

## Article

## Reliability and agreement on embryo assessment: 5 years of an external quality control programme

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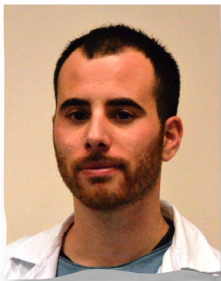
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### KEY MESSAGE

A reliability and agreement study, based on a national external quality programme for morphology-based embryo quality assessment, has helped identify specific early embryo characteristics that are difficult to assess, including multinucleation, vacuolation and inner cell mass morphology. These findings have implications for the design of external quality-control programmes.

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## A B S T R A C T

An external quality-control programme for morphology-based embryo quality assessment, incorporating a standardized embryo grading scheme, was evaluated over a period of 5 years to determine levels of inter-observer reliability and agreement between practising clinical embryologists at IVF centres and the opinions of a panel of experts. Following Guidelines for Reporting Reliability and Agreement Studies, the Gwet index and proportion of positive (Ppos) and negative agreement were calculated. For embryo morphology assessment, a substantial degree of reliability was measured between the centres and the panel of experts (Gwet index: 0.76; 95% CI 0.70 to 0.84). The agreement was higher for good- versus poor-quality embryos. When multinucleation or vacuoles were observed, low levels of reliability were obtained (Ppos: 0.56 and 0.43, respectively). In blastocysts, the characteristic that presented the largest discrepancy was that related to the inner cell mass. In decisions about the final disposition of the embryo, reliability between centre and the panel of experts was moderate (Gwet index: 0.51; 95% CI 0.41 to 0.60). In conclusion, the ability of clinical embryologists to evaluate the presence of multinucleation and vacuoles in the early cleavage embryo, and to determine the category of the inner cell mass in blastocysts, needs to be improved.

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## Introduction

The aim of embryo morphological grading is to determine which embryo has greatest potential for implantation, a question of crucial importance in deciding which embryo to transfer. To ensure the highest possible reliability and agreement between centres on embryo morphological grading, scientific societies have published an atlas of embryology (Magli et al., 2012) and recommend the use of standardized embryo grading systems (Racowsky et al., 2010; ALPHA Scientists in Reproductive Medicine and ESHRE Special Interest Group Embryology, 2011; ASEBIR Special Interest Group of Embryology, 2015). Embryologists, however, may interpret the guidelines differently and, depending on various factors, may reach a correct or an incorrect judgment. The existence of differing interpretations of the guidelines can impair reliability and prevent agreement between embryologists at different centres (Arce et al., 2006; Baxter Bendus et al., 2006; Storr et al., 2017).

Another recommendation to ensure the highest possible reliability and agreement between centres on embryo grading is that of participation in external quality control (EQC) programmes for embryo evaluation (Practice Committee of the Society for Assisted Reproductive Technology, Practice Committee of the American Society for Reproductive Medicine, 2006; ASEBIR Special Interest Group of Embryology, 2015; ESHRE Guideline Group on Good Practice in IVF Labs et al., 2016).

It has been shown that participation in EQC programmes increases the degree of inter-laboratory agreement in embryo morphology assessment (Castilla et al., 2010). Even when they take part in such programmes, however, the generalized lack of standardization of evaluation criteria is a major problem facing embryologists when they must decide the final disposition of an embryo, i.e., whether to transfer, cryopreserve or discard. The existence of diverse classification methods makes it difficult to establish target values for the embryo images used in the EQC programme. Ruiz de Assin et al. (2009), after analysing the results of a 5-year EQC programme, highlighted the merits of incorporating standardized classifications into EQC programmes. Moreover, after observing lower rates of variability among experts than among centres, they recommended not using the category most commonly chosen by the centres as their target value, suggesting that, instead, the opinion of a panel of expert embryologists should be taken. On the basis of these con-

siderations, since 2012, the ASEBIR EQC has included the embryo classification scheme published by the ASEBIR Special Interest Group of Embryology (2015), and the target value is based on a consensus of the panel of experts.

When reporting the results of interobserver studies, a parameter of reproducibility, such as agreement and reliability, should be used. Agreement parameters are used to indicate the degree of agreement between the results obtained by different observers; the level of agreement is obtained by estimating how often assessors of the same morphological characteristic of the same embryo chose the same response category. Reliability parameters assess how well embryos can be distinguished from each other based on a morphological characteristic or the ASEBIR classification or the final disposition (Mokkink et al., 2010). Agreement was calculated for each category of each characteristic, whereas reliability was calculated only as the total for the characteristic. Reliability and agreement are not fixed properties of measurement tools but depend on interactions among these tools, the study objects and the context of the assessment. Ultimately, the information provided should be sufficient to enable the reader to understand how each study was designed and conducted, and how its results were obtained. In 2011, the Guidelines for Reporting Reliability and Agreement Studies (GRRAS) were developed to outline and describe key methodological issues that should be addressed when reporting on reliability and agreement studies in the medical field (Kottner et al., 2011). These Guidelines included 16 recommendations referring to the presentation of study methods and the interpretation of results.

The aim of the present study, following GRRAS recommendations, is to determine the level of reliability and agreement between centres and a panel of experts on embryo morphological assessment, and to identify specific early embryo characteristics that are difficult to assess. To do so, the results obtained over a period of 5 years from an EQC programme on embryo grading that includes standardized early cleavage and blastocyst grading scheme were analysed.

## Materials and methods

Between 2012 and 2016, an average of 48 centres participated voluntarily in the ASEBIR EQC programme (Castilla et al., 2010; Ruiz de Assin et al., 2009) (42 centres in 2012, 39 in 2013, 39 in 2014, 55 in

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