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**First pregnancies with a simplified IVF procedure: a crucial step to universal and accessible infertility care**

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**Study question**

Infertility care is probably the most neglected health care issue in developing countries, affecting more than 200 million couples. Most cases of infertility are only treatable by using assisted reproductive technologies (ART), which are either unavailable or too costly. Is it possible to make infertility care universally accessible?

**Summary answer**

We showed that IVF methodology can be significantly simplified and result in successful outcomes at levels that compare favourably to those obtained in high resource programs. We estimate the cost of our simplified laboratory system between 10% and 15 % of current costs in Western-style IVF programs.

**What is known already**

Numerous attempts have been made to find a simple system that substitutes a large and expensive IVF laboratory installation. Various devices have been described to provide a simple suitable culture environment, but none has proven valuable for resource-poor settings. A simple and low-cost IVF system to equilibrate culture medium and maintain a stable environment has not been described before.

**Study design, size, duration**

Interim analysis of a prospective study (study period: February - December 2012) in which oocytes were cultured according (1) regular IVF culturing or (2) the **'WE lab IVF culture system'** (50/50%). The primary outcome parameter was embryo quality at day 3, secondary outcome parameters were embryo implantation rate and ongoing pregnancy rate.

**Participants/materials, setting, methods**

Only first IVF attempts in women < 36 years with  $\geq 8$  oocytes were included. Severe male factor infertility cases were excluded. We always performed single embryo transfer. In our system an optimal culture environment was reproducibly obtained without the need for medical gases, complex incubation equipment and expensive infrastructure.

**Main results and the role of chance**

Similar rates of fertilization and cleavage were observed in both groups. In 2 cases no fertilization occurred, all embryos were cryopreserved in 3 cycles because of an increased risk for ovarian hyperstimulation. SET was performed in the remaining 35 IVF cycles. In 23 out of 35 cycles (65.7 %) the top quality embryo selected by an independent embryologist originated from the <sup>1</sup>WE lab system. In this group the implantation rate was 34.8 % (8/23) with an ongoing pregnancy rate of 30.4 % (7/23) and one miscarriage at 8 weeks gestation. The first <sup>1</sup>WE lab baby was a healthy boy (3500 grams, 52 cm) born at 40 weeks of gestation. Up to December 31, 2012, three healthy <sup>1</sup>WE lab babies have been born vaginally.

### **Limitations, reason for caution**

At least 1000 good motile sperm cells per oocyte (post-wash) are needed to achieve acceptable fertilization rates in the <sup>1</sup>WE lab system. Since this study was performed in a high resource IVF centre, we need to investigate if acceptable results can also be obtained in low-cost IVF settings in resource-poor countries.

### **Wider implications of the findings**

Our initial results are proof of principle that a simplified culture system designed for developing countries can offer affordable and successful opportunities for infertility treatment where IVF is the only solution, a major breakthrough towards universal infertility care. If combined with SET and low stimulation protocols we estimate the cost of a <sup>1</sup>WE lab cycle to be less than €200 with laboratory costs between 10% and 15 % of those in Western-style programs.

### **Study funding/competing interest(s)**

Not applicable

### **Trial registration number**

Not applicable