Effect of powdered gloves, worn at the time of embryo transfer, on the pregnancy outcome of IVF cycles

Antoine Hannoun · Tony G. Zreik · Ghina Ghaziri ·
Antoine Abu Musa · Johnny Awwad

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Abstract

Purpose To assess the effect of wearing powdered gloves during embryo transfer as compared to un-powdered gloves on the pregnancy outcome of IVF cycles.

Methods Patients, undergoing embryo transfer procedures, were prospectively randomized into two groups: In the first (group A, $n=356$) group embryo transfer was performed while wearing powdered gloves; in the second (group B, $n=356$) group embryo transfer was performed while wearing un-powdered gloves. The primary end point of the study was the clinical pregnancy rate.

Results The two groups were comparable with respect to the mean age, mean number of grade one embryos obtained, and the mean number of embryos transferred. The clinical pregnancy rates of the two groups were not different.

Conclusions Powdered gloves, worn during embryo transfer, have no adverse effect on the pregnancy outcome of IVF cycles.

Keywords Embryo transfer · IVF · Powdered gloves

Introduction

Ever since the use of surgical gloves by surgeons, has become routine powder, whether talc (magnesium silicate) or starch, has been added in order to help in putting on

those gloves and in the manufacturing process. However, not too long after reports about granulomatous peritonitis, resulting from a reaction to the powders used, started appearing in the literature and a safer powder was sought [1].

The optimal culture and handling of human embryos in an IVF program require the selection of non-embryo-toxic equipment and reagents. In 1985 Kruger et al. were the first to show that surgical glove powder and glove material were potent inhibitors of early embryonic growth and cleavage [2]. Another study showed that surgical glove powder particles would inhibit the growth of adult human vascular endothelial cells in cultures [3]. Simply touching the medium of embryo growth or the embryo transfer catheter the surgical glove powder was shown to be embryo-toxic by mouse embryos assay or by human sperm survival assay [4, 5].

All those studies led to the recommendation that only un-powdered gloves should be used in all aspects pertaining to embryo handling especially during embryo transfer. But to complete the picture, it was later shown that even un-powdered gloves are embryo-toxic and that this toxicity depended on the commercial brand [6–8]. It was recommended to keep testing the available gloves as part of an ongoing quality control program in the IVF unit [8].

In our IVF unit, at the American University of Beirut Medical Center, some attending physicians were still using powdered gloves during embryo transfer with the rationale that those gloves would not come in direct contact with the portion of the catheter that will go inside the uterine cavity and hence would not affect the pregnancy rate. In an attempt at unifying the protocols and procedures in our unit it was agreed to randomize cases of embryo transfer into one of two groups: in the first group the transfer was done while wearing powdered gloves whereas in the second one un-powdered gloves were utilized. The pregnancy

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A. Hannoun (✉) · T. G. Zreik · G. Ghaziri · A. Abu Musa ·
J. Awwad

Department of Obstetrics and Gynecology,
American University of Beirut, Medical Center,
P.O. Box: 113-6044 / 12 B, Beirut, Lebanon
e-mail: ahannoun@aub.edu.lb

outcomes of these two groups were compared in order to assess the effect of glove powder at the time of embryo transfer on the pregnancy rate.

Materials and methods

All IVF cases reaching to the stage of embryo transfer, at the IVF Center of the American University Hospital of Beirut between June 2003 and June 2004 were included in the study. Indications for IVF treatment included patients with male factor infertility, tubal factor, endometriosis, and unexplained infertility. Seven hundred and twelve cases of embryo transfer were prospectively randomized between two groups according to a randomization table generated by the computer. In the first group, (group A, $n=356$), embryo transfer was performed under the guidance of ultrasonography while the gynecologist was wearing powdered gloves (“Top Glove”, from TG Medical SDN. BHD., Malaysia). In the second group, (group B, $n=356$), the same method of embryo transfer was used while wearing un-powdered gloves (same brand of gloves). The three attending physicians performing the IVF procedures took extra care to avoid the direct contact between the gloves and the embryo transfer catheter.

Controlled ovarian stimulation and IVF procedure

Controlled ovarian hyperstimulation (COH) was performed by a long standard protocol with GnRH agonist (GnRH-a; Decapeptyl, Beaufour Ipsen Pharma, France), and recombinant FSH (rec-FSH; Puregon, Organon, The Netherlands). In brief, GnRH-a was started in the mid-luteal phase at a daily dose of 0.05 mg until the day of human chorionic gonadotropin (hCG) injection. Rec-FSH 200 U/day was started on the 3rd day of the cycle. Follicular development was assessed by transvaginal ultrasonography.

Table 1 Patients characteristics and IVF laboratory outcomes in the two groups A and B

	Group (A) ($n=356$)	Group (B) ($n=356$)	<i>P</i> value
Age (years)	33.4±4.7	33.6±6.1	0.6243
Dose of FSH (IU)	2979.8±1276.7	2867±980.3	0.1893
# of oocytes (mean)	11.0±6.7	10.8±5.9	0.6726
Total # of embryos obtained (mean)	6.6±4.1	6.7±3.9	0.7389
# of grade I embryos obtained (mean)	4.7±3.5	4.5±3.1	0.4199
# of embryos transferred (mean)	4.1±1.3	4.1±1.2	1.0000
Fertilization rate	60.0%	61.8%	0.0986

Table 2 Pregnancy rates in both groups (A & B)

