FEATURES, LIFESTYLE MODIFICATIONS OF POLYCYSTIC OVARIAN SYNDROME PATIENTS

Taalia Nazeer Ahmed, Roya Rozati
Medical Health and Research Institute, India

Study question: An Indian evidence-based study of prevalence, phenotypic features, lifestyle modifications of polycystic ovarian syndrome patients

What is currently about the subject: This prospective study is assessed under the NIH criteria to have a prevalence of probable PCOS cases was 8.8% which is closed to the study conducted in Central India, which is 8.2%. Our results are in closely agreement with the study of Choudhary et al. (9.13%). Vaidya et al. (3.4% of women) found that globally, prevalence estimates of PCOS are highly variable, ranging from 2.2% to as high as 26%. This value was slightly higher than the 6.5% to 6.8% obtained in three other prevalence studies that also used the NIH criteria. The methodological strengths of this study include it being the largest and only community based prevalence study of PCOS to be carried out on an urban and rural areas of Hyderabad in Southern India. Unfortunately, no statistical evidence was supplied in these prevalence studies to determine the representativeness of participants. Furthermore, the representation of prevalence under the current diagnostic criteria.

Study design, size, duration, material and methods: In this prospective, cross-sectional, observational study, patients with PCOS were included who were screened at hospital or who visited their outpatient departments for a routine checkup in Maternal health research trust hospital at Hyderabad. The study sample comprised females of reproductive age who met the inclusion criteria based on the NIH 1990 criteria for PCOS and were admitted to or visited the outpatient department of any of the participating hospital – Maternal health research trust hospital at Hyderabad for a routine checkup as well as those who had infertility problems or repeated miscarriages and visited infertility clinics. It is a population based study conducted in the state of Telangana, which included eight urban constituencies and 10 rural constituencies of the state. The diagnostic criteria of PCOS on the basis of the NIH 1990 criteria include hyperandrogenism and oligo ovulation and exclude other disorders mimicking PCOS, such as adult-onset congenital adrenal hyperplasia and hyperprolactinemia.

Results: In total, 688 patients were screened for PCOS, 573 patients were enrolled of which 281 were from urban and 292 were from rural, respectively. Of the probable PCOS cases 28 were probable PCOS, 17 were known cases, and 83 were controls in the urban region. Seventeen were probable PCOS, 10 were known cases, and 73 were controls in the rural region. The overall count of probable cases was 45, known PCOS cases were 27, and controls were 153. Three hundred forty eight patients were excluded due to various reasons. Probable cases were 27.29 + 7.14, control cases that were 29.67 + 6.88 with a *P*-value 0.001 had PCOS from urban and rural Area. The PCOS phenotypes were 8% clinical HA (hirsutism, H), alopecia (7%), acanthosis (3%), acne was (6%), and USG (35%) in urban and rural regions. 55% and 45% biochemical assessment done in urban and rural area, respectively. Hormonal assay was 75% and 25% of the women with PCOS resided in urban and rural regions, respectively. Hyperinsulinemia was observed in probable cases compared to the controls.

Limitations of study: The cross-sectional design of this study does not allow causal conclusions, and as such, the interpretability of our findings is limited. Only a limited number of patients turned up.

Conclusion: Based on the NIH diagnostic criteria, there is a similar prevalence of PCOS between 6% and 10% is documented in the world. PCOS is a heterogeneous clinical syndrome with a multifaceted pathogenesis and is associated with lifelong morbidity. The clinical manifestations of PCOS include oligomenorrhea, hirsutism, excessive acne, and hair loss.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Yes.

S.No: 70Dr. S59

DOI:10.4103/fsr.fsr_2_23-ABS61

NO 62 CURRENT PREVALENCE OF HYPERINSULINEMIA AND IMPAIRED GLUCOSE TOLERANCE AMONG PCOS WOMEN OF TELANGANA REGION, SOUTH INDIA

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Medical Health and Research Institute, India

Study question: Finding out the association of elevated insulin and impaired glucose tolerance with PCOS and to study the current scenario among the population of Telangana

What is currently about the subject: Our study demonstrates that there is a strong alliance of PCOS with insulin resistance in Telangana, South India, and is the first study in this region to evaluate these parameters and has discussed the most current scenario. We have conducted a study on the population, that is, relatively young suffering from PCOS and mostly having low BMI. The mean age of our subjects was 24.08 ± 4.45 years. The majority of such studies conducted have included subjects with a higher mean age than ours. Overall abnormalities of glucose intolerance observed in our cases were 35% and 10% in controls which shows a significant difference. Insulin resistance has a very significant role in the pathophysiology of both type 2 diabetes mellitus and PCOS. Although numerous females with PCOS are at a high risk of insulin resistance, impaired glucose tolerance, and pancreatic beta-cell dysfunction, the exact cause is unknown

Study design, size, duration, material and methods: A cross-sectional community-based study was conducted in Maternal Health and Research Institute, Hyderabad, Telangana, India. Ethical approval had been obtained from the institution and subjects were recruited after taking written informed consent. The main objective of the study was to find out the prevalence of patients with hyperinsulinemia or an abnormal Oral Glucose Tolerance Test (OGTT) who are probable for PCOS and compare them with healthy control subjects for the same parameters. This will enable us to find the link between PCOS and hyperinsulinemia. Our inclusion criteria were women of age between 18 and 40 years who were dwelling in that area for more than 10 years, who were non-pregnant and non-lactating, and willing to give informed consent. Subjects who had cognitive or physical abnormalities and couldnot respond to questionnaires, subjects who had a history of drug intake that interfered with glucose metabolism were excluded from the study.

Results: Significant results were observed for fasting glucose, fasting insulin, presence of sub-capsular follicular cysts which measure 10 nm in sonography, HOMA-IR when probable PCOS were compared to healthy controls. Prevalence of hyperinsulinemia was 31% in probable PCOS and 8.3% among controls whereas the prevalence of impaired glucose tolerance was 35% in probable PCOS and 10% in controls.

Limitations of study: Need to screen patients from the above-mentioned constituencies and screening for PCOS

Conclusion: Our study suggested a strong association of PCOS with hyperinsulinemia and impaired glucose tolerance in the Telangana region of South India. We thereby conclude that glucose intolerance and insulin resistance are usual among women with PCOS in our county and its association with uncontrolled diabetes mellitus in the general population.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS62

NO 63 HUMAN UMBILICAL CORD BLOOD DERIVED MESENCHYMAL CELLS FOR THE TREATMENT OF MYOCARDIAL INFARCTION IN RAT MODEL

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Study question: The present study was designed to know the possible protective and regenerative effects of human umbilical cord blood (UCB) derived MSCs in myocardia infarction (MI)

What is currently about the subject: CVD is the foremost cause of morbidity and mortality in patients suffering with diabetes. Advancement and progression of MI may lead to heart failure which is much more complex and multifactorial. MI is a trademark of various heart diseases and reflected as a chief factor in the evolution of heart failure. CVD accounted for less than 10% of all deaths worldwide at the commencement of the 20th century. But at the foundation of the 21st century, CVD accounted for nearly half of all deaths in the developed world and 25% in developing world. Thus, preclusion of MI is a serious goal in the treatment of heart failure, and the degree of myocardial fibrosis is a key factor of rejoinder to treatment and prognosis in a several cardiac conditions.

Study design, size, duration, material and methods: Isoproterenol injection was given subcutaneously for 2 days to induce MI in rat model. After development of MI various blood and tissue parameters were assessed such as urea, creatinine, SGOT, SGPT, troponin I, lactic dehydrogenase (LDH), and creatine kinase (CK). Treatment was given by single dose of MSCs. After treatment period all the parameters were assessed again and comparison were done before and after treatment. Different groups in myocardial infarction (MI) in rat model were following: 1. Group I: Healthy controls (n = 10) (Control Group); 2. Group II: Isoproterenol induced myocardial infarction in normal rats (n = 10) (MI Group); 3. Group III: hUCB-MSCs transplantation once in rats with myocardial infarction (n = 10) (MI + MSCs).

Results: All biochemical parameters were elevated after MI development. MSC transplantation performed when MI had already developed showed better results. It inhibits the degradation of normal collagen and the formation of poorly cross-linked collagens, resulting in attenuation of MI and improvement of heart function by means of troponin I, lactic dehydrogenase (LDH), and creatine kinase (CK) levels. In addition, this impact is not instantaneous but is persistent for at least 90 days, supporting the role of MSC transplantation.

Limitations of study: A total of five UCB samples were collected during cesarean under sterile conditions.

Conclusion: Our data suggested that transplantation of MSCs in MI model has improved the cardiac function. Till now, there is no evidence attributing this improvement to regeneration and other paracrine mechanisms are also believed to contribute in the improvement of cardiac function.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS63

NO 64 SUCCESSFUL APPLICATION OF PLATELET RICH PLASMA IN A CASE OF SEVERE ASHERMAN SYNDROME AND SUBSEQUENT IN VITRO FERTILIZATION CONCEPTION

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Study question: Does subendometrial injection of platelet rich plasma could be an alternative for surrogacy in patients with severe Asherman syndrome and secondary amenorrhea?

What is currently about the subject: Successful application of platelet-rich plasma in a case of severe Asherman syndrome and subsequent in vitro fertilization conception. The success rate of assisted reproduction techniques (ART) has long been less than satisfactory despite the great progress made in recent years, demonstrating the need for alternative options in the ART cycles. A thin endometrium is an important cause of cancelled or less successful frozen embryo transfer cycles. Growing evidence correlates the effect of intrauterine platelet-rich plasma (PRP) infusion on the endometrium with reassuring reproductive results. We present a case report of a patient with severe Asherman syndrome who was successfully treated with adhesiolysis and the use of platelet-rich plasma, leading to a successful in vitro fertilization-conceived pregnancy. Patient consent and required ethical clearance were taken before starting the procedure. Keywords: Asherman syndrome, infertility, platelet rich plasma, in vitro fertilization

Study funding/Competing interest(s): Yes.

Is it a clinical trial: Yes.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS64

NO 65 TO STUDY THE RELATIONSHIP OF AMH AND FOLLICLE AND OOCYTE RATIO IN PATIENTS WITH ENDOMETRIOSIS.

