Abstract Details

Session title: Session 49: Intelligent automation in the embryology laboratory
Session type: Selected oral communications
Presentation number: O-170

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Clinical validation of an automatic time-lapse algorithm classification system for blastocyst selection

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Study question:

Is there a correlation between an automatic time-lapse algorithm classification(Xtend) with blastocyst implantation potential? If so, is standard morphology compatible or combinable with Xtend analysis?

Summary answer:
There is a direct correlation between Xtend-categories with implantation potential of blastocysts. This relationship is even more evident in good-quality embryos according to standard morphology.

What is known already:
Aparicio-Ruiz et al. 2016 validated an automatic algorithm by which embryos were classified based on the values of P2 (t3-t2; second cell cycle) and P3 (t4-t3; synchrony). This algorithm was improved including more parameters (number of cells on day 3, egg age and changes of the texture of the embryo from 42 to 60 hours after ICSI) in order to classify embryos in 5 different categories (1-5).

Study design, size, duration:
Retrospective cohort study (egg donation program) performed in a University-affiliated infertility clinic on 1031 embryos analyzed from April 2016 to October 2018.

Participants/materials, setting, methods:
The study includes 362 patients and 1031 embryos generated by ICSI in the egg donation program and incubated in a GERI Time-Lapse Incubator (Genea, Australia) with especially designed scopes that used dark field microscope and an automatic cell-tracking software (Eeva, Xtend).

Main results and the role of chance:
A total of 1031 embryos were incubated in the Geri-system. Without distinguishing if embryos transferred were fresh or previously thawed, implantation rates of KID blastocysts(n=514) were directly correlated with the Xtend classification(1:53.91%; 2: 52.63%; 3:45.68 %; 4:39.02%; 5:24%). These differences were statistically significant p=0.017.

We assembled different Xtend categories and studied implantation rates in two groups: 1-3(52%) or 4-5(32.90%), showing significant differences between both groups (p= 0.003).

To check if algorithm selection properties were conditioned by morphology of blastocysts, we separated good quality(A/B according to ASEBIR morphology classification) from those with worse quality(no A/B).When Xtend categories were grouped, important differences were observed in percentage of A/B blastocyst between 1-3(83.9%) and 4-5(16.10%) that were less evident for not good quality blastocysts: 1-3(54.1%) and 4-5(45.9%)(p<0.0001).

Even though no significant differences were observed, the algorithm seemed to define better implantation potential in good quality blastocysts(1:56.7%; 2:55.9%; 3:51.6%; 4:39.35; 5:27.8%) than in those not classified as A/B(1:33.3%; 2:36.4%; 3:23.5%; 4:41.7%; 5:18.2%). We also performed a logistic regression model for implantation, in which BMI, number of MII donated and standard morphology were included. The model assembled Xtend(1-3 vs 4-5) presented an OddsRatio(OR) of 1.917(CI95%1.40-3-77) and blastocyst morphology(A/B vs not A/B) OR of 2.30 (CI95% 1.11-3.30).

Limitations, reasons for caution:
Retrospective nature of this study may be a reason for caution; nevertheless, is the largest sample size reported with this test, based in blastocyst transfer with>90% of single-embryo-transfer, additionally a multivariable-analyisis confirmed the magnitude of the results. The classification system has some errors due to difficulties in cell-tracking generating “none-result”.

Wider implications of the findings:
To our knowledge, this is the biggest set of data using Xtend-algorithm. Results obtained validate the utility of this classification and showed higher accuracy in good-morphology blastocysts. It confirms that morphology and time-lapse classifications are independent and combinable showing that not all embryos classified morphologically asA/B correspond with better Xtend-categories.

Trial registration number:
Not applicable

Keywords:
Embryo
Morphokinetics
time-lapse
Algorithm
implantation