	Group (A) ($n=356$)	Group (B) ($n=356$)	<i>P</i> value
Total pregnancy	145 (40.7 %)	142 (39.9 %)	0.8786
Clinical pregnancy	134 (37.6 %)	133 (37.4 %)	1.0000
Chemical pregnancy	11 (7.6 %)	9 (6.3 %)	0.8175
Missed abortion	15 (11.2 %)	14 (10.5 %)	1.0000
Multiple pregnancy	35 (26.1 %)	33 (24.8 %)	0.8884

When at least two dominant follicles were 18 mm or larger, 10,000 IU of hCG (Pregnyl, Organon, The Netherlands) was administered. Oocyte retrieval by transvaginal ultrasonographic guidance was performed approximately 36 h after the hCG administration. The ET was performed with Wallace transfer catheter (Smiths Medical, UK) 2 days after oocyte recovery under ultrasound guidance. The embryos were scored and graded by the same embryologist. All patients received vaginal micronized progesterone 200 mg every 8 h starting the afternoon of the oocyte pickup, continuing up to the day of B-HCG measurement, and maintained throughout the first trimester if the B-HCG was positive.

The primary outcome of the study was the clinical pregnancy rate that was defined as the presence of a positive fetal heart beat detected by vaginal ultrasound done 20 days after a positive pregnancy test. The secondary outcomes included oocyte and embryo qualities, multiple pregnancy rate and chemical pregnancy rate. Multiple pregnancy was defined as the presence of two or more gestational sacs with positive fetal heart beats. Chemical pregnancy was defined as the initial increase in B-HCG levels followed by a decrease in levels with the absence of gestational sac in the uterine cavity.

Statistical analysis

The sample size for the study was calculated as follows: using the pregnancy rate as the primary outcome and assuming a pregnancy rate of 40% with IVF treatment, a decrease to a 30% pregnancy rate in the study group would require a sample size of 356 subjects in each group with an α of 0.05 and β of 80%. Statistical analysis was carried out

Table 3 Comparison of pregnancy rates with respect to the infertility cause

	Group (A) ($n=356$)	Group (B) ($n=356$)	<i>P</i> value
Male factor	83/214 (38.8 %)	81/217 (37.3 %)	0.7668
Tubopelvic factor	17/49 (34.7 %)	20/51 (39.2 %)	0.6825
Unexplained	20/65 (30.8 %)	20/62 (32.3 %)	1.0000
Endometriosis	14/28 (50.0%)	12/26 (46.2%)	0.7926

using the unpaired Student *t*-test for continuous variables. For discrete variables, Fisher exact test was applied especially if the expected number in a cell was less than five. A *P* value < 0.05 was considered statistically significant.

Results

Both groups A and B were similar with respect to the age of patients, total dose of FSH given, number of oocytes and embryos obtained, and number and quality of embryos transferred (Table 1). There was no significant difference between the two groups in the total pregnancy rates, the clinical and chemical pregnancy rates, the missed abortion rates, and the multiple pregnancy rates (Table 2). When the pregnancy rates were compared according to the causes of infertility, there was no significant difference between the two groups A and B (Table 3).

Discussion

This study showed that wearing powdered gloves at the time of embryo transfer did not adversely affect the pregnancy rate of IVF cycles. To start with, the two groups were comparable with respect to age, number of oocytes retrieved, number of embryos and grade 1 embryos obtained. The number and quality of embryos transferred was similar between the two groups and the only variable in this study was the nature of the worn gloves: powdered versus un-powdered. This variable, as shown in this study, did not affect the pregnancy rate, and hence the feared toxicity of the gloves' powder on the transferred embryos during the procedure of embryo transfer might not be justified.

Toxicity of the powdered gloves was shown by very early studies that attributed granulomatous peritonitis to the powder of the gloves used [1]. In IVF cycles, the warning came out following the well-designed study performed by Kruger et al in 1985 [2]. In that study they showed that contaminating the growth medium of mouse embryos by the gloves' powder and by the well-rinsed gloves decreased the cleavage rate of those embryos to the blastocyst stage to 7% and 56% respectively as compared to 90% in the control group. The recommendation was to avoid contaminating embryos in IVF laboratories with gloves at all costs. Later more studies confirmed the powder toxicity on adult human vascular endothelial cells [3] and on embryos [4].

In 1989, Critchlow et al reported that the toxic powder of the gloves could be transferred to the embryo transfer catheter by simple touch and that physicians should wear un-powdered gloves at the time of embryo transfer [5]. There is no doubt now that the powder of the gloves used is

toxic when it comes in contact with embryos. Furthermore the un-powdered gloves were shown to be also embryo-toxic and this toxicity depended on the commercial brand of the gloves used [6, 8]. But it is very unlikely that the embryos, or even the embryo transfer catheter, will come in contact with the gloves or their powder during the embryo transfer procedure if direct contact is avoided. If acceptable, as a practice, not wearing any gloves during embryo transfer might be a safe and non-embryo-toxic procedure.

The spread of the gloves' powder from the gloves to the embryo transfer catheter via air is possible but the evidence from this study, showing that the pregnancy rate was not adversely affected, makes it unlikely. In IVF centers, the whole list of equipments and materials that come in contact with embryos should always be tested for embryo toxicity. Gloves' powder and gloves' materials were shown previously to belong to the list of embryo-toxic substances. However, gloves (powdered or un-powdered), worn at the time of embryo transfer, do not belong to that list as long as direct contact is carefully avoided.

In conclusion, the use of powdered gloves during embryo transfer was not associated with any decrease in the pregnancy rates of those IVF cycles. Therefore powdered, like un-powdered, gloves can be considered safe during such procedures.

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