When to perform the embryo transfer

The blastocyst transfer should be performed in the same type of cycle and on the same day in which a receptive result was obtained. A receptive result indicates the ideal day on which the blastocyst transfer should be performed. A day 3 embryo should therefore be transferred 2 days earlier.

Comparison of clinical results

<table>
<thead>
<tr>
<th>CLINICAL OUTCOME</th>
<th>ET</th>
<th>pET</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>17</td>
<td>17</td>
</tr>
<tr>
<td>Source of oocytes</td>
<td>Ovum donation</td>
<td>Ovum donation</td>
</tr>
<tr>
<td>Age</td>
<td>40.7 ± 4.7 (32-49)</td>
<td>40.7 ± 4.7 (32-49)</td>
</tr>
<tr>
<td>Number of embryos transferred</td>
<td>1.8 ± 0.4</td>
<td>1.7 ± 0.5</td>
</tr>
<tr>
<td>Implantation rate</td>
<td>12.9% (4/31)</td>
<td>34.5% (10/29)</td>
</tr>
<tr>
<td>Pregnancy rate</td>
<td>23.5% (4/17)</td>
<td>52.9% (9/17)</td>
</tr>
<tr>
<td>Ongoing pregnancy rate</td>
<td>0% (0/4)</td>
<td>66.7% (6/9)</td>
</tr>
<tr>
<td>Clinical abortion</td>
<td>100% (4/4)</td>
<td>0% (0/9)</td>
</tr>
<tr>
<td>Biochemical pregnancy</td>
<td>0.0% (0/4)</td>
<td>33.3% (3/9)</td>
</tr>
</tbody>
</table>

Results

>32,000 patients

Endometrial biopsy

69.8% Receptive

30.2% Non-receptive

>70 countries

More than 1,000 clinics

Data from a pilot study comparing Frozen Embryo Transfer (FET) to personalized Embryo Transfer (pET) in the same patient cohort. Patients underwent an FET before performing their first ERA test, on a day that was later diagnosed as non-receptive by the ERA. Patients then received a pET on their receptive day, after confirmation from a 2nd ERA biopsy.

What is the ERA test?

The Endometrial Receptivity Analysis (ERA), developed and patented by Igenomix (PCT/ES2009/000386), is a test designed to evaluate endometrial receptivity.

This molecular diagnostic tool uses NGS to analyze the expression level of 248 genes related to the status of endometrial receptivity.

To do so, RNA obtained from an endometrial tissue sample is analyzed and then classified by our ERA predictor as receptive or non-receptive, depending on the expression profile of the RNA.

What is the purpose of the ERA test?

The ERA test is used to evaluate the stage of an endometrium to determine if a receptive or non-receptive genetic profile is present at the time of biopsy. If the case where the endometrium is non-receptive, the test enables us to find a personalized window of implantation for each patient.

Sample extraction and shipment

An endometrial biopsy taken from the uterine fundus must be immediately introduced into an ERA cryotube and stored in a refrigerator (4-8°C/39-46°F) for at least 4 hours.

In order to ensure the highest sample quality, we recommend that shipment to our laboratory takes less than 120 hours at room temperature. In addition, the sample should never reach more than 35°C/95°F.

Advantages of the ERA test

The ERA test has been shown to be highly sensitive and specific in the detection of genetic expression profiles associated with receptivity. It allows the personalized window of implantation to be detected before the patient starts using assisted reproduction techniques. This is more sensitive than the classical method of endometrial dating, based on histological criteria, which is highly subjective and has been proven to be unable to discriminate between fertile and infertile patients.

Methodology

MAIN STAGES OF THE PROCEDURE

1. MESSENGER RNA (mRNA) IS OBTAINED
2. THE QUALITY OF THE EXTRACTED mRNA IS DETERMINED
3. RNA IS SEQUENCED TO ANALYZE THE EXPRESSION OF 248 GENES
4. THE DATA OBTAINED IS MEASURED AND THE SAMPLE IS CLASSIFIED BY THE COMPUTATIONAL PREDICTOR
5. REPORT

7. Limits of the technique. The ERA test has a specificity of 0.97 and a sensitivity of 0.90 for receptivity profile classification. The biopsy procedure, though simple, has a risk (less than 5%) of not obtaining a sufficient quantity and/or quality of endometrial tissue, in which case it is impossible to perform the test and a new sample extraction is required.

IGENOMIX PUBLICATIONS:


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