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Matritava Advanced IVF, India

Study question: Is AMH enough for checking ovarian reserve in patients with endometriosis?

What is currently about the subject: Endometriosis is a benign gynecological disease with up to 50% of the women being infertile. Endometriosis is seen to be associated with increased expression of TGFb superfamily with increased cell proliferation. AMH is a member of this superfamily. In a study done in Italy by Patrizia *et al*., increased AMH-II receptor mRNA and protein expression were seen. In another study done by Younis *et al*., it was observed that patients with grade 3 endometriosis had high levels of AMH. This study shows high levels of AMH in patients with grade 3 and 4 endometriosis, in comparison to lower antral follicular count and oocyte retrieval rate.

Study design, size, duration, material and methods: It is a retrospective study done at the Matritava Advanced IVF Center, Delhi. Records of 25 patients with endometriosis grades 3 and 4 were taken all of whom had gone through IVF/ET cycles in the last 1 year. Serum AMH levels were measured in all the patients. A Baseline scan was done on the second day of menses to observe the antral follicle count. Individualized controlled ovarian stimulation was done as per our protocol. Oocyte retrieval was done 34 to 36 hours after the maturation trigger. Data on AMH levels, follicle seen, and oocytes retrieved were compiled. Statistical analysis is done.

Results: Normal AMH (2–5.5 ng/mL) was found in 88% (n = 22), with average AMH being 2.8 ng/mL. The average AFC seen at baseline scan was 3.2 (range 0–5). Average oocytes retrieved was 1.5 (range 0–4). P-value was found significant (P = 0.05). Out of 25, three women had AMH <2 ng/mL and hence had to be excluded from the study.

Limitations of study: small sample size.

Conclusion: It has been observed that AMH levels are increased in patients with endometriosis, which can be due to ovarian injury. AMH does not directly correlate with the oocytes retrieved. Hence in patients with endometriosis, AFC is a better marker of ovarian reserve.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS65

NO 66 OBSTRUCTIVE MULLERIAN ANOMALIES–DIAGNOSTIC AND THERAPEUTIC DILEMMAS–EXPERIENCE AT TERTIARY CARE REFERRAL CENTER

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AIIMS, New Delhi, India

Study question: Knowledge about atypical Mullerian anomalies leading to progressive dysmenorrhea is poor among radiologists and clinicians. Imaging findings and laparoscopic and hysteroscopic procedures are discussed.

What is currently about the subject: Mullerian anomalies are classified broadly as agenesis, fusion, or resorption defects. Patients may present with primary amenorrhea with or without cyclical abdomen pain. Sometimes the diagnosis is delayed and the patient presents with infertility and/or recurrent pregnancy loss. But there are atypical Mullerian anomalies where diagnosis is delayed due to poor knowledge among radiologists and treating clinicians. Although ultrasonography (USG) and magnetic resonance Imaging (MRI) help in clarifying the diagnosis, sometimes the wrong diagnosis is made even after detailed imaging, leading to inappropriate surgeries.

Study design, size, duration, material and methods: We are presenting 10 cases of severe progressive dysmenorrhea who presented to our outpatient department (OPD) since last 18 months (April 2021–October 2022). The data have been collected prospectively about these girls, including demographic details, clinical presentation, previous medical or surgical interventions, and imaging finding. The diagnosis was confirmed on MRI, but the wrong diagnosis was made even on MRI in a few cases. Data about imaging diagnosis and final diagnosis are presented. Surgical interventions are presented along with post-surgery follow up and relief of symptoms. Out of 10 patients, one was juvenile cystic adenomyoma (JCA), one had a rudimentary functional horn, five cases of Robert uterus, two cases of obstructed hemivagina and ipsilateral renal agenesis (OHVIRA), and one case of accessory cavitated uterine malformations (ACUM).

Results: Age range of patients was 14 to 29 years. Three had been operated inappropriately before coming to our center, which led to the persistence of symptoms. One case of JCA was diagnosed on MRI and underwent laparoscopic adenomyomectomy. Of two cases of OHVIRA, one underwent successful vaginal septum resection, and another patient was operated on outside by vaginal hematometra drainage. This led to a recurrence of symptoms along with pyocolpos and hematosalpinx. After one attempt of hematosalpinx drainage and vaginal septum excision, she underwent repeat surgery in view of persistent pyosalpinx. One patient with rudimentary functional horn underwent laparoscopic horn excision. Five cases of Robert uterus have been consulted, of which three have been operated on. Of the three Robert uterus cases, one underwent laparoscopic horn excision, which was done due to a large lesion and severe symptoms. The second and third patients underwent hysteroscopic resection of the septum and drainage of hematometra. One patient, 29 years old, diagnosed with accessary cavitated uterine malformation (ACUM) is on expectant management as symptoms are mild. All the operated patients had almost complete relief of symptoms after surgery, except two cases of Robert uterus who have underwent hysteroscopic septal resection. These patients have had follow up <3 months and are waiting for relook hysteroscopy.

Limitations of study: Nil

Conclusion: The case series emphasizes the need to increase knowledge about less common Mullerian anomalies among clinicians. MRI helps to understand the pathology but surgery should be done by surgeon with sufficient expertise and knowledge about the anomalies and their impact on future reproductive outcomes.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS66

NO 67 COMPARISION OF OUTCOME OF FRESH ET AND FROZEN ET.

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Study question: (1) To study the ratio of frozen embryo transfer to fresh embryo transfer. (2) Success rate of FET/TET. (3) Pregnancy outcome of FET versus TET.

What is currently about the subject: During earlier times frozen embryo transfer was a choice in cases of PCOD patients to prevent OHSS. Now frozen embryo transfer is preferred over fresh embryo transfer in almost all patients as it gives higher success rates.

Study design, size, duration, material and methods: It is a retrospective study of women who underwent IVF at the Isha IVF Center in Vadodara between April 2013 and December 2021. During the IVF treatment, after controlled ovarian hyperstimulation, ovum pick-up was done in all patients. ICSI (IntraCytoplasmic Sperm Injection) was done for all patients. Day 3/5 fresh embryo transfer was done in some patients, while in other patients embryos were frozen; FET was done in them, and Serum b-hcg was done 15 days after embryo transfer in all patients. Maternal and perinatal outcomes of all positive IVF conceptions were studied.

Results: The total ratio of TET/FET was 25% and 75%, respectively. The success rate of FET is 32% and that of TET is 39%. Out of all women who conceived via FET, 42% delivered a full-term baby, while 40% of TET patients delivered a full-term baby. Sex ratio was calculated for TET versus FET, the FET majority were males, while in TET, the majority were females.

Limitations of study: (1) Retrospective study, (2) less number of patients, (3) single center, (4) single consultant's study.

Conclusion: Frozen embryo transfer gives better results than fresh embryo transfer, further studies are required to know the implication of frozen embryo transfer in childhood and adulthood diseases.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS67

NO 68 RELATIONSHIP BETWEEN INFERTILITY TREATMENT AND CANCERS IN FEMALE REPRODUCTIVE SYSTEM

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Study question: To evaluate the type of cancer that is related to infertility and identify the molecular aspects linked to its morbidity with ART treatment.

What is currently about the subject: Inherently, females who are nulliparous, obese, and have polycystic ovary syndrome (PCOS) are at greater risk of developing gynecological cancers, but most of the studies done so far have only explored the metabolic aspects related to it. And since it has been well documented that cancer risk and treatment outcomes are significantly influenced by inherited germline genetic variants, with the monumental developments being made in medical genomics and pro-

teomics in recent years, we now have a better understanding of individual variances that exist among the populations that makes them more or less susceptible to the treatment complications associated with various medical procedures and treatments including cancer.

Study design, size, duration, material and methods: A hospital-based, prospective study was conducted at the Medical Health and Research Institute, MHRI, Hyderabad over the span of 20 months (February 2021–October 2022). After obtaining approval from the Institutional Ethics committee, written informed consent was obtained from all the subjects along with their familial and clinical histories. Detailed information on infertility along with the history of ART procedures and management was taken. Tissue and blood samples were then obtained for nucleic acid extraction and made to undergo RNA sequencing using high throughput next-generation sequencing (NGS) and pathway analysis was later utilized to obtain a correlation.

Results: From our study, it was revealed that a total of 12 upregulated and 10 downregulated differentially expressed genes were identified, which were enriched in Gene Ontology terms including integrin binding, protein binding, structural constituents of the cytoskeleton, and in KEGG pathways. Three major modules from the PPI networks and 10 hub genes were identified, including MSH6, CHEK2, PMS2, ATM, BRCA1, BRCA2, SEC23B, ESR, and TP53. Overall survival was low when these 10 hub genes were highly expressed.

Limitations of study: Explorations of the genetic and epigenetic pathophysiology of cancers related to infertility and its treatments by using integrative bioinformatic tools are still in their nascency and yet to be fully explored with the constantly growing genomic data sets.

Conclusion: It has been concluded from our study that although genomics plays an integral role in the development and pathogenicity of ovarian and breast cancers and has a strong link with infertility, the influence of infertility medications seems to confer no significant impact on its development.

Study funding/Competing interest(s): Yes.

Is it a clinical trial: No.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS68

NO 69 PERINATAL AND OBSTETRIC OUTCOMES OF PREGNANCIES FOLLOWING IN VITRO FERTILIZATION VERSUS NATURAL CONCEPTION—A CASE CONTROL STUDY

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Study question: To explore association between singleton pregnancies by in vitro fertilization (IVF) and maternal and perinatal outcomes compared with similar outcomes following spontaneous conception.

What is currently about the subject: Use of assisted reproductive technology (ART) has increased dramatically and made pregnancy possible for many infertile couples. Despite this success, there are many studies that show that pregnancy conceived by IVF has an increased risk of adverse maternal and perinatal outcomes, mainly represented by the development of hypertensive disorders, preeclampsia, fetal growth restriction, preterm births, low birth weights, and congenital anomalies. These side effects have been attributed to the increased incidence of multiple pregnancies, especially in older women. However, studies have shown that the risk of complications was maintained in the case of singleton pregnancies obtained after ART compared to the general population. The impact of IVF on maternal and pregnancy outcomes is discussed in this study.

