Assessing the Integrity of Randomised Controlled Trials in Obstetrics and Gynaecology: A Systematic Evaluation

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Background and Aim

Background

Concerns regarding the reliability of randomised controlled trials (RCTs) are increasing, with evidence that a proportion of published studies may contain inconsistencies or errors. Detecting such issues retrospectively is challenging, particularly when these trials contribute to systematic reviews and inform clinical practice.

Aim

To systematically evaluate a cohort of obstetrics and gynaecology RCTs, identified during a meta-analysis, for methodological consistency, data integrity, and reproducibility of reported findings.

Material and Methods

RCTs identified during a meta-analysis were assessed for methodological quality, internal consistency, p-value accuracy, and trial registration details. All included studies were authored by a single first author. Pairwise comparisons of baseline characteristics and outcome data were undertaken to identify identical values or recurring patterns suggestive of overlap or duplication. Reported statistical results were independently recalculated, and recruitment timelines were compared against trial registry records.

Figure 1

Similarities between different studies. The blue dots represent identical values. The red circle represents identical values in different categories.

Eftekhar 2012b[1] (tables on left) was published in *Arch Gynecol Obstet.* In this study, 134 women with previous failed IVF were randomised to culturing vitrified-thawed cleavage stage embryos to blastocyst stage or 1 day before embryo transfer.

Eftekhar 2012d[2] (tables on right) was published in *Int J Fertil Steril.* In this study, 130 women with previous failed IVF were randomised to receive intrauterine HCG injection on the first day of progesterone administration and day of embryo transfer, or were allocated to control.

Table 1: Basic patient characteristics in the two groups

Variables	HCG group Mean (SD)	Control group Mean (SD)	P value
Age (Years)	28.47 ± 4.14	28.84 ± 3.71	0.549
Duration of infertility (Years)	6.58 ± 2.9	6.09 ± 2.74	0.368
Basal FSH (IU/L)	5.15 ± 1.66	5.60 ± 1.72	0.135
BMI (kg/m²)	23.67 ± 2.43	23.86 ± 2.3	0.661

Table 2: Cycle characteristics and outcome of vitrification

Variables	HCG group Mean (SD)	Control group Mean (SD)	P value
Duration of freezing (Months)	6.58 ± 3.1	6.09 ± 2.74	0.326
Number of thawed embryos	2.96 ± 0.17	2.89 ± 0.31	0.086
Survival rate after thawing (%)	91.79 ± 0.20	94.87 ± 0.12	0.299
Numbers of transferred embryos	2.73 ± 0.44	2.60 ± 0.49	0.095

Table 3: ART outcome in both groups

Variables	HCG group	Control group	P Value
Implantation rate (%)	21.02	17.44	0.488
Chemical pregnancy rate, n (%)	27 (41.5)	25 (38.5)	0.429
Clinical pregnancy rate, n (%)	22 (30.8)	20 (30.8.7)	0.426
Ongoing pregnancy rate, n (%)	20 (30.8)	18 (27.7)	0.424
Miscarriage rate, n (%)	7 (25.9)	7 (28.0.4)	0.556
Endometrial thickness (mm)	8.83±1.6	9.08±1.2	0.528

Table 1 Baseline characteristics of patients in both groups

Variables	Blastocyst group ($n = 63$)	Cleavage group ($n = 65$)	*P* value
Female age (years)	28.20 ± 3.94	28.84 ± 3.71	0.347
Duration of infertility (years)	5.85 ± 2.32	5.47 ± 2.86	0.412
Basal FSH (IU/L)	5.66 ± 2.03	5.60 ± 1.72	0.842
BMI (kg/m²)	23.23 ± 3.43	23.86 ± 2.36	0.236

Table 2 The cycle characteristics and outcome of vitrification in both groups

Variables	Blastocyst group ($n = 63$)	Cleavage group ($n = 65$)	*P* value
Duration of freezing (months)	6.70 ± 3.10	6.09 ± 2.70	0.220
Number of thawed embryos	2.92 ± 0.27	2.89 ± 0.31	0.586
Survival rate after thawing (%)	94.18 ± 0.12	94.87 ± 0.12	0.754
Number of transferred embryos	1.82 ± 0.58	2.70 ± 0.44	0.000

Table 3 ART outcome in both groups

Variables	Blastocyst group ($n = 63$)	Cleavage group ($n = 65$)	*P* value
Implantation rate	30 %	17.44 %	0.000
Chemical pregnancy rate	30 (47.6 %)	23 (35.4 %)	0.209
Clinical pregnancy rate	27 (42.9 %)	18 (27.7 %)	0.053
Ongoing pregnancy rate	27 (42.9 %)	16 (24.6 %)	0.023
Miscarriage rate	3 (10 %)	7 (21.4 %)	0.063

Results

Eighteen RCTs were included, all originating from a single first author.

- **Data Duplication:** Multiple study pairs demonstrated substantial similarities, including baseline data findings highly suggestive of duplication.
- **Statistical Inconsistencies:** Recalculation of reported p-values failed to reproduce statistical significance in several studies with positive findings, reversing the original conclusions.
- **Registry Discrepancies:** Inconsistencies between reported recruitment periods and trial registry data were identified, including implausible durations.

Conclusion

These findings highlight important challenges in ensuring the integrity and reliability of published RCTs within obstetrics and gynaecology. Incorporating systematic data verification and reproducibility checks into evidence synthesis may help identify problematic studies. Strengthening transparency, trial reporting standards, and access to underlying data is critical to maintaining confidence in the evidence base guiding clinical practice.

[1] *Eftekhar M, Aflatoonian A, Mohammadian F, Tabibnejad N. Transfer of blastocysts derived from frozen-thawed cleavage stage embryos improved ongoing pregnancy. Arch Gynecol Obstet. 2012;286:511-6.*
[2] *Eftekhar M, Rahmani E, Eftekhar T. Effect of Adding Human Chorionic Gonadotropin to The Endometrial Preparation Protocol in Frozen Embryo Transfer Cycles. Int J Fertil Steril. 2021;15:305-306. Erratum for: Int J Fertil Steril. 2012;6:175-8.*

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