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Original Research Article

Bridging the donor gap: a prospective comparative study of obstetric and perinatal outcomes based on gamete sources in IVF at a tertiary care centre of South India

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ABSTRACT

Background: The assisted reproductive technology (regulation) act of 2021 has standardized third-party gamete donation in India. However, the introduction of non-maternal genetic material creates an allogenic state that potentially compromises placentation and increases obstetric risks. This study evaluated maternal and perinatal outcomes across different gamete configurations in a South Indian tertiary care facility.
Methods: This prospective comparative observational study consecutively enrolled 125 IVF-conceived pregnancies over an 18-month period. The cohort was stratified into: autologous (n=98), donor sperm (n=11), donor egg (n=8), and dual donor (n=8). Relative risks (RR) and 95% confidence intervals (CI) were calculated. Multivariable logistic regression adjusted for maternal age and pre-existing comorbidities to identify independent predictors of adverse outcomes.
Results: In crude analysis, the dual donor cohort carried the highest risk for hypertensive disorders of pregnancy (HDP) (100% incidence; RR: 1.707) and severe pre-eclampsia (75% incidence; RR: 4.641). On multivariable regression, dual donor status emerged as the only significant independent predictor for HDP, showing a 12-fold increase in disease odds (OR: 12.06, 95% CI: 0.68–214.80, p=0.040). Isolated donor sperm or oocyte configurations did not show independent risk predictions for HDP or preterm delivery (p>0.05). Caesarean section rates were exceptionally high across all donor arms (81.8% to 100%). Perinatal outcomes, including neonatal intensive care admissions and congenital anomalies, were reassuringly similar across cohorts, although extremely low birth weight was selectively elevated across all donor categories.
Conclusions: Dual donor gamete use is an independent predictor of hypertensive disorders of pregnancy. The elevated clinical risks warrant early high-risk triaging, timely tertiary referral, and proactive first-trimester prophylactic strategies.

Keywords: Donor gametes, IVF, Dual donor, Pre-eclampsia, Hypertensive disorders of pregnancy, ART regulation act

INTRODUCTION

The landscape of reproductive medicine in India has experienced a paradigm shift following the enforcement of the assisted reproductive technology (regulation) act of 2021, which standardized third-party gamete donation within structured clinical boundaries.[1] While these advancements have pushed clinical pregnancy rates higher, they introduce unique biological variables that alter the physiological course of gestation. Robust data from extensive Western registries, such as the European IVF-monitoring consortium (EIM) and the society for assisted reproductive technology (SART), consistently demonstrate that pregnancies derived from donor gametes

face a significantly higher rate of adverse obstetric and perinatal outcomes compared to autologous cycles.[2,3] This variance is predominantly driven by distinct immune-biological factors; the introduction of completely non-maternal genetic material creates an "allogenic" state that challenges conventional maternal-fetal immune tolerance.[4] Consequently, early trophoblast invasion is frequently compromised, leading to defective placentation as a primary pathological driver for severe hypertensive disorders of pregnancy, restricted fetal growth, and placental abruption.[5]

Despite the wealth of epidemiological data available in Western settings, clinicians within the Indian subcontinent operate under a distinct "counselling handicap." There is a critical lack of localized, prospective Indian data demonstrating the precise risk-stratification and clinical trade-offs when transitioning from autologous to non-autologous gametes. This data deficit makes it exceptionally difficult for clinicians to know exactly what to expect, or how to counsel couples regarding the precise multifold risk expansion for pre-eclampsia or spontaneous preterm delivery specific to their demographic.[6] Consequently, this lack of regional data frequently blunts antenatal surveillance and delays the identification of preventable complications. To bridge this gap, this prospective study was designed to systematically evaluate and compare adverse obstetric and perinatal outcomes across varied gamete configurations within a high-volume tertiary facility in Southern India, establishing a baseline risk-benefit matrix for clinical counselling and management.

METHODS

This prospective comparative observational study was conducted between September,2023 to March,2025 at a high-volume tertiary referral center in Southern India SAT Hospital, Government Medical College, Thiruvananthapuram. Ethical approval was obtained from the Institutional Review Board prior to study initiation, and written informed consent was secured from all participating couples before data collection.

