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Equivalence observed in fertilisation rates between microICSI, a new ICSI tool, and conventional ICSI. The first evaluation of microICSI fertilisation of human oocytes.

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**Study question:**

Does a new microfabricated device that replaces the holding pipette (microICSI) support equivalent fertilisation rates compared to conventional ICSI?

**Summary answer:**

No difference in 2PN and all fertilised oocytes was observed with microICSI (80%) compared with conventional ICSI (73%,  $P=0.49$ ). No other differences were observed.

**What is known already:**

The microICSI is a new device developed by Fertilis Pty Ltd, which requires only one set of micromanipulators to operate. Previous studies comparing microICSI in a porcine model and sham-injected human discarded oocytes have suggested improvements in development (porcine) and procedural efficiency (porcine and human). Here, we utilised delayed maturation and vitrified human MII oocytes which were not used for treatment and obtained with informed consent from patients, to evaluate microICSI devices for fertilisation.

**Study design, size, duration:**

This study is an experimental laboratory-based research using a randomized comparative design. A total of 106 vitrified and delayed maturation human MII oocytes were randomly assigned to either conventional ICSI ( $N=52$ ) or microICSI ( $N=54$ ) across three replicates.

**Participants/materials, setting, methods:**

The study utilised vitrified and delayed maturation human MII oocytes that were not used for treatment and obtained with informed consent from patients. Fertilisation outcomes, including pronuclear formation and post-injection viability, were assessed 18 hours after injection. All materials were disposed of following assessment. Time required to set up and perform each injection procedure was also measured. Statistical analysis was performed using Fisher's exact test for proportional data and t-test for procedure times.

**Main results and the role of chance:**

This is the first study reporting results of human oocytes injected with human sperm using the microICSI microfabricated device. Total fertilisation rate (including 3 or 4 PN's) tended higher using the microICSI device compared to conventional ICSI (80% vs 73%, respectively,  $P=0.49$ ). The percentage of normally fertilised oocytes, as assessed by the formation of 2PN, did not differ (57% vs 58%). Lysis rates tended lower for microICSI compared with conventional ICSI, (3% vs 10%,  $P=0.26$ ). Time to set up the two different procedures and perform the injections also did not differ. The difference in total fertilisation and lysis rates did not reach statistical significance, so there is a strong chance that this difference could be obtain with further additional data.

**Limitations, reasons for caution:**

The use of delayed maturation and vitrified human MII oocytes may not sufficiently replicate what occurs with on-time matured oocytes; the difference in oocyte quality could be more variable, therefore exaggerate potential differences.

**Wider implications of the findings:**

The microICSI is at least equivalent to conventional ICSI in terms of fertilisation rate for compromised MII oocytes. Further data and analysis is required to properly evaluate the benefits of microICSI compared to conventional ICSI.

COI

No conflict of interest

Keywords

microICSI

New ICSI device

fertilisation