Study design, size, duration, material and methods: This Case-Control study was carried out in tertiary care hospital, Government Medical college Jammu from August 1, 2020 to August 1, 2022. A total of 110 singleton pregnancies conceived by IVF were included. Another 110 singleton pregnancies conceived naturally were selected as comparison group (1:1) matched by age. Only those pregnancies leading to live birth included in the study. Data were retrospectively extracted from medical records and various characteristics compared between two groups.

Results: Incidence of primary infertility was more common in IVF pregnancies (76.3% vs. 61.8% $P = 0.019$). Women conceived after IVF were more likely to develop gestational hypertension compared with spontaneous conception (9% vs. 2.7%, $P = 0.045$). Mean gestational age was lower in IVF group (37.8 ± 2 vs. 38.6 ± 2). Caesarean sections rates were significantly higher in IVF pregnancies (78.18% vs. 38.1%, $P < 0.001$). Low birth weight (<2.5 kg) were more commonly seen in IVF pregnancies than normal (16.3% vs. 7.27%, $P = 0.036$). Rate of preterm labor, small for gestational age, gestational diabetes, anemia, placenta previa, NICU admissions were comparable between two groups.

Limitations of study: Small sample size errors in retrospective database studies. Not all possible confounding factors were assessed, like the type or number of ART used before conception.

Conclusion: When compared, IVF singleton pregnancies have higher risk of gestational hypertension, low birth weight, higher caesarean section rates. However, they do not differ much with regard to other obstetric and perinatal outcome. Keywords: in vitro fertilization, obstetric outcomes, perinatal outcomes.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS69

NO 70 CAESAREAN SECTION FOR NON-REACTIVE CTG AND ITS CORRELATION IN PREDICTING PERINATAL OUTCOME

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Study question: To evaluate the success of fetal cardiotocography in predicting perinatal outcome

What is currently about the subject: Fetal distress detected by CTG has been the most common indication for a C-section. Many fetuses show heart changes without showing poor outcomes and CTG has been criticized for an unnecessary high rate of C-sections. Thus, there is a need to access the efficacy of electronic fetal monitoring. This study evaluated the success of fetal cardiotocography in perinatal outcome.

Study design, size, duration, material and methods: This was a prospective observational study enrolling 300 pregnant women admitted for delivery to SMGS Hospital, a tertiary care hospital, and underwent C-section at 36 to 40 week's for non-reassuring fetal heart in labor detected by CTG and not responding to intrauterine resuscitation. The fetal APGAR score at 1 and 5 minutes was recorded and cord blood pH was measured. The neonatal outcome was studied with regards to the need for supportive ventilation and admission to the NICU.

Results: Out of 2000 cesarean, 300 (15%) are being performed for non-reassuring fetal heart rate. The mean age of the patients in the study group is 26 years. 260 (72%) women were primigravida, 84 (28%) were multigravida, only 21% (64) actually showed poor neonatal outcome with NICU admission..

Limitations of study: I. Small sample size. 2. Study also included unbooked pregnant women presented for the first time during labor and no antenatal regard available.

Conclusion: CTG is insufficient for predicting the perinatal outcome. Therefore, labor is evaluated on an individual basis. Keywords: fetal distress, CTG, perinatal outcome.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS70

NO 71 EFFECT OF COMBINED ORAL CONTRACEPTIVES ON USG ASSESSED POLYCYSTIC OVARIAN MORPHOLOGY AND SERUM ANTI-MULLERIAN HORMONE LEVELS IN WOMEN WITH POLYCYSTIC OVARIAN SYNDROME

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Study question: Do combined oral contraceptives have an effect on ultrasound assessed polycystic ovarian morphology and anti-mullerian hormone levels in women with polycystic ovarian syndrome?

What is currently about the subject: PCOS is one of the most common gynecological disorders faced by women in the reproductive age group. The Rotterdam criteria define PCOS as having at least two of the following: oligomenorrhea with anovulatory cycles; signs of hyperandrogenism, which may be clinical or biochemical; or having an ultrasound appearance of polycystic ovarian morphology. AMH is produced by the granulosa cells of the primary, preantral, and small antral follicles in the ovary. Levels of AMH in women with PCOS are two to three times higher than in healthy women. Combined oral contraceptives, along with life-style modification have been used as the primary management strategy for the patients with polycystic ovarian syndrome. This study is done to see the effects of combined oral cotraceptives on polycystic ovarian morphology and serum AMH levels in PCOS women.

Study design, size, duration, material and methods: A prospective observational study was conducted in the Department of Obstetrics and Gynaecology in collaboration with the Department of Biochemistry and the Department of Radiology at ABVIMS and Dr. RML Hospital, New Delhi from January 1, 2020 to May 31, 2022, where a total of 35 patients were enrolled. A detailed history and examination were done along with the BMI. Hirsutism was quantified using the modified Ferriman–Gallwey score, and note was made for acne. Ultrasonographic assessment was done along with all the hormonal parameters namely serum LH, serum FSH, serum total testosterone, serum AMH, DHEAS, and 17 OHP. Women in the study group were started on combined oral contraceptives for 3 months, and changes in all the parameters were recorded for evaluation.

Results: Serum AMH levels were found to be elevated in the women in the study group, with only 20% women had normal levels of below 5 ng/mL, 37.1% had levels between 6 and 9.9 ng/mL, 17% were between 10 and 14.9 ng/mL, 20% were between 15 and 19.8 ng/mL, and 5.8% were above 20 ng/mL with a mean serum AMH level of 10.08 + 6.76 ng/mL. After the treatment with combine oral contraceptives for 3 months, the serum AMH levels reduced with a mean serum AMH level of 5.89 + 3.37 ng/ml. Before the treatment, only 20% had normal serum AMH levels (<5 ng/mL), and after the treatment 48.6% women had normal serum AMH levels. This decrease in serum AMH values was statistically significant with *P*-value of <0.001. Polycystic ovarian morphology, as assessed by transabdominal ultrasound, was found in all 35 women enrolled in the study; after treatment with combined oral contraceptives for 3 months, 82.9% had normal ovarian morphology, while in 17.1% polycystic ovarian morphology persisted. Serum LH levels and LH:FSH ratio showed a significant decrease in pre-treatment and post-treatment values with a *P*-value of <0.001. Whereas the serum FSH levels were not significantly affected after 3 months.

Limitations of study: Study due to a relatively small sample size, a shorter duration of study period, and a restricted ethnicity that would make the results difficult to generalize to the general population. Also, as the study is being conducted at a tertiary care center, an element of referral bias cannot be ruled out.

Conclusion: Baseline serum anti-Mullerian hormone levels were increased in the women in the study group and the serum AMH levels decreased significantly after treatment with COC. The polycystic ovarian morphology was present in all the women before the treatment, which improved with respect to ovarian volume and total follicle count.

Study funding/Competing interest(s): No.

Is it a clinical trial: Yes.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS71

NO 72 TO EVALUATE THE DIFFERENT ETIOLOGIES OF DIMINISHED OVARIAN RESERVE (DOR) AMONG INDIAN INFERTILE WOMEN

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Study question: What are the factors leading to DOR in Indian infertile women?

What is currently about the subject: Background: Diminished ovarian reserve (DOR) or poor ovarian response (POR) always pose a challenge to clinicians and stress to patients. So, it is important to find the possible etiologies that leads to DOR/POR. If we can modify the factors responsible for DOR, then we can prevent these females to go into POR, which formed the base for this study.

Study design, size, duration, material and methods: Study design: A prospective cohort study. Material methods: Out of 250 women were screened in an infertility clinic, 107 women were evaluated in the DOR group, and 73 women were evaluated in non-DOR group (control group). They were evaluated according to the questionnaire-based Performa and were followed for 6 months. Study duration: 1 year (January 28, 2021 to January 27, 2022).

Results: Result: The mean age in the DOR group was 31.68 $\pm$ 3.97 years and in non-DOR group was 28.69 $\pm$ 3.49 years ($P < 0.001$). The BMI was high in DOR group (25.93 $\pm$ 3.79 kg/m^2) as compared to non-DOR group (24.58 $\pm$ 4.02 kg/m^2) ($P = 0.022$). On applying logistic regression, women's age, women's occupation, and socioeconomic status were significantly related to DOR, whereas BMI and T.B. were related to DOR but the difference was not statistically significant. Other factors like ovarian reserve, uterine factor, ovulation induction number, cooking fuel, prolactin, coffee intake, fasting blood sugar, TSH, and family type had no effect on DOR.

Limitations of study: Sample size was less. Many patients got lost to follow and other parameters could not be studied due to COVID-19 crisis.

Conclusion: Conclusion: With world-wide rising incidence of sub-fertility and DOR, further prospective studies are warranted to evaluate different causes of decreased ovarian reserve among different ethnic populations. Early intervention can prevent the DOR and its consequences on fertility.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS72

NO 73 THE EFFECT OF BODY MASS INDEX (BMI) ON OUTCOMES OF ASSISTED REPRODUCTION CYCLES

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Study question: Whether BMI calculated from data collection of height and weight parameters affects the various outcomes of assisted reproduction

What is currently about the subject: Obesity is a worldwide concern with detrimental health effects including decreased fecundity. However, obesity impacts on invitro-fertilization (IVF) is inconclusive. This study explored the effects of overweight and obesity on IVF outcomes. Women predominantly bear the burden of obesity as compared to men, with more impact on their fertility, success with treatment, and significant maternal and perinatal morbidity and mortality. Obesity is a complex endocrinological condition that has bearing on every step of assisted reproduction, starting from the preconception period to the ovarian stimulation and its outcomes.

Study design, size, duration, material and methods: This was a retrospective study with a total sample size of 75 ($n = 75$). It was undertaken in the year 2021 and the records of patients undergoing IVF cycles at the Department of Reproductive Biology, Loknayak Hospital, Delhi in the study period of 2017–2019 were included in the study. Patients were categorized into three groups based on their BMI. Group 1 was normal weight patients (BMI 18.5–24.9 kg per square meter, $n = 25$), Group 2 was overweight (BMI 25.0–29.9 kg per square meter, $n = 25$), and Group 3 was obese patients (BMI more than 30 kg per square meter, $n = 25$). The primary outcome would be clinical pregnancy rate per initiated cycle. The secondary outcomes were dose of gonadotropin consumed per cycle, number of oocytes, embryo quality, pregnancy rates, miscarriage rates, hyperstimulation, etc.

