Risk analysis using EuroGTP II and reliability of the semi-automatic time-lapse annotation system Geri Assess 2.0 in embryo evaluation

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ABSTRACT

Aim: To assess the risk associated with the implementation of the semi-automatic time-lapse system Geri® Assess 2.0 for the morphokinetic analysis of embryos from fertilisation to...

Objective: Risk assessment associated with the implementation of the semi-automatic time-lapse system Geri® Assess 2.0 for morphokinetic analysis of embryos, from fertilisation to blastocyst, using artificial intelligence to predict implantation quality and capacity; with integration of software reliability results using the Euro-GTP II framework.

Methods: The risk assessment è was conducted according to the three phases foreseen by EuroGTP II, taking into consideration the results of the study *"Investigation of the reliability of semi-automatic annotation by the Geri time-lapse system"* (Reprod Biomed Online, 2022), including identification of the technological novelty, risk analysis and determination of the extent of studies required.

Results: The EuroGTP II analysis identified critical risks related to non-detection of anomalies (R=16) and over-dependence on software (R=20). The experimental study showed automatic detection rates between 0% and 94.4%, with sensitivity 68.2–94.4% and specificity 63.8–97.3%. Automatic annotation required manual intervention in 55.2% of the oocytes and showed a concordance with manual scoring of 42.1%, which increased to 66.0% after correction. The software showed important limitations in detecting "direct cleavage" (in some cases 0%) and"reverse cleavage".

Conclusions: Geri Assess 2.0 is a useful tool as an aid to morphokinetic assessment, but cannot be used as a primary decision-making system, so verification with the EURO GPT II system results in a moderate risk. The EuroGTP II approach enables systematic risk management by defining the necessary mitigation measures to ensure quality and safety in clinical use. Mandatory review of all automatic annotations by qualified embryologists è manual verification è essential for risk mitigation.

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Introduction

Substances of human origin (SoHO) are being used in an increasing number of innovative clinical applications, including time-lapse technologies applied to medically assisted procreation (MPA). The rapid development of new blood, tissue and cell (BTC) components, as well as new preparation protocols, makes it necessary to adopt standardised processes to identify, quantify and manage the potential risks associated with their clinical implementation.

In this context, the EuroGTP II tool, developed by the EDQM, is a risk assessment system designed to:

1. determine whether a BTC or process represents a novelty compared to the standard (Phase 1);
2. evaluate associated risks through a combination of probability, severity and detectability (Phase 2);
3. define the extent of studies and follow-up required to ensure safety and efficacy (Phase 3).

The introduction of the semi-automatic time-lapse system Geri Assess 2.0 for embryo morphokinetic annotation is fully among the processes requiring a EuroGTP II assessment, given the innovative nature of the technology and its potential impact on the quality of clinical outcomes. GERI Assess 2.0 è a semi-automated time-lapse system that analyses embryonic morphokinetics, from fertilisation to blastocyst, using advanced imaging and artificial intelligence. It provides a score to predict embryo quality and implantation capacity, optimising selection and improving results in IVF treatments.

Materials and Methods

Evaluation Process via lthe EuroGTP II methodology applied to the Geri Assess 2.0 system followed the three steps provided:

Phase 1 – New Technology

Geri Assess 2.0 è been classified as “new process”, requiring:

- deep local validation,
- specific staff training,
- quality system enhancement,
- defining performance criteria (performance specifications).

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Step 2 – Risk analysis

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Risks related to:

were identified and assessed

- failure to detect critical anomalies,
- excessive reliance on automation,
- variability between operators,
- incorrect timing of kinetic events,
- possible integration errors and data loss.

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Each risk has been classified on the basis of the EuroGTP II criteria:
Probability (P), Severity (G), Detectability (R)
with risk calculation: **R = P × G**

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Phase 3 – Extension Study

The phase included:

- defining the extent of validation,
- implementation of specific KPIs,
- introduction of detailed Operating Procedures,
- indication of mandatory manual review.