Study population and sampling method

Using a consecutive sampling method, IVF-conceived antenatal women attending the outpatient department (OPD) of the tertiary care centre were recruited into the study. To be included, patients had to provide written informed consent at study entry. Patients were excluded only if their detailed IVF treatment and laboratory records were unavailable for verification. Following this protocol, a final study cohort of 125 patients was established.

Cohort architecture

To evaluate how varying degrees of genetic allogenicity impact pregnancies, the final study population was stratified into four distinct clinical cohorts based on the origin of the gametes utilized: autologous cohort (n=98): pregnancies utilizing both maternal oocytes and paternal spermatozoa, serving as the baseline control. Donor sperm cohort (n=11): Pregnancies utilizing autologous maternal oocytes fertilized by third-party donor spermatozoa. donor egg cohort (n=8): Pregnancies utilizing third-party donor oocytes fertilized by paternal spermatozoa. Dual donor cohort (n=8): Pregnancies derived from both donor oocytes and donor spermatozoa, representing total allogenicity.

The sample distribution across the donor arms reflects a pragmatic, naturally occurring cohort sample within a tertiary care setting. Rather than using artificial matching or over-sampling, this distribution represents the true, unmanipulated clinical frequency of third-party gamete utilization under recent national regulatory frameworks, ensuring high external validity and an un-biased depiction of real-world obstetric practice. The systematic tracking, exclusion parameters, and cohort allocations are visually mapped in the primary study flow diagram (Figure 1).

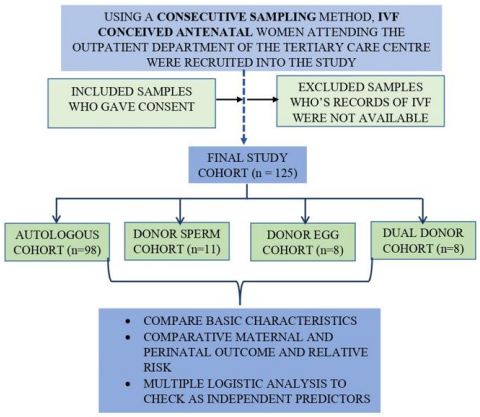

Figure 1: Illustration of methodology.

Data protocols and statistical analysis

The analytical plan was executed in three sequential phases.

Baseline comparison

A comprehensive cross-analysis of maternal basic characteristics, demographic profiles, and baseline physical parameters across all four cohorts.

Obstetric & perinatal trajectories

Evaluation of comparative maternal complications (including hypertensive disorders of pregnancy and gestational diabetes) and perinatal outcomes (gestational age at delivery, birth weight, and neonatal intensive care unit admissions) across the groups, with the calculation of RR and 95% CI to quantify risk expansion.

Multivariable regression

A multiple logistic regression analysis was performed to evaluate these gamete configurations as independent predictors of adverse outcomes while adjusting for potential maternal confounding factors. All statistical analyses were executed using SPSS Version 26.0, with statistical significance established at a two-tailed p value of <0.05.

RESULTS

The study population was stratified by gamete source into four operational exposure arms: an autologous control group (n=98; 78.4%), a donor sperm cohort (n=11; 8.8%), a donor egg cohort (n=8; 6.4%), and a completely allogenic dual donor (donor egg and sperm) cohort (n=8; 6.4%).

Baseline maternal profile and group distributions

Age-wise distribution analysis revealed clear demographic variations across the groups: younger maternal age cohorts correlated more frequently with donor sperm utilization, whereas advanced maternal age groups clustered around the donor egg and dual donor categories. Notably, 100% of the patients in the donor egg and dual donor groups already exhibited pre-existing medical comorbidities at the time of tertiary registration. Distribution of age and pre-existing co-morbidities as shown in Figure 2 plays an important role in the discussions later.

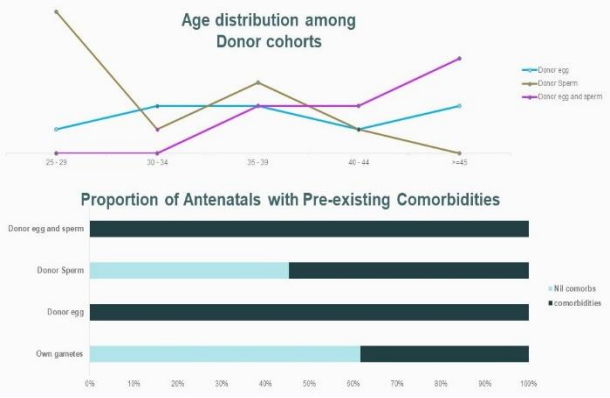

Figure 2: Distribution of age and proportion of antenatals with pre-existing comorbities across the four cohorts.

Comparative adverse maternal obstetric outcomes

Incidences and relative risks of adverse maternal outcomes in all 4 cohorts as shown in Table 1 and Table 2 respectively. From this the following can be concluded.

Donor egg cohort (n=8)

Demonstrated an increased risk for GDM by approximately 50% (75% vs 50.5% baseline; RR: 1.485) and maternal anemia by 75% (87.5% vs 50.5% baseline; RR: 1.732), alongside a nearly 2-fold expansion in multiple pregnancies (50% vs 26.3% baseline; RR: 1.904).

Donor sperm cohort (n=11)

Exhibited a higher clinical presentation of HDP by about 40% (81.8% vs 58.6% baseline; RR: 1.397), severe pre-eclampsia by about 70% (27.3% vs 16.2% baseline; RR: 1.687), and preterm delivery by about 30% (81.8% vs 63.6% baseline; RR: 1.286).

Dual donor cohort (n=8)

Showed increased risk for HDP by 70% (100% incidence; RR: 1.707) and severe pre-eclampsia by 4.5 times (75% incidence; RR: 4.641), along with an elevated risk of maternal anemia by about 50% (75% incidence; RR: 1.485) and preterm birth by about 60% (100% incidence; RR: 1.571). Multiple pregnancy showed increased risk by 2 times.

But none of the cohorts showed increased risk of miscarriage, liver disorder, GDM requiring insulin, placenta previa, abruption, FGR, hypothyroidism, PROM, PPROM, gest, thrombocytopenia.

Termination and delivery outcomes

Obstetric management protocols revealed very low induction of labor (IOL) rates and extremely high cesarean section (CS) delivery rates within all third-party gamete recipient sub-cohorts (Table 3). While the autologous baseline CS rate was 78.6% (77/98), the surgical delivery rate escalated to 87.5% (7/8) in the donor egg arm, 81.8% (9/11) in the donor sperm arm, and reached 100% (8/8) in the dual donor arm.

Perinatal and neonatal trajectories

A comprehensive total of 159 neonates derived from the 125 maternal cases was structurally analyzed comparing the incidence and relative risks across the cohorts (Table 4). The data showed a distinct, elevated incidence of extremely low birth weight (ELBW) infants across all third-party gamete exposure categories compared to the autologous control group (15% in donor egg, 23% in donor sperm, and 14% in dual donor vs 12% baseline). To summarise there is increased risk of ELBW of about 31 % with donor ovum, 96% with donor sperm 21 % with donor egg and sperm. Conversely, there was no statistically significant variance or raw baseline increase observed across the groups regarding standard low birth weight (LBW) frequency, intrauterine death (IUD) incidence, or overall neonatal intensive care unit (NICU/SNCU) admission rates. Furthermore, structural tracking demonstrated that donor gamete exposure did not present a statistically significant correlation with congenital anomalies or fetal abnormalities requiring therapeutic MTP.

Multivariable logistic regression and predictor modeling

Since we already saw the elderly and pre-existing comorbidities distribution are more among the donor cohorts, this might significantly be the reason of adverse outcomes. In the present study, we have done multiple logistic Regression analysis to find if donor status is an individual predictor of selected adverse outcomes.

Hypertensive disorders of pregnancy

To determine the true independent predictive value of specific gamete sources, a multiple logistic regression model adjusted for maternal age age>35 years, and comorbities like pre-gestational diabetes, maternal obesity, chronic hypertension, antiphospholipid syndrome (APLA) positivity etc was compiled (Table 5).