Results: When the groups were compared, the primary outcome (clinical pregnancy rate, CPR) was not significantly different between the three groups but the CPR was 30% each in the overweight and obese groups which is lesser than in normal BMI group of 45%. Total dose of gonadotropin consumed was significantly higher in the obese group ($P = 0.002$). The fertilization rates were also significantly lower in group 3 ($P = 0.004$). The total number of oocytes retrieved and embryos transferred were also similar among the three groups. The remaining secondary outcomes including baseline characteristics of the groups like age, duration of infertility, ovarian reserve tests, etc. were found to be similar between the three groups with no significant differences. Keywords: IVF, obesity, pregnancy

Limitations of study: Limitations include retrospective nature of the study and non-inclusion of long-term obstetric follow up beyond 12 weeks of gestation of the study subjects.

Conclusion: Despite similar number of retrieved oocytes, obese study subjects had decreased fertilization and pregnancy rates. They had greater consumption of gonadotropins to produce equivalent number of oocytes or embryos. Obesity rather than overweight significantly decreased IVF outcomes.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS73

NO 74 DAY 3 VERSUS DAY 5 QUARTER LASER ZONA THINNING-ASSISTED HATCHING (QLZT-AH) IN FROZEN EMBRYO-TRANSFER

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Study question:
1. Advantage of qLZT-AH over other traditional assisted hatching procedures.
2. When to use qLZT-AH?

What is currently about the subject: To check efficacy of qLZT-AH in FET cycles. To compare PR and IR of days 3 and 5 qLZT-AH.

Study design, size, duration, material and methods: It is a retrospective-study in which 139 patients were randomly divided into two groups: test (patient received qLZT-AH before ET, $n = 60$) and control (transfer was done without qLZT-AH, $n = 79$), in both day 3 and 5 FET. Inclusion criteria: women aged between 23 and 38 years were included in this study with BMI ranging between 20 and 38. Patients with good ovarian reserve, ICSI, Normo-responders. Previous failure of ART (recurrent implantation-failure) patients with good endometrial thickness (>7 mm). Exclusion criteria: first ART cycle, poor responders, Poor ovarian reserve (low-AMH) €¢ Patients with un-corrected Asherman syndrome, submucosal-polyp or fibroid and uterine anomaly.

Results: In day 3 control versus test group, sd ($P = 0.02$) was observed on day 3 PR. No significance difference was observed in IR ($P = 0.15$). Similarly, in day 5 control versus test group, significance difference ($P = 0.03$) was observed in PR. No significance difference was observed in IR ($P = 0.38$). No significance difference was observed in either PR ($P = 0.25$) or IR ($P = 0.63$) when day 3 and 5 test groups were compared.

Limitations of study: The study size was small. A larger sample size was required to assess the actual effect of implantation rate on quarter laser zona assisted hatching of embryos.

Conclusion: From the above results, it can be concluded that qLZT-AH improves PR in patients receiving day 3 and 5 FET, while the IR remains similar, whether qLZT-AH was performed or not. On comparing day 3 and 5, no sd was observed in patients receiving qLZT-AH.

Study funding/Competing interest(s): No.

Is it a clinical trial: Yes.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS74

NO 75 MICROFLUIDIC TECHNIQUE VERSUS DENSITY GRADIENT TECHNIQUE IN HIGH DNA FRAGMENTATION INDEX SPERM SAMPLES: RANDOMIZED CONTROLLED STUDY

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Study question: Is microfluidic sperm sorting technique better than density centrifugation technique in terms of clinical pregnancy rate and miscarriage rate?

What is currently about the subject: Approximately, one in every seven patients are suffering from infertility, out of which male factor is responsible in 50% of cases. Recent evidences have revealed that sperm DNA integrity is a fundamental factor for normal fertilization, embryo development, and subsequent offspring health. The standard centrifugation and swim up procedure are useful in collecting high motility sperms and removing impurities, but it also leads to formation of reactive oxygen species that result in DNA damage. Microfluidic systems are capable of working with small volumes of samples

resulting in high sensitivity and low response time. Microfluidic based sperm sorting technique allows for the selection of highly motile and morphologically normal sperms from unprocessed specimen. It has been demonstrated that microfluidic technique could provide sperms with almost zero DNA damage.

Study design, size, duration, material and methods: A prospective randomized controlled study was conducted from June 1, 2021 to July 31, 2022 at a tertiary center in Delhi. One hundred patients were randomized by a computer based program into two groups of 50 each. In Group A, sperms were processed by microfluidic sperm sorter while in group B, sperms were processed by density gradient technique and morphologically normal motile sperms were injected by intracytoplasmic sperm injection (ICSI) technique in all mature oocytes. Patients with normozoospermic with high DNA fragmentation index (>25%) were included while oligospermic, asthenozoospermic patients, patients with poor ovarian reserve, and patients with advanced age were excluded from the study. All grade A embryos were vitrified and transferred in programmed frozen embryo transfer cycles. Both groups were compared on the basis of fertilization rate, day 3 grade A embryos, clinical pregnancy rate, and miscarriage rate.

Results: Cycle characteristics in terms of female age, length of stimulation, gonadotrophin dose, number of oocytes, and number of transferred embryos were similar in both the groups. Between the two groups, there was a significant increase in day 3 grade A embryo development rate (62% vs. 40%, *P*-value = 0.003), clinical pregnancy rate (60% vs. 39%, *P*-value = 0.004) while a significant decrease in miscarriage rate (13% vs. 26%, *P*-value = 0.03). There was no statistical difference observed in fertilization rate (82% vs. 80%, *P*-value = 0.48).

Limitations of study: We need large randomized controlled trials to strengthen our results.

Conclusion: Microfluidic sperm sorter technique is an efficient means of sperm separation. It not only results in almost zero DNA damage but also results in better reproductive outcome. Using it in routine practice can help in reducing the extraneous effect of standard sperm processing techniques and achieving higher pregnancy rate.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS75

NO 76 TRANSDERMAL ESTROGEN VERSUS ORAL ESTROGEN IN FROZEN THAWED BLASTOCYST TRANSFER CYCLES: PROSPECTIVE RANDOMIZED CONTROLLED TRIAL

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Study question: Is transdermal estrogen better than oral estrogen for achieving endometrial thickness >7 mm in frozen thawed cycles?

What is currently about the subject: Advances in cryopreservation through vitrification have resulted in an increase in the frozen embryo transfer (FET) cycles as it almost eliminates the risk of ovarian hyper stimulation syndrome (OHSS) and gives us a higher number of embryos after thawing. Hormone prepared cycles give us the advantage in practicality of patient's cycle monitoring and is a good option in an anovulatory cycles. Estrogen can be given either as an oral tablet, through a transdermal route or vaginal route, or through subcutaneous/intramuscular injections. An international survey in 2014 showed that 86% of participants used the oral route and 8% used the transdermal route. Compared to oral route, transdermal route has a better bioavailability as it bypasses the intestine and hepatic metabolism and achieves a better plasma concentration of active form of estrogen (estradiol).

Study design, size, duration, material and methods: A prospective randomized controlled study was done at a tertiary hospital in Delhi from May 2021 to April 2022. One hundred twenty patients underwent hormone replacement FET and were randomized into two groups of 60 by a computer based program. Group 1 received transdermal estradiol gel, three actuations/day (one actuation containing 1.25 g gel containing 0.75 mg estradiol) and Group 2 received oral estradiol tablet 2 mg thrice a day starting from day 2. Transvaginal ultrasound (TVS) was done on day 2, 7, 11, and 14 to monitor the endometrial thickness, and the dose of estradiol gel/tablet was adjusted accordingly, going up to maximum of six applications/day in case of transdermal gel and 12 mg per day in case of oral tablets. On day 5 of progesterone, single blastocyst was transferred. Primary outcome was to compare endometrial thickness on the day of starting progesterone. Secondary outcomes were to compare clinical pregnancy rate, miscarriage rate, and adverse effects.

Results: There was no difference in the demographic parameters of both the groups, with average age in group 1 being 32.7 years and in group 2 being 31.8 years. Between the two groups, there was a significant difference in the endometrial thickness on the day of the start of the progesterone. It was higher in the transdermal group as compared to the oral group. (9.91 ± 0.761 vs. 9.39 ± 0.712; *P*-value = 0.02) The clinical pregnancy rate was higher in the transdermal route but it was not statistically significant (54% vs. 51%; *P*-value = 0.67). Miscarriage rates were lower in the gel group (3.7% vs. 10.5%; *P*-value = 0.30), but it was not statistically significant. The overall patient satisfaction was significantly higher in transdermal group as compared to the oral group (8.4 ± 2 vs. 6.6 ± 1.7, *P*-value = 0.02). The major side effect in the oral group was nausea 71.66% versus 25% in transdermal group (*P*-value < 0.001). The major side effect with the transdermal gel was itching and redness at the site of the application which occurred in 33.3% of the women and no itching was reported in the oral group (*P*-value < 0.001).

Limitations of study: We need large randomized controlled trials to strengthen our results. It is difficult to determine the other confounding factors leading to clinical pregnancy. A comparison between transdermal and vaginal estrogen should also be done.

Conclusion: Study concluded that there was a significant increase in the endometrial thickness in the transdermal group with a higher overall satisfaction rate. There was no significant difference in clinical pregnancy rate and miscarriage rate. Transdermal gel is a good alternative in the women who are unable to tolerate oral preparations.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS76

NO 77 TO FIND THE BEST LABORATORY IVF KEY PERFORMANCE INDICATOR FOR PREDICTION OF CLINICAL OUTCOME IN TWO DIFFERENT LABORATORY PROCESSES OF AN ALL FREEZE PROGRAM.

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Study question: Which is the best IVF laboratory KPI that can reflect the changes in laboratory processes to predict shift in the clinical outcome?

What is currently about the subject: The impact of deterioration in IVF laboratory quality is reflected in the clinical pregnancy rate (CPR) and implantation rates (IR). However, these indices will be available much later. There is no way to go back in time and institute remedial interventions in order to salvage the remaining cases. Vienna consensus defined KPIs

for monitoring fresh IVF and ICSI cycles, which can serve to predict early warning signs (EWS) for relevant shifts in clinical outcome. EWS, if available, can give timely alerts and help in trouble shooting. But which is the best and most reliable KPI is yet to be known. With more and more cycles going for all freeze and frozen embryo transfer (FET) cycles, new KPIs are required to further evaluate the quality and developmental potential of frozen thawed embryo cycles.

Study design, size, duration, material and methods: This was a retrospective study of fresh and FET cycles with respect to laboratory KPIs in two different culture media. The change in media was done following a fall in clinical outcomes. All 41 fresh and 53 FET cycles done within 1 month after the change of culture media referred to as media-B were compared with the same number of fresh and frozen cycles with the previous media referred to as media-A being used immediately before the change. Fresh cycle KPIs compared were fertilization rate, cleavage rate, Day-2 embryo development rate, Day-2 usable embryo rate. The frozen cycle KPIs analyzed were Day-5 usable blastocyst rate (D-5UBR), total blastocyst rate (TBR). The clinical outcome KPI analyzed were CPR and IR. The data were collected from standard hospital records and analyzed with SPSS-22 using appropriate methods.

Results: KPIs of fresh cycles like fertilization, cleavage, Day-2 embryo, and Day-2 usable embryo rate in Media A were 87.11%, 94.43%, 95.21%, 91.95% respectively while in Media B were 92.13%, 97.30%, 98.05%, 93.86%, respectively. These differences were insignificant. KPIs of frozen cycles, that is, Day 5 usable blastocyst rate (D5UBR) and total blastocyst rate (TBR) in Media A were 35.58% and 36.23% respectively while in Media B were 56.87% and 61.26%, respectively. These differences was statistically significant. implantation rate (IR) and clinical pregnancy rate (CPR) in Media A were 32.08% and 45.28%, respectively while in Media B were 51.52% and 60.61%, respectively. The difference in these clinical outcome KPIs was also statistically significant.

Limitations of study: It is a single center retrospective study with small sample size and only 1 month duration. Outcome of fresh cycle is not known as only frozen embryo transfer done with embryos developed during earlier cycles.

Conclusion: The media-B was better than media-A in terms of clinical outcome. D-5 usable blastocyst rate and total blastocyst rates were most significant KPIs to predict outcome of IVF cycles. A subtle change in any fresh cycle KPI can reflect a major clinical outcome difference between two IVF lab processes.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS77

NO 78 ROLE OF SERUM-FSH LEVEL AND TESTICULAR CYTOLOGY IN PREDICTION OF SURGICAL SPERM RETRIEVAL AND CLINICAL PREGNANCY IN NON-OBSTRUCTIVE AZOOSPERMIA.

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Study question: What is the likelihood of successful surgical sperm retrieval (SSR) based on serum-FSH level and testicular cytology (FNAC) in non-obstructive azoospermia?

What is currently about the subject: Azoospermia is reported in 10% to 15% of infertile males and is classified as either obstructive azoospermia (30–40% of azoospermia cases) or non-obstructive azoospermia (NOA) (60–70% of azoospermia cases). In-vitro fertilization (IVF) with SSR and intracytoplasmic sperm injection (ICSI) is the only viable method for these males to become a biological father. It is known that even in presence of high serum FSH and poor testicular cytology, there can be niches of spermatogenesis in testis in NOA. Microsurgical-testicular-sperm-extraction (micro-TESE) has shown promising results in retrieval of sperm in NOA. There have been multiple studies to look for predictive factors of successful surgical retrieval in azoospermic males considering S.FSH, inhibin B levels, and testicular cytology. The effects of these factors on pregnancy outcome also need consideration.

Study design, size, duration, material and methods: This was a retrospective study of 7 years duration from 2016 to 2022 done at a tertiary IVF center. SSR was done in 157 couples with male factor infertility. Among them, 57 had obstructive azoospermia, 100 had non-obstructive azoospermia who underwent micro-TESE. These were included in analysis. These men were grouped based on S.FSH levels as Group A – S.FSH 35 mIU/mL. They were also grouped on the basis of FNAC as follows: (1) hypo spermatogenesis; (2) normal spermatogenesis; and (3) Sertoli cell only. Successful sperm retrieval was defined as the presence of viable sperms obtained. Clinical pregnancy rate (CPR) was defined as presence of cardiac activity at 6 weeks of gestation. The data were collected from standard hospital records and analyzed with SPSS-22 using appropriate methods.

Results : Mean S.FSH level of 8.47 ± 7.81 mIU/mL in 73 successful SSR cases was significantly lower ($P = 0.005$) than unsuccessful cases with 13.82 ± 9.48 mIU/mL. Out of 73 successful SSR, 63 patients underwent embryo transfer. Mean S.FSH level of 8.53 ± 7.03 mIU/mL in 43 clinical pregnancy cases was similar ($P = 0.757$) to 20 unsuccessful cases of 7.96 ± 6.27 mIU/mL. SSR was significantly high in group A (82.3%), although successful SSR was found in group B–33.3%, group C–50%, and group D–100% (*P*-value 0.002). CPR was 66% in group A, 83.3% in group B, and 100% in group C. So, CPR was found to be independent of S.FSH levels (*P*-value 0.544). Testicular cytology showed normal spermatogenesis was associated with significantly higher successful SSR (100%), 81.1% SSR with hypospermatogenesis (*P*-value 0.002) while no sperms were retrieved in Sertoli cell only syndrome. CPR was found to be 75% in the hypospermatogensis group, 77.8% in normal spermatogenesis. So, CPR was also independent of testicular cytology (*P*-value 0.142).

Limitations of study: It is a single center retrospective study.

Conclusion: There is high likelihood of obtaining sperms with serum FSH.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS78

NO 79 RECURRENT (THREE) ECTOPIC PREGNANCIES AFTER IVF-ET: A RARE CASE PRESENTATION WITH DISCUSSION ON STRATEGIES TO DECREASE CHANCES OF EP AFTER IVF-ET

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Study question: To discuss rare case scenario of recurrent (three) ectopic pregnancies following IVF-ET in patient; twice interstitial and once cervical and explore strategies to reduce EP.

What is currently about the subject: One to two in 100 pregnancies (1–2%) are found to be ectopic in nature. IVF-ET is one of the major risk factors for the development of ectopic pregnancy. Various reasons suggested for an increased risk of ectopic pregnancies after IVF-ET are altered hormonal milieu, multiple embryo transfers, procedural issues, fresh embryo transfer, cleavage embryo transfer, and laser assisted hatching. A

previous ectopic pregnancy itself is a main risk factor for a subsequent ectopic pregnancy, with incidence rising to 15% after one and 30% after two ectopic pregnancies. Bilateral salpingectomy is a common procedure done before IVF-ET in patients with hydrosalpinges but the procedure itself is known to increase the risk of interstitial and heterotopic pregnancies.

Study design, size, duration, material and methods: This is a case study with retrospective analysis and search of medical literature carried out to learn the potential interventions or procedures which can be done prior, during, or after an IVF-ET on the patients which are considered high risk for an ectopic pregnancy.

Results: Blastocyst transfer has been advocated as a strategy to reduce ectopic pregnancy as there is a better synchronization and receptivity of the endometrium which along with a declining uterine junctional activity might not push a larger sized blastocyst towards tubes. Ectopic pregnancy rates have been suggested to be low in frozen embryo transfer compared to fresh as supraphysiological levels of hormones during COH has a tendency to compromise endometrial receptivity along with upsurge of uterine contractility leading to dys-synchronization of uterine musculature. The oocyte retrieval procedure itself might release implantation mediators in the vicinity of fallopian tubes. Single embryo transfer appears to be lesser controversial in this regard. Various procedural techniques like fundal transfer, high volume of media, strong push can increase the chances of an embryo landing in the fallopian tube, and should be avoided. Similarly, manipulation of the cervix or use of volsellum or other equipment leads to increased chances of uterine contractility and may escalate chances of ectopic pregnancies. Although not investigated sufficiently in this regard, uterine quiescence by Atosiban and use of embryo glue seem to decrease ectopic chances. Recommending bilateral salpingectomy to patients with diseased tubes/hydrosalpinx may also decline chances of fallopian tube ectopic pregnancy.

Limitations of study: It's a retrospective medical literature search following a rare case presentation.

Conclusion: Various strategies have been investigated for reducing the chances of ectopic pregnancy after IVF-ET. Although all these strategies have been counter-debated but one can learn, understand, and apply them according to the patient history or at least be thoughtful in patients at high risk of developing ectopic pregnancies.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS79

NO 80 MAGNETIC-ACTIVATED CELL SORTING (MACS): A USEFUL SPERM SELECTION TECHNIQUE IN CASE OF POOR OOCYTE QUALITY

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Study question: To determine whether the assisted reproductive technique (ART) outcomes such as blastocyst rate, pregnancy can be improved by using magnetic-activated cell sorting versus density gradient

What is currently about the subject: MACS is a sperm separation technique used in ART. It is said to separate morphologically normal sperms which displays higher potential for fertilization. It allows separation of good sperms from apoptotic sperm which may be one of the causes for failure of IVF. In our study we aim to compare the reproductive outcome in case of poor oocyte quality.

Study design, size, duration, material and methods: This was a retrospective observational study of our couples ($n = 68$). Data were taken only from self ICSI cycles performed in our fertility center during January 2021 to April 2022. Patients with poor oocyte quality were split into two groups using semen samples who had underwent standard density gradient centrifugation or an added sperm selection technique using MACS. Group A ($n = 34$) comprises of sperm selected using MACS technique in patients with poor oocyte quality, and Group B ($n = 34$) includes normal density gradient centrifugation with poor oocyte quality. All women included in this study underwent controlled ovarian hyper stimulation and oocyte retrieval procedures were carried out using our standard operating protocols. ICSI was the choice for insemination and resulting embryos were cultured till day 5 or day 6 and frozen. Frozen embryo transfer cycles were followed after the endometrial preparation. Blastocyst rate and pregnancy outcomes were observed as the primary outcome measure.