513 oocytes from from 34 women were analysed. The annotations made by the Geri Assess 2.0 system for ten kinetic events (the time of pronuclei (PN) appearance and disappearance, the cleavage time for two-, three-, 4-, up to 8-cell (t2–t8) cell divisions up to the annotation of the time of blastocyst formation) were compared with manual annotations made blindly by embryologists.

The following were evaluated:

- detection rates,
- sensitivityà and specificityà,
- embryonic score matching,
- ability to identify “direct cleavage” and“reverse cleavage”
- percentage of images/events that required manual review.

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Results

EuroGTP II evaluation

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Phase 1 – Evaluation of the new process (GERI 2.0)

The technology è was new to the Centre for Medically Assisted Procreation, requiring full validation.

Stage 2 – Risk assessment

- The main risks identified in Table 1 include: false negatives in clivings anomalies (R=16, critical); over-reliance on software without expert review (R=20, critical); tincorrect filling of key events such as t2, t3, tPN (R=12, high); fpositive bias, data loss, insufficient traceability, inter-operator variability (R=8–9, moderate).

Risk identification	Prob. (1–5)	Grav. (1–5)	Rilev. (1–5)	Risk (PxG)	Level
False negatives (direct/reverse cleavage)	4	4	2	**16**	Critic
False positives: incorrectly reported events	3	3	2	9	Moderate
Incorrect timing (t2, t3, PN)	3	4	2	**12**	High
Software dependency/non-review	4	5	2	**20**	Critic
Integration/data loss errors	2	4	3	8	Moderate
Variability between operators	3	3	3	9	Moderate
Insufficient traceability	2	4	3	8	Moderate

Table 1

Results of the experimental study

- Detection rates: 0–94.4%
- Sensitivityà: 68.2–94.4%
- Specificità: 63.8–97.3%
- Concordance with manual annotation: 42.1%
  → 66% after manual annotation
- Corrections required: 55.2% of oocytes
- Direct cleavage: detection also 0%

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· Reverse cleavage: low and variable detection

These results confirm the need for expert review to ensure accuracy and security.

Risk mitigation measures

- Mandatory review of all automatic annotations by qualified embryologists.
- Double check for embryos intended for transfer/biopsy.
- Detailed Operating Procedures for Correcting Annotations.
- Initial and periodic validation of the system on local dataset.
- Complete audit trail with logging of all changes.
- Data backup and version control.
- Regular staff training on time-lapse reading.
- monthly KPIs for monitoring concordance and error rates.
- Introduction of quality controls aimed at monitoring Critical Process Parameters (CPPs)

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Discussion

The integration of the EuroGTP II results with the experimental study clearly shows that Geri Assess 2.0 can contribute to the standardisation of morpho-kinetic annotation, but cannot replace the embryologist’s analysis. The main critical issues are related to the detection of cleavage abnormalities (e.g. t1-t3 “direct cleavage” or t2-t1 “reverse cleavage"), which have a direct clinical impact on embryonic developmental potential.

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Figure 1 Risk assessment

The new tool also emphasises the need to accompany the introduction of the technology with a structured clinical follow-up programme, allowing for a rigorous comparison of the results obtained before and after its implementation and to verify its effectiveness over time. This evaluation must be complemented with a systematic comparison against data available in the literature to ensure that the performance obtained is consistent with morphokinetic data reported by other centres. With this new GERI 2.0 è it is possible to have under control the main embryo morphokinetic points and to standardise the laboratory KPIs ensuring an objective evaluation in the critical steps from fertilisation to blastocyst.

Conclusions

The EuroGTP II report explicitly concludes:

“The semi-automatic annotation of the Geri® Connect & Assess system can only be used safely with mandatory manual review and after documented local validation. Residual risk è acceptable as an aid, not as a primary decision-making tool.”

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