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P-145 Direct-ICSI results in good embryological outcomes. A time-lapse study

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Study question: Is there a correlation between the method of sperm injection and morphokinetic and morphologic characteristics?

Summary answer: Results were comparable between the groups whereas the rate of utilizable embryos was significantly higher using Direct-ICSI. This suggests safety and efficacy using this technique.

What is known already: Maintaining high fertilization- and embryo development rates are key objectives of the IVF-laboratory. Little effort has been put into studying the effects of different manipulation techniques when performing manual microinjections. Specifically, we wanted to compare two methods for achieving cell-membrane puncture: Traditional cytoplasm aspiration technique versus membrane stretching and injection without aspiration –the so-called Direct ICSI method. This method has been proposed to give higher fertilization rates and is being implemented in IVF-laboratories to try to increase ICSI-results. As far as we are aware, no detailed comparison between the two methods on embryo development using time-lapse documentation has been published.

Study design, size, duration: The study included 44 ICSI-treatments from April 2020 to October 2021 with 119 oocytes injected with Direct-ICSI and 349 sibling oocytes using the conventional aspiration-ICSI technique. In this way, each patient contributed oocytes for both test- and control groups. However, as this was a pilot study, typically only a minority of the oocytes for each patient was injected using the Direct-ICSI method. All fertilized oocytes were included in the assessments up to the blastocyst stage.

Participants/materials, setting, methods: The center is a public funded University clinic performing >500 ICSI cycles annually. Inclusion criteria were treatment cycles using fresh own oocytes with ejaculated sperm and at least 5 injectable oocytes after denudation. Time lapse culture was performed using the Embryoscope+ with GTL culture media, both supplied by Vitrolife. Clinical and laboratory procedures were performed according to standard practice. Fisher's exact test (categorical variables) and Mann-Whitney U test (continuous variables) were used for statistical analysis.

Main results and the role of chance: In total, 314 oocytes (67,1%) were fertilized and included in the morphology and morphokinetic assessments up to the blastocyst stage (day 5 or day 6 post-fertilization). Time-lapse parameters such as timing of cell division events and time to morula, time to blastocyst and similar were not significantly different between the groups. Rates of categorical classification of embryological anomalies such as degree of fragmentation, rate of multinucleated cell events, uneven cell size and irregular cell division events also did not differ significantly between the groups. Interestingly however, although fertilization rates did not differ between the two groups (68,1% in the test group vs 67,6% in the control group), the rate of utilizable embryos per injected oocyte was significantly higher in the Direct-ICSI group (40,3% vs 29,5%, $p < 0.03$), whereas the pregnancy rates did not differ between the groups.

Limitations, reasons for caution: The present study is a small pilot study with a limited number of cycles, however with 468 oocytes included. The study utilized internal (sibling) controls although oocytes were not truly randomized between the groups. To fully test the efficiency of Direct-ICSI a larger randomized study should be performed.

Wider implications of the findings: Our results indicate that Direct-ICSI is a safe method with no visible indication of irregularities in preimplantation cell division events using time-lapse monitoring. Aspirating an excess amount of cytoplasm during ICSI might impact embryo development, possibly explaining the increase of utilizable embryos in the Direct-ICSI group, where aspiration is avoided.

Trial registration number: Not applicable