Results: Sperm selected using MACS technique showed an increased pregnancy rate (71.5% vs. 45.45%) in comparison with the density gradient centrifugation. However, there was no significant difference comparing the blastocyst rate (64.69% vs. 64.17%) in both the groups MACS and DGC, respectively.

Limitations of study: Further research on implantation rate, live birth rate, and a greater sample size is needed to determine its effects.

Conclusion: To conclude our observational study, we suggest that ICSIs done using MACS as a sperm selection technique in patients with poor oocyte quality showed a beneficial effect in terms of pregnancy rate, although there is no significant association with blastocyst.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS80

NO 81 EFFECT OF EMBRYO GLUE AND SINGLE STEP AS A TRANSFER MEDIUM IN THE OUTCOMES OF PREGNANCY RATES BETWEEN AVERAGE AND POOR OOCYTE QUALITY.

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Study question: To compare the efficacy of both embryo glue and single step on pregnancy outcomes in relation with average and poor oocyte quality

What is currently about the subject: Embryo glue is a hyaluronan-enriched embryo transfer (ET) medium that aids in implantation of embryos, and hence improves pregnancy rates in frozen embryo transfer cycle (FET). It is evident that embryo glue improved implantation rate and in our study we aim to observe if any correlations exist between oocyte quality and embryo transfer medium.

Study design, size, duration, material and methods: This is a retrospective study of our couples ($n = 204$) who had undergone assisted reproductive cycles (ART) between December 2020 and May 2022 in our private fertility clinic. Only self-gamete cycles were considered for this study. All women had undergone endometrial preparation for frozen embryo transfer cycles using our clinic standard operating protocols. Only the blastocyst stage transfer cycles were included in this study. Embryo transfers were divided into two groups. Group A includes the addition of laser assisted hatching (LAH) on embryos ($n = 41$) while Group B consists of non-assisted hatching (NAH) ($n = 41$). From both the groups, live birth and implantation rate were considered as the primary outcome whereas the secondary outcome measures are biochemical pregnancy and miscarriage rate.

Results : In comparison, there was no significant difference observed in the pregnancy rates in patients with average oocyte quality (Group A) using embryo glue and single step as a transfer medium (64.28% and 63.04%),

respectively. Whereas, the use of embryo glue showed a positive effect over single step (51.8% vs. 41.66%) in terms of pregnancy outcomes for patients with poor oocyte quality (Group B).

Limitations of study: Only pregnancy rate was observed. To validate these results further study on implantation rate, live birth rate is required. This study has limited sample size.

Conclusion: The enrichment of transfer medium with hyaluron showed good prognosis in the pregnancy rates with poor oocyte quality. However, this beneficial effect was not observed in average oocyte quality.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS81

NO 82 USE OF CLOMIPHENE CITRATE (CC) PATIENTS WITH POOR OVARIAN RESERVE: A RETROSPECTIVE PILOT STUDY

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Study question: How effective is clomiphene citrate (CC) only in patients with poor ovarian reserve?

What is currently about the subject: Although not many studies reported, CC is known to decrease the dose of gonadotropins in subsequent IVF cycle. For ovulation induction, CC is considered as the first line drug.

Study design, size, duration, material and methods: This is a retrospective study from January 22 to September 22 conducted in Phoenix Hospitals and Aveya Fertility Center, New Delhi. Fifteen patients were recruited. Inclusion criteria were age between 25 and 45 years, no previous pregnancy, poor ovarian reserve with AMH of <1 ng/mL and AFC of ≤3. All the patients recruited were given clomiphene citrate 100 mg once a day till trigger. Ultrasound for follicular study was done by transvaginal scan after six doses of CC and the patients were followed every second day. Once one or two follicles reached 18 mm, they were triggered with recombinant human chorionic gonadotropin. After oocyte retrieval, all patients had ICSI and embryo cleavage monitored from day 3 to day 5. All embryos were frozen on day 3 and some on day 5. All patients had frozen embryo transfer (FET) in the following cycle using hormone replacement.

Results: Fifteen patients were recruited. Out of 15, no eggs were retrieved in four of them (26%). The mean number of oocytes was 1.6. The mean number of m2 oocytes was 8.7. The fertilization rate was 95%. Five embryo transfers were done. All of them were transfered on day 3. Out of five, two were positive; hence clinical pregnancy rate was 40%. The embryos were taken to blastocyst stage in three patients where we were successful. The embryos were arrested at day 3 in two patients. The embryos were frozen at day 3 in five patients. In one of the patients the day 3 embryo was of grade c, so it was not frozen.

Limitations of study: The limitations are a small sample size,short study duration, and lack of controls.

Conclusion: The initial results allude to the fact that CC alone can be used in IVF/ICSI cycles. However, more patients are needed to confirm this observation. CC is a more economical way in which one can stimulate a poor ovarian reserve patient.

Study funding/Competing interest(s): No.

Is it a clinical trial: Yes.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS82

NO 83 PSYCHOLOGICAL DISTRESS AND QUALITY OF LIFE IN INFERTILE COUPLE ATTENDING INFERTILITY CLINIC: A PILOT STUDY

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Study question: Is psychological distress and QOL is affected more in infertile couples?

What is currently about the subject: Infertility is a biopsychosocial crisis, which can cause psychological distress in the form of depression and anxiety, and can impair quality of life .It often has a stressful impact on relationships and can affect a couple's sex life. Assessing the psychological distress and quality of life contributes to decrease the stress and helps to improve the outcome of management by improving the relationship of the individual to achieve pregnancy.

Study design, size, duration, material and methods: This is a cross-sectional study involving 100 infertile couples aged between 25 and 40 years attending fertility clinics were included for period of 1 year. The severity of depression and anxiety was measured using the Hospital Anxiety and Depression Scale (HADS Scale) and Quality of Life (QoL) was assessed with the Fertility Quality of Life (FertiQoL) questionnaire (local language).

Results: The average ages (SD) of men and women were 33.6 (4.29) and 31.3 (4.03) years, respectively. Women reported higher levels of depression ($P < 0.001$) and anxiety ($P < 0.001$) as compared to their husbands. The total FertiQoL scores were significantly higher in the husbands than the wives ($P < 0.001$). Poor Qol were significantly associated with male cause of infertility ($P = 0.004$), primary infertility ($P = 0.022$), and previous history of receiving multiple treatments ($P = 0.020$).

Limitations of study: The weakness of the cross-section study design is the small sample size, which involved only one study center. Self-reported questionnaires. Several confounding variables.

Conclusion: The levels of psychological distress and quality of life seem to be affected more in men than in women. Couples present with varying degrees of emotional moods swing ranging between anxiety and depression, a psychological counsellor who can empathize with the couple will form an integral part of the ART team.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS83

NO 84 EFFICACY OF COMBINATION OF LETROZOLE OR CLOMIFENE CITRATE (CC) WITH GONADOTROPINS FOR OVULATION INDUCTION IN CLOMIPHENE RESISTANT POLYCYSTIC OVARIAN SYNDROME: A RANDOMIZED CONTROLLED TRIAL

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Study question: Is using letrozole with gonadotropins better than clomifene with gonadotropins for ovulation induction in clomifene resistant PCOS?

What is currently about the subject: Gonadotropins have been used for ovulation induction in clomiphene-resistant infertile women with polycystic ovary syndrome (PCOS), but its use is limited due to its cost and is associated with overstimulated cycles with the development of many follicles. There are very limited studies reporting the efficacy and safety of combination of clomiphene or letrozole with gonadotropins.

Study design, size, duration, material and methods: Study design: Randomized controlled trial. Objectives: The aim and objective of the study was to evaluate the efficacy and effectiveness of combination of letrozole and HMG with CC and HMG for ovulation induction among infertile women with CC-resistant PCOS. Materials and methods: A total of 128 patients were randomized to either Letrozole + HMG ($n = 64$) or CC + HMG ($n = 64$). Letrozole 5 mg/day or CC 100 mg/day was administered from day 2 to day 6 of a spontaneous or progestogen-induced withdrawal of bleeding, plus HMG 75 IU on alternate days daily starting from day 7 based on folliculometry. On reaching follicle maturity, human chorionic gonadotropin (hCG) was administered. Women were monitored for folliculometry and endometrial thickness on TVS. The primary outcomes were ovulation and pregnancy rates.

Results: Population characteristics between the two groups showed no statistical difference. The monofollicular cycle rate in Letrozole + HMG group (53.8%) was higher and multifollicular rate was high in CC + HMG group (56.8%). Mean endometrial thickness between the groups showed no statistical significance although it was higher in letrozole group. Ovulation rate in Letrozole + HMG group (80%) was higher than CC+ HMG group (75.1%), though not statistically significant. Pregnancy rate in Letrozole + HMG group (32%), which was higher than CC + HMG group (18.5%), but not statistically significant.

Limitations of study: The sample size is smaller to conclude results for the study and the need for additional doses of gonadotropins was not studied.

Conclusion: The combination of Letrozole and human menopausal gonadotropins has better ovulation rate and pregnancy rate than Clomiphene citrate and human menopausal gonadotropin with an efficacy of 4.3% and 13.5%, respectively.

Study funding/Competing interest(s): No.

Is it a clinical trial: Yes.

Ethical clearance done or not: No.

DOI:10.4103/fsr.fsr_2_23-ABS84

NO 85 OVARIAN VASCULARIZATION PARAMETERS AND" CAN THEY REPLACE CONVENTIONAL PARAMETERS FOR PREDICTION OF OVARIAN RESPONSE TO STIMULATION

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Study question: Can vascularization parameters of the ovary be better predictors of ovarian response than the conventional parameters?

What is currently about the subject: Prediction of ovarian response is an important step in individualization of ovarian stimulation. Conventional ovarian response predictors are age, body mass index (BMI), anti-Mullerian hormone (AMH), follicular stimulating hormone (FSH), antral follicle count (AFC), ovarian volume. Vascularization index (VI), flow index (FI), and vascularization flow index (VFI) are newer vascularization parameters of ovary measured by 3D ultrasound and power Doppler angiography. Primary objective is to evaluate if the newer vascularization parameters of ovary are better predictors of ovarian response than the conventional predictors. Secondary objective is to study the association between vascularization parameters and the reproductive outcome in terms of clinical pregnancy rate.

Study design, size, duration, material and methods: A prospective observational study conducted at the Department of Reproductive Medicine, SAT Hospital from July 2020 to March 2022. Both conventional and newer predictors were measured before stimulation. All underwent antagonist protocol. Ovarian response was measured in terms of the number of mature MII oocytes. All participants were followed up till clinical pregnancy.

Results: The ovarian response predictors with significant positive correlation with ovarian response were serum AMH ($r = 0.475$), AFC ($r = 0.680$), average ovarian volume ($r = 0.341$), and average FI (flow index) ($r = 0.020$). Significant negative correlation was seen with age ($r = -0.212$), basal FSH ($r = -0.195$). In the regression analysis, only AMH and AFC were significant independent predictors of ovarian response.

Limitations of study: Type and dose of gonadotropin used, and type of trigger used was not evaluated. We were not able to study association of ovarian response parameters with live birth rate.

Conclusion: The newer vascularization indices of the ovary were not better predictors of ovarian response than conventional predictors. Vascularization parameters were not associated with clinical pregnancy rate.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS85

NO 86 DIFFERENCES IN BLASTOCYST DEVELOPMENTAL RATES IN CONTINUOUS (CCM) VERSUS SEQUENTIAL (SCM) CULTURE MEDIA: A SIBLING OOCYTE STUDY

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ART Fertility Clinics, Ahmedabad, India

Study question: Do embryonic developmental rates differ between single and sequential media?

What is currently about the subject: Two types of culture media have been generally applied in routine IVF to support embryonic development: a continuous culture media (CCM) and sequential culture media (SCM). Most IVF providers generate these two types of media nowadays and therefore their composition varies among the producers. Many reports have studied the effect of culture media on embryonic development and pregnancy outcomes, with results ranging from superiority of one culture media over the other to no significant difference in any outcomes. Sibling oocyte analysis of euploidy rates has also been studied with conflicting results. Different culture media have also shown to affect embryo morphokinetics and ammonia accumulation during the culture period.

Study design, size, duration, material and methods: Multicentric observational study in ART Fertility Clinics-India during the period of March 2021 to November 2022. A total of 62 patients undergoing self IVF/ICSI cycles were included in this study of age 40 years with at least two COCs in each group of comparison: CCM (Global®Total®LP) or SCM (Sage Quinn€™s Advantage® Cleavage and Blastocyst) media types, and that had at least one fertilized oocyte in each arm. Normally fertilized zygotes were cultured till blastocyst stage under 6% CO_2, 5% O_2, and 89% N_2 environment until maximum day 7. Media was replenished for both the groups on day 3. The fertilization rate, cleavage stage, and blastocyst utilization rate (frozen and/or transferred blastocysts/2PN) were analyzed and compared using Mann–Whitney *U* test. Values are presented as mean ± SD.

Results: A total of 1157 oocytes from 62 couples presenting 31.75 ± 3.62 years were randomly distributed between CCM ($n = 396$) and SCM ($n = 544$). Fertilization rates were similar between CCM and SCM (mean ± SD: 76.52% ± 26.28 vs. 77.31% ± 27.05, respectively; $P = 0.835$). Embryos developed on day 3 in both culture media, (CCM vs. SCM), with similar proportion of good quality embryos (66% vs. 69%, $P = 0.555$). However, blastocyst utilization rate was superior in SCM compared to CCM (55.73% ± 28.50 vs. 42.21% ± 34.43, respectively; $P = 0.0171$).

Limitations of study: The retrospective nature of the study.

Conclusion: The present analysis shows differences in blastocyst utilization rates between the culture media. Each laboratory should choose the type of culture medium based on internal validation of outcomes. This is because several factors may impact media properties and reflect on embryonic development, such as laboratory air quality, as well as conditions of media transportation by the providers.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS86

NO 87 A RARE CASE REPORT OF AN ACCESSORY AND CAVITATED UTERINE MASS MANAGED BY LAPAROSCOPIC EXCISION

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Study funding/Competing interest(s): Is it a clinical trial:

Ethical clearance done or not:

DOI:10.4103/fsr.fsr_2_23-ABS87

NO 88 IMPACT OF ASYMPTOMATIC OR MILD SARS COV 2 INFECTION ON FEMALE FERTILITY AND IVF OUTCOMES–A RETROSPECTIVE STUDY

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Study question: 1. Does asymptomatic/mild/moderate COVID-19 infection affect the ovarian reserve and clinical outcomes of IVF cycles?

What is currently about the subject: SARS CoV 2 has thrown the human race off the balance as regards its effects on human body. During the COVID-19 pandemic, there has been an ambiguity of views on the impact of virus infection on female fertility and ovarian reserve. Anti-Mullerian hormone (AMH) is one such marker, produced by the granulosa cells of primary, preantral, and small antral follicles in the ovaries that reflects quantity and quality of ovarian follicles. However, due to the limitation of samples and controls, most of the existing studies on this topic are speculative and have a low grade of the evidence hierarchy.

Study design, size, duration, material and methods: A retrospective observational study was conducted between April 2021 and June 2022 at Nova Southend Fertility & IVF-Centre. Women managed at the unit for fertility issues by in vitro fertilization, intracytoplasmic sperm injection (IVF/ICSI), and with an anti-Mullerian hormone (AMH) test carried out within 6 months preceding ART treatment, were included. The study population consisted of 53 patients who tested COVID positive by RT-PCR. Out of these 53 patients, 25 underwent ICF/ICSI cycle who were compared with 25 control cases after age matching. Statistical analysis of data was carried out using R-package. Mean and median were computed for comparing group averages to represent parametric and non-parametric measures. Paired *t* test and its non-parametric equivalent Wilcoxon-Sign test were carried out for testing the significance study-question-1. Independent-Sample *t*-test and its non-parametric equivalent Mann–Whitney *U* test were attempted for testing the significance study-question-2.

Results: The average AMH was observed to decrease after SARS CoV infection. Pre-COVID AMH showed a decline (median) −2.20 , IQR (1.59–4.47) whereas post-COVID AMH was median −1.60 (0.83–3.50), *P*-value 0.1064. The average values of FSH increased after COVID but these were not statistically significant (*P*-value 0.509). Evaluation of the early embryogenesis in patients who had COVID infection, when compared with age-matched controls revealed a decline in M2 oocytes (*P*-value 0.745) and fertilization rates (*P*-value 0.52). However, the decline in number of top quality embryos was observed to be statistically significant (*P*-value 0.0271).

Limitations of study: 1. Retrospective study. 2. Small sample size.

Conclusion: The number of top quality embryos was seen to fall in post-COVID patients which was statistically significant. However, these findings need to be reinforced by a multicenter long-term investigation with a larger sample size.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS88

NO 89 PARACERVICAL BLOCK – PCB IN MANAGING DIFFICULT EMBRYO TRANSFERS – CASE SERIES

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Study question: To analyze the role of paracervical block (PCB) in difficult embryo transfers

What is currently about the subject: Paracervical block is mainly used as an obstetric analgesic procedure and in gynecological procedures. It had been used as a mode of pain relief during oocyte aspiration too. But there are few literature to explore and expand its utility in overcoming difficult embryo transfers.

Study design, size, duration, material and methods: Retrospective analysis of the role of PCB in 11 patients with history of difficult ET or cancelled ET due to cervical stenosis for a period of 12 months. We attempted ET in such patients using PCB. About 10 mL of 2% lignocaine is administered at 3 and 9 o' clock position at cervicovaginal junction and proceeded with ET after 10 minutes of PCB administration. We then analyzed the difficulty level of ET, pregnancy rate, and live birth rates.

Results: The difficulty level decreased significantly, pregnancy rate was about 81%, and live birth rate was 80%. All the patients analyzed in our case series had no difficulty in negotiating the previously difficult cervical pathway.

Limitations of study: Retrospective study; though difficulty levels could be compared, the pregnancy rates and live birth rates did not have a control to compare.

Conclusion: PCB – paracervical block helps in handling difficult embryo transfers by preventing endometrial injury and replacing general anesthesia in patients with difficult cervical cannulation.

Study funding/Competing interest(s): No.

Is it a clinical trial: Yes.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS89

NO 90 INTRACYTOPLASMIC SPERM INJECTION IS NOT SUPERIOR TO CONVENTIONAL IN VITRO FERTILIZATION IN OOCYTE DONOR AND SELF-CYCLES: A SIBLING OOCYTE STUDY

Abhinav Dudeja, Surleen Kaur, Daniela Nogueira, Aakshi Mahajan
ART Fertility Clinics

Study question: Does intracytoplasmic sperm injection (ICSI) improves fertilization and blastocyst developmental rates compared to conventional in vitro fertilization (IVF) in non-severe male factor?

What is currently about the subject: Studies have shown that insemination by IVF is as effective as ICSI in patients with non-male factors. Nevertheless, IVF is still an under used mode of insemination. Suboptimal results with conventional IVF may be due to an unsuitable laboratory procedure rather than patient related factors. Applying IVF as a mode of insemination using donor oocyte cycles can be used as a procedure to validate laboratories standard operating protocols (SOP's) for IVF insemination. The aim of the present study was to evaluate the efficiency of the IVF method of insemination as compared to ICSI in patients presenting a non-severe male factor in a multicenter fashion following a single standard operating protocol of insemination.

Study design, size, duration, material and methods: A multicenter observational study was performed between March 2021 and November 2022 at ART Fertility Clinics–India, including 173 self- and 38 donor-cycle. All non-male factor cycles with female age 5 COCs collected and inseminated using fresh ejaculate during their 1st or 2nd attempt were included in the analysis. Insemination was performed by both IVF and ICSI in sibling oocytes from the same patient. Conventional IVF protocols and embryo culture conditions were standardized in all centers. Fertilization was observed 16–18 hours post-insemination. Zygotes were cultured to blastocysts until Day 7. The fertilization rate (FR) was calculated using total number of 2PN/ total number of MII on day 1. Blastocyst utilization rate (BR) was calculated using the total number of usable blastocysts (frozen and/or transferred)/total number of 2PNs). The FR and BR were analyzed using Mann–Whitney *U* test and results presented as mean ± SD with $P < 0.05$ considered significant.

Results : A total of 962 sibling oocytes were included in the study: fertilization rates were 74.4 9% ± 30.13% in IVF and 77.43% ± 19.78% in ICSI using self-sibling oocytes (NS); and Blastulation utilization rates were 52.82% ± 34.75% in IVF and 50.59% ± 30.43% in ICSI using self-sibling oocytes (NS); for the donor sibling oocytes fertilization rates were 81.82% ± 22.27% in IVF versus 84.92% ± 15.93% in ICSI (NS) and 60.08% ± 25.56% in IVF versus 59.66% ± 27.78% in ICSI (NS) using donor sibling oocytes.

Limitations of study: Retrospective analysis of data in a non-selective self-patient population that included only patients with >5 COCs. The study outcome should be investigated for patient with 1–5 COCs

Conclusion: ICSI is not superior to IVF in non-severe male factor and can be applied in self and donor oocyte cycles in patients with >5 COCs retrieved without decreasing chances of blastocyst development.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS90

NO 91 IN VITRO FERTILIZATION DELIVERS SIMILAR RESULTS TO INTRACYTOPLASMIC SPERM INJECTION IN PATIENTS PRESENTING MODERATE OR SEVERE TERATOZOOSPERMIA

Aakshi Mahajan, Surleen Kaur, Abhinav Dudeja, Daniela Nogueira
Art Fertility Clinics, India

Study question: Is in vitro fertilization (IVF) comparable to intracytoplasmic sperm injection (ICSI) in teratozoospermia for fertilization and blastocyst development when sibling oocytes are used?

What is currently about the subject: In clinical practice, the decision to use ICSI or conventional IVF is dependent mostly on semen quality. Fundamental studies in the eighties determined that there is a threshold among normal sperm morphologic features at 14% and that this threshold was strongly correlated with the fertilization of oocytes. Furthermore by proposing Kruger strict criteria it was shown that only patients with less than 4% of normal morphology had significantly lower fertilization rate of oocytes after conventional IVF. In the early 1990s, researchers considered sperm morphology as one of the most informative indices for predicting the pregnancy rate associated with ART and revealed its relationship with poorer fertilization outcomes. However recent studies concur that employing ICSI solely for teratozoospermia is unnecessary. Therefore, the clinical management of teratozoospermia is usually empirical, and there is no consensus on the influence of sperm morphology in ART procedure and the optimal clinical outcomes.

Study design, size, duration, material and methods: This multi-center observational study was performed at ART Fertility Clinics-India during the period of March 2021 to November 2022, including sibling oocytes from self-oocyte and donor oocyte cycles in normal, mild, and severe teratozoospermia samples. The inclusion criteria for the study were female patients between 25 and 45 years old with at least 6 cumulus-oocyte complexes (COCs) retrieved and male patients between 25 and 55 years old with teratozoospermia. COCs from 216 couples were randomly distributed between IVF and ICSI as normal morphology samples (morphology 4%, $N = 35$), mild teratozoospermia samples (morphology 1–3%, $N = 110$), and total teratozoospermia (morphology 0–1%, $N = 71$). The semen samples were prepared by density gradient method and count, motility, and morphology were assessed based on WHO manual 6th edition criteria. Fertilization, cleavage, and blastocyst utilization rates were analyzed and compared using Tukey's multiple comparisons test. Results were presented as mean ± SD and *P*-value.

Results: A total of 3688 oocytes from 216 women were randomly distributed between IVF (4.2 ± 3.12 MII oocytes) and ICSI (8.29 ± 4.25 MII oocytes) in normal morphology samples ($N = 35$), mild ($N = 110$), and severe teratozoospermia ($N = 71$) samples. Fertilization rate (FR) was similar between IVF and ICSI when using normal samples (79.2% ± 22.87% vs. 78.74% ± 19.79%; NS), or mild teratozoospermia samples (80.22% ± 26.15% vs. 80.66% ± 16.08%; NS), or severe teratozoospermia samples (69.18% ± 31.82% vs. 78.24% ± 20.97%; $P = 0.3$). No statistical differences were encountered in IVF between normal versus mild and normal versus severe teratozoospermia samples; neither for ICSI. Embryonic development on day 3 was similar between IVF versus ICSI within same patient, and among all groups of normal or teratozoospermia samples. The blastocyst utilization rates (BR) were similar between IVF and ICSI when using normal samples (59.21% ± 34.4% vs. 55.89% ± 31.6%; $P = 0.9$), or mild teratozoospermia samples (50.65% ± 34.72% vs. 53.72% ± 28%; $P = 0.9$), or severe teratozoospermia samples (54.13% ± 31.97% vs. 46.77% ± 31.37%; $P = 0.7$). No statistical differences were encountered in IVF between normal versus teratozoospermia samples, neither in ICSI.

Limitations of study: Retrospective analysis of data in a non-selective patient population. Also, the study included only patients with 6COCs retrieved, hence the outcome should be investigated for patients in which <6 COCs were retrieved.

Conclusion: Conventional IVF can be used as a method of choice in mild to severe teratozoospermia condition, delivering equally good fertilization and blastocyst utilization rates without any detrimental impact on embryonic developmental outcomes.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Not required.

DOI:10.4103/fsr.fsr_2_23-ABS91

NO 92 ROLE OF MULTIFETAL PREGNANCY REDUCTION (MFPR) AND CERVICAL ENCERCLAGE IN PREVENTION OF PRETERM DELIVERY IN HIGHER ORDER MULTIFETAL PREGNANCIES POST IN VITRO FERTILIZATION (IVF).

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Study question: To study if prophylactic use MFPR or cervical encerclage helps in preventing preterm labor.

What is currently about the subject: Iatrogenic multifetal pregnancies have increased due to the increased use of assisted reproductive techniques (ART). The incidence of preterm delivery and its complications is 66€"100% in higher-order multiples. Multifetal pregnancy reduction and prophylactic cervical encerclage can improve the outcomes. But, some studies have found no benefit of cervical encerclage. With the help of this study we will try find out an evidence based approach to better management.

Study design, size, duration, material and methods: Study design: Case series. Study site: Centre of Reproductive Medicine, Kalinga Institute of Medical Sciences, Bhubaneswar. Study Duration: 2018–2022 (4 years). Inclusion criteria: Multiple pregnancies with three or more fetuses post-IVF. Exclusion criteria: ïƒ¼ singleton or twin pregnancies ïƒ¼ that had to be terminated due to serious maternal complications. Sample size: Around 500 successful embryo transfers were done in our CRM department in 4 years out of which 120 were twins, nine triplets, and two quadruplets. Procedure: Case records of patients with high-order pregnancies were accessed after due permission from concerned authorities. Details regarding the use of MFPR and cervical encirclage along with the pregnancy outcome recorded.

Results: Two triplets were excluded. Seven triplets and two quadruplets were studied. Out of nine, MFPR was done in seven cases. After MFPR we got one triplet, which spontaneously delivered at 26 weeks (early neonatal death) and six twins out of which three got spontaneously reduced to singleton and delivered healthy babies at term and the other three delivered healthy twins at term/late preterm. MFPR was not done in two cases who spontaneously aborted at 21 to 22 weeks. Out of nine cases, cervical encerclage was given in four cases. Two triplets who refused MFPR were given encerclage but had a spontaneous miscarriage at 21 to 22 weeks. It was also given to two twin pregnancies who continued till term.

Limitations of study: Small sample size and lack of randomization.

Conclusion: MFPR improves the outcome. Cervical encerclage has controversial role.

Study funding/Competing interest(s): No.

Is it a clinical trial: No.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS92

NO 93 MATERNAL AND NEONATAL OUTCOME OF IVF/ICSI CONCEIVED PREGNANCIES WITH SPONTANEOUS CONCEIVED PREGNANCIES: A COMPARATIVE STUDY

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Study question: Are maternal and neonatal outcome of IVF/ICSI conceived pregnancies better than spontaneous conceived pregnancies?

What is currently about the subject: Assisted reproductive techniques have contributed to increases in incidence of pregnancies with increased maternal morbidity and perinatal complications. There are very few literature on studies done in the Indian population. Therefore, it becomes imperative to have a thorough knowledge about the investigations, methodology, and outcomes of ART, and hence the importance of this study.

Study design, size, duration, material and methods: This is a prospective observational study conducted in the department of Obstetrics and Gynecology, JIPMER, Pondicherry from December 2018 to October 2021. Hundred ART derived pregnancies were randomly matched for gestational age at delivery with women who conceived naturally. The categorical data between two groups were analyzed using chi-square test and results expressed by *P*-value. All maternal and fetal outcomes were analyzed by using multivariate logistic regression.

Results : We found that pregnancies conceived by ART were associated with a significantly increased incidence of gestational diabetes mellitus (47% vs. 10%), gestational hypertension (43% vs. 18%), placenta previa (7% vs. 3%), placental abruption (4% vs. 2%), placental adherence (7% vs. 3%), postpartum hemorrhage (17% vs. 6%), polyhydramnios (6% vs. 3%), preterm labor (30% vs. 10%), LSCS (77% vs. 37%), low birth weight (7% vs. 4%), and small-for-date infant (5% vs. 3%) compared with spontaneously conceived births.

Limitations of study: The pregnancies were not matched for their chorionicity and therefore higher number of twin pregnancies in ART group was a confounding risk factor. The study was not matched for other variables like maternal age, BMI, or parity from which more data could have been interpreted.

Conclusion: IVF/ICSI pregnancies are at higher risk for obstetrical and perinatal complications than spontaneous pregnancies, and close surveillance during pregnancy should be considered and increased rate of obstetrical interventions such as induced labor and elective caesarean delivery should be properly counselled.

Study funding/Competing interest(s): Yes.

Is it a clinical trial: Yes.

Ethical clearance done or not: Yes.

DOI:10.4103/fsr.fsr_2_23-ABS01