The model demonstrated that dual donor gametes (combined donor ovum and sperm) emerged as a powerful, highly significant independent predictor for the development of HDP, triggering an approximate 12-fold expansion in disease odds (OR: 12.06, 95 % CI 0.68-214.80, p=0.040). Isolated donor sperm or donor ovum configurations did not demonstrate an independent, statistically significant risk prediction for HDP once adjusted for confounders (p>0.05).

Preterm birth

Multivariable regression modelling confirmed that donor gamete placement of all 3 donor cohorts were not an independent predictor of preterm delivery (p>0.05) as shown in table 6

Gestational diabetes mellitus

Cross-tabulation modelling evaluating the use of donor gametes against management tracks (medical nutrition therapy, oral hypoglycemic agents, or insulin dependency) proved that third-party gametes do not independently predict GDM development (p>0.05).

Congenital anomalies

Multiple logistic regression analysis showed that none of the donor cohorts displayed any significant prediction or increased risk of congenital anomalies.

Table 1: Incidence of adverse maternal outcomes are across the 4 cohorts.

Adverse outcomes	Own sperm and egg (99)		Donor egg (8)		Donor sperm (11)		Donor egg and sperm (8)	
	Incidence %		Incidence %		Incidence%		Incidence%	
Threatened miscarriage (46)	36	36.4	6	75	1	9.1	3	37.5
GDM (71)	56	50.5	6	75	5	45.5	4	50
HDP (82)	58	58.6	7	12.5	9	81.8	8	100
S.PE (26)	16	16.2	1	12.5	3	27.3	6	75
Anemia (68)	50	50.5	7	87.5	5	45.5	6	75
Preterm birth (85)	63	63.6	5	62.5	9	81.8	8	100
Multiple pregnancies (40)	26	26.3	4	50	5	45.5	5	62.5
FGR (97)	79	79.8	5	62.5	8	72.7	5	62.5

Table 2: Relative risk of adverse maternal outcomes across the cohorts.

	RR of donor egg	RR of donor sperm	RR of donor egg and sperm
GDM	1.485	0.900	0.990
HDP	0.213	1.397	1.707
S.PE	0.773	1.687	4.641
Anemia	1.732	0.900	1.485
Preterm birth	0.982	1.286	1.571
Multiple pregnancies	1.904	1.731	2.380
FGR	0.783	0.911	0.783

Table 3: Comparison of IOL rates, caesarean section rates and category 1 CS rates across the four cohorts.

	Own sperm and egg (99)	Donor egg (8)	Donor sperm (11)	Donor egg and sperm (8)
IOL rates (13)	10 (10%)	1 (12%)	2 (18%)	0
CS rates (101)	77 (77%)	7 (88%)	9 (81%)	8 (100%)
Cat 1 CS (17)	13	0	2	2

Table 4: Comparison of incidence and relative risk of adverse fetal outcomes across the cohorts.

Fetal outcomes	Own sperm and egg (119)	Donor egg (13)		Donor sperm (13)		Donor egg and sperm (14)	
	Incidence	Incidence	RR	Incidence	RR	Incidence	RR
LBW	80%	77%	0.964	85%	1.060	86%	1.074
ELBW	12%	15%	1.308	23%	1.962	14%	1.214
NICU/SNCU admission	77%	92%	1.194	85%	1.094	100%	1.293
IUD	1%	0	0	0	0	1%	-
Congenital anomalies	24%	15%	0.654	15%	0.654	0	0

Table 5: Multiple logistic regression analysis of HDP.

Variables	Ref	B	S.E.	p	Odds (95% CI)
Age >=35	<35	0.54	0.53	0.302	1.72 (0.61 - 4.82)
Pre gestational diabetics	No	7.57	22.79	0.740	1.56 (0.5 – 2.3)
Obesity	No	1.91	1.09	0.049**	10.72 (1.8 - 56.41)
Chronic hypertension	No	6.49	26.22	0.804	2.6 (0.12 – 3.2)
APLA+	No	1.60	1.25	0.200	4.95 (0.43 - 57.2)
Use of donor ovum	Own egg and sperm	1.60	1.09	0.142	4.95 (0.59 - 41.06)
Use of donor sperm	Own egg and sperm	1.16	0.81	0.152	3.18(0.65-15.50)
Use of donor ovum and sperm	Own egg and sperm	2.49	1.47	0.04**	12.06 (0.68- 214.8)

: Among donor cohort, donor ova and sperm group is a strong independent predictor and increased risk up to 12 times as shown. (: p<0.05 significant).

Table 6: Multiple logistic regression analysis of preterm birth.

Variables	REF	B	S.E.	p	Odds (95% CI)
Age (>=35)	<35	0.30	0.45	0.504	1.35 (0.56 - 3.29)
Pre gestational diabetics	No	8.08	23.53	0.731	0.61 (0.1 – 2.13)
Chronic hypertension	No	7.86	26.40	0.766	1.8 (0.07 - 8)
Apla	No	0.47	1.02	0.47**	9.6 (2 - 11.85)
Use of donor ovum	Own gametes	0.05	0.76	0.949	1.68 (0.49 -10.9)
Use of donor sperm	Own gametes	0.94	0.81	0.243	2.57 (0.53-12.56)
Use of donor ovum and sperm	Own gametes	2.28	1.47	0.121	9.77 (0.55-174.27)

: Among donor cohorts none of them displayed significant prediction for preterm birth. (: p<0.05 significant).

DISCUSSION

This prospective comparative study of 125 IVF-conceived pregnancies is among the first from the Indian subcontinent to stratify obstetric and perinatal outcomes across all four gamete-origin configurations-autologous, donor sperm, donor oocyte, and dual donor in the post-ART (Regulation) Act 2021 regulatory era. A reviewer's first instinct on seeing donor arms of 8–12 patients against an autologous arm of 98 is to question power. We would argue, however, that this distribution is not a sampling artefact but a faithful mirror of real-world ART practice in India.

Consecutive, non-selective recruitment was used deliberately instead of matched or quota sampling, precisely so that the cohort would reflect the true clinical case-mix of a tertiary referral unit rather than an artificially balanced trial population. Although published Indian data on the actual proportion of donor-gamete cycles among total ART cycles remain scarce, available evidence about attitude of Indian infertile couples towards donor gametes suggests relatively low acceptability of donor gametes 7, a pattern broadly consistent with the modest overall donor-gamete utilization observed in our own cohort that is 21.6% combined donor-gamete proportion (n=27/125) observed in our cohort.

In an Indian retrospective study spanned over 7 years (2011-2017) to get a sample of 102 ovum donor cohort, similarly several large Western series used for outcome benchmarking—including the Brussels matched-pair series (205 donor oocyte pregnancies over 10 years) and the Swedish national cohort (76 donor oocyte

recipients)—While these long study periods yield larger cohorts, they inherently introduce confounding variables.[8-10] Over a span of 7 to 10 years, shifts in clinical guidelines, evolving definitions of ovarian response, advancements in laboratory media, and changes in embryo transfer strategies (such as the transition from cleaved-stage to routine blastocyst transfer) can drastically alter outcomes. Consequently, data pooled across a decade may reflect historical shifts rather than contemporary clinical efficacy. In contrast, the merit of our study is in evaluating a donor cohort within a compressed, contemporary 18-month window offers a precise, real-time snapshot of modern reproductive medicine.

Coming to baseline profile comparison, our donor oocyte and dual donor recipients were older and carried a 100% burden of pre-existing comorbidity at registration, while donor sperm recipients skewed younger. This pattern recapitulates findings from both Western and Indian comparative cohorts. An AIIMS cohort comparing donor-oocyte IVF with spontaneous conception reported a similar older sample in donor egg cohort.[8] In Western literature, the large Israeli cohort study of women aged 40–45 years found that oocyte donation recipients were, had a divergent comorbidity and socioeconomic profile than autologous IVF or spontaneously conceiving women of the same age band.[11]

Recipient-predictor data from a large Indian private ART centre likewise documented declining endometrial receptivity and adverse outcome trends in recipients above 40 years of age, reflecting a similar demographic skew in the Indian donor-recipient population at large.[12] Taken together, the demographic signature in our cohort—older, comorbid donor oocyte and dual donor recipients alongside younger donor sperm recipients with predominantly male-factor or severe oligospermic indications—is therefore not an idiosyncrasy of our centre but a consistent, internationally reproducible feature of who self-selects into each donor pathway, and this must be accounted for when interpreting crude risk ratios, which is precisely why our multivariable models adjusted for age and comorbidity before attributing risk to gamete source itself.

The leading biological explanation for the excess hypertensive and placental morbidity in donor-conceived pregnancies remains the allogenic/immune-maladaptation hypothesis: in pregnancies conceived with completely non-maternal oocytes, the trophoblast presents a wholly paternal-and-donor antigenic load to the maternal immune system, attenuating the regulatory T-cell-mediated tolerance that normally permits adequate spiral artery remodelling, with consequent shallow trophoblast invasion and a preeclampsia-like phenotype. Several independent meta-analyses converge on this point.

A pooled analysis of eleven cohort studies estimated roughly a three-fold increase in the odds of preeclampsia with oocyte donation compared with autologous IVF, and a later systematic review covering studies up to mid-2016 calculated a comparably elevated relative risk of approximately 2.614.[13] Separately, the largest synthesis to date—drawing on more than 86,000 pregnancies—reported roughly a two-fold rise in preeclampsia risk and a threefold rise in gestational hypertension risk with oocyte donation relative to other forms of ART, with the gap widening further against natural conception15. One meta-analysis of insemination pregnancies calculated a pooled adjusted odds of 1.77 for preeclampsia and 1.55 for hypertensive disorders generally when donor sperm was used in place of partner sperm16. May be both these added double donor cohort as an independent predictor of HDP.

Our own data show the dual donor cohort posting the single highest point estimate for nearly every adverse outcome we measured a pattern that would fit an additive or cumulative-risk model. Yet a 2022 review that set out specifically to compare oocyte donation against double gamete donation found the two groups did not differ significantly in preeclampsia or gestational hypertension risk, which raises the alternative possibility that the immunological burden from a donor oocyte alone is already close to a "ceiling," beyond which an additional donor-sperm contribution adds comparatively little.[17] The dual donor arm is too small to settle which model fits better, but the consistently higher point estimates we observed still support treating dual donor recipients as the highest-priority subgroup for individualised counselling until larger studies clarify the picture.

Donor oocyte and dual donor cohorts in our study also carried a disproportionate burden of multiple gestation, a well-recognised independent driver of hypertensive disease, preterm birth, and low birth weight in its own right. Because embryo-transfer practices in donor cycles have historically favoured transfer of more than one embryo to maximise per-cycle success, some of the excess morbidity attributed to "donor status" in older literature may in fact be transfer-practice-related rather than purely immunological; the Indian recipient-predictor cohort specifically demonstrated that single (rather than double) embryo transfer reduced multiple pregnancy rates in donor cycles without compromising outcome, an important, modifiable lever for Indian ART practice going forward.[12]

A striking and clinically actionable observation in our cohort was that more than half of the donor egg and dual donor patients presented as late referrals to the tertiary unit, by which point comorbidities were already established and the window for early risk-stratified antenatal planning had narrowed. While donor-gamete pregnancies are not unique in this regard, the broader obstetric literature consistently links delayed engagement with specialised antenatal care to a higher burden of adverse maternal and perinatal outcomes, largely because early risk-stratification, baseline investigations, low-dose aspirin prophylaxis where indicated, and surveillance scheduling are all time-sensitive interventions that lose effectiveness the later they are instituted.[18,19] In the setting,

donor oocyte and dual donor pregnancies are frequently initiated at private fertility clinics and only referred to a tertiary obstetric unit once a complication has already declared itself by which time the opportunity for first-trimester risk stratification (uterine artery Doppler, biochemical markers, prophylactic aspirin initiation before 16 weeks) has typically passed. We believe this referral pattern, rather than biology alone, plausibly contributes to part of the excess severe morbidity seen in our donor oocyte and dual donor cohorts, and represents a modifiable system-level factor rather than an immutable biological one. We would advocate that fertility clinics performing donor-gamete IVF establish structured early-pregnancy referrals to tertiary or high-risk obstetric units immediately upon confirmation of a donor-conceived pregnancy, rather than waiting for a complication to trigger referral.

The near-universal caesarean delivery rate in our donor cohorts (87.5–100%) considerably exceeds even our already-high autologous-cohort rate (78.6%), a pattern that echoes findings from a Swedish national registry-linked cohort, which reported markedly raised adjusted odds of both caesarean delivery (up to roughly 5-fold) in oocyte donation pregnancies relative to spontaneous conception and to autologous IVF alike.[10]

This likely reflects a combination of genuine obstetric indication (higher rates of HDP, growth concern, and multiple pregnancy necessitating operative delivery) and a lower threshold for operative intervention driven by the "precious pregnancy" phenomenon—clinicians and patients alike being less willing to accept the risks of labour in a donor conceived, often long-awaited pregnancy.

Despite this maternal morbidity gradient, our perinatal findings are somewhat reassuring: rates of LBW, NICU/SNCU admission, intrauterine death, and congenital anomaly did not differ significantly by gamete source. This fits with a recurring observation in the donor gamete literature that, even where maternal complications are clearly more frequent, fetal and neonatal outcomes tend to remain comparatively favourable—the Brussels matched pair cohort, for instance, found no meaningful difference in gestational age, birth weight, or Apgar scores between donor and autologous groups once matched for age and plurality.[9]

The selectively elevated ELBW incidence we observed across all three donor arms, however, stands out and warrants closer attention. Author think the most likely explanation is not a distinct fetal pathology of donor conception, but rather a downstream consequence of the same hypertensive and placental pathway driving the maternal morbidity described above—that is, early, often iatrogenic, preterm delivery undertaken because of severe maternal hypertensive disease or growth-restriction concern.

The principal strengths of this study are its prospective design, consecutive (non-selective) sampling reflecting real-world donor-gamete case-mix, and inclusion of all four gamete origin permutations including the rarely reported dual donor group within a single comparative framework, an approach seldom available even in larger Western registries.

Limitations include the modest absolute size of the donor arms (discussed above), the single-centre tertiary referral setting which may itself enrich for higher-risk, later-referred donor pregnancies and thereby overestimate population-level risk, the wide confidence intervals around several regression estimates, and the inability to fully separate the contribution of embryo-transfer practices (such as multiple embryo transfer) from gamete source itself.

CONCLUSION

In this prospective South Indian tertiary care cohort, conducted in the regulatory context of the ART (Regulation) Act 2021, the use of donor gametes and particularly dual donor gametes was associated with a consistently higher burden of hypertensive disorders of pregnancy, severe pre-eclampsia, gestational diabetes, anaemia, multiple pregnancy, and preterm birth compared with autologous IVF, with dual donor status emerging as the only independent predictor of HDP on multivariable analysis (OR 12.06).

Donor oocyte and dual donor recipients were older and uniformly carried pre-existing comorbidity at presentation, and more than half were late referrals to tertiary care, a pattern that likely compounds the underlying immunological risk by delaying early risk-stratified surveillance and prophylaxis.

Caesarean delivery rates were markedly elevated across all donor cohorts, and although most perinatal outcomes were reassuring, extremely low birth weight was increased across all donor categories, plausibly reflecting iatrogenic early delivery for maternal indications. While the small absolute size of our donor cohorts reflects the genuine rarity of these pregnancies in real-world Indian ART practice rather than a sampling flaw, it does limit the precision of our risk estimates, and larger, ideally multicentric, Indian data are needed to refine these findings.

In the interim, our results support three concrete practice changes: first, that all donor-gamete pregnancies particularly dual donor pregnancies be counselled and managed as high-risk from conception; second, that fertility clinics establish early, structured referral pathways to tertiary obstetric care rather than waiting for complications to declare themselves; and third, that first-trimester risk stratification and prophylactic strategies (such as aspirin for pre-eclampsia prevention) be proactively offered to donor-gamete recipients rather than

reactively deployed after a complication has already developed

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