Embryo transfer by midwife or gynecologist: a prospective randomized study

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Background. Embryo transfer (ET) in assisted reproduction treatments has traditionally been performed by gynecologists in the Nordic countries. As gynecologists often have a busy schedule, midwives and nurses have become increasingly important in performing the treatment, providing subject information, ultrasound monitoring and assistance at ET.

As part of the continuous development of our IVF treatment we have carried out a prospective randomized pilot study where either a midwife or a gynecologist has performed ET. The aim of this study was to see if a skilled IVF midwife could perform ET with similar results to a gynecologist.

Methods. On the day of oocyte aspiration the subjects were randomized, by means of closed envelopes, for ET to be performed either by a midwife or a gynecologist. A total of 102 subjects were included in the study, 51 for ET by a skilled midwife and 51 by a gynecologist. There were no differences in the groups in respect to ET routine and catheters used.

Results. No significant differences were observed in subject characteristics as regards age, method of pituitary down-regulation or proportion of IVF/ICSI cycles. Similar clinical pregnancy rates between ETs performed by midwives vs. gynecologists, 31% vs. 29%, respectively, were seen. Subject experience as judged by a questionnaire also showed high acceptance of ET by a midwife.

Conclusion. The results show that it is a feasible option to allow midwives to carry out ETs.

Key words: midwife; embryo transfer; invited fertilisation; pregnancy

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Nurses and midwives take an active part in planning and organizing fertility treatments, informing the couples as well as performing various aspects of the clinical treatment such as ultrasound scanning (1–3). In Swedish clinics offering assisted reproductive techniques (ART), gynecologists have traditionally performed embryo transfers (ETs). They often have busy schedules and midwives are available as active participants during treatment. A Swedish midwife has education and experience in counselling. They are also educated in the placement of intrauterine devices for prevention of pregnancy. In many cases midwives perform intrauterine insemination (4). This procedure is similar to introducing an ET catheter into the uterine cavity. In our Fertility Unit some of the midwives

Abbreviations:
have experience in performing vaginal ultrasound scanning for monitoring follicular development and for intrauterine insemination as well as experience in assistance with abdominal ultrasonography during the ET. Experience from the UK shows that midwives can perform ETs without compromising pregnancy results (5, 6). As part of a developmental project in the Fertility Unit we performed a prospective randomized study to see if ET performed by midwives works in our circumstances. This was a pilot study to show that a system where the midwives carry out ETs works in the IVF unit of a large teaching hospital. Our clinical results and the experiences of the subjects shows that it is feