Abstract Details

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Abstract title:

Is ICSI ethically supported by evidence as the method of fertilisation in donor oocyte cycles, in the absence of a medical indication?

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Study question:

Does ICSI improve success in donor oocyte cycles in the absence of a medically indicated reason?

Summary answer:
IVF results in a higher clinical pregnancy and live birth rate whilst ICSI has a lower failed fertilisation rate.

What is known already:
Donor oocytes have expanded the scope of assisted reproductive technology (ART) for women unable to conceive with autologous oocytes, and resulting in higher live birth rates. However, the degree of anxiety surrounding donor cycle outcomes is increased, with some advocating ICSI for all donor oocyte cycles to reduce the likelihood of failed fertilisation. ICSI has a clear role in the management of male factor subfertility, but its use for other indications has yet to be proven. A recent RCT performed in autologous oocyte cycles demonstrated no additional benefit with ICSI in cases of non-male factor subfertility.

Study design, size, duration:
Retrospective cohort analysis of all cycles conducted between 2002-2016, from the Human Fertilisation and Embryology Authority database. 23,589 fresh donor cycles (12,989 IVF cycles; 12,400 ICSI cycles), excluding male factor subfertility were undertaken. Assuming that the live birth rate for IVF is 30% and 40% for ICSI cycles, a power calculation demonstrated that 712 cycles would need to be analysed for 80% power and a 5% significance level to detect 10% difference.

Participants/materials, setting, methods:
The database was analysed for singleton live birth rate (SLBR), stratified by recipient age, donor age, number of previous IVF treatments and type of cycle (fresh IVF versus fresh ICSI). Cycles complicated by male factor subfertility were excluded from the final analysis as this is known to influence the method of fertilisation. Statistical analysis was performed using Logistic Regression and Chi-square; $p<0.05$ was considered statistically significant.

Main results and the role of chance:
The overall IVF to ICSI ratio for donor oocyte treatment cycles in the absence of male factor subfertility favoured IVF (68:32) in 2002, with a yearly rise seen in ICSI cycles reaching 42:58 in 2016.

The clinical pregnancy rate is statistically higher with donor IVF (n=4721;40.5%) versus donor ICSI cycles (n=4280;38.3%) (odds ratio [OR] 1.10, 95% confidence intervals [CI] 1.04-1.16, p=0.0009).

The overall live birth rate per embryo transferred was higher in the IVF group (n=5,230;26.6%) compared with ICSI (n=4,593;24.1%). The OR was calculated using binary logistic regression and adjusted for recipient age, donor age, number of previous IVF cycles and cause of subfertility, giving IVF an OR 1.13 (95% CI 1.04-1.23, p=0.004).

The failed fertilisation rate was higher for IVF (n=270;2.08%) compared with ICSI (n=196;1.58%) (relative risk [RR] 1.32, 95% CI 1.09-1.58, p<0.0001). Furthermore, the data from this study suggests that the number needed to treat to prevent one failed fertilisation through IVF is 200 cycles of ICSI.**Limitations, reasons**

for caution:
The accuracy of the database is dependent on the information submitted to the HFEA. Until 2007, this data was manually captured adding the risk of data entry error. Furthermore, information on embryo quality is not available including the inability to account for cumulative pregnancy rates in women with previous attempts.

Wider implications of the findings:
The reduction in the failed fertilisation rate does not translate to an improvement in the live birth rate and therefore, ICSI does not confer any additional benefit compared to IVF. This provides patients with the ability to make an informed choice of IVF over ICSI, with an overall cost saving.

Trial registration number:
Not applicable

Keywords:
in-vitro fertilisation
intracytoplasmic sperm injection
donor oocytes
non-male factor subfertility
failed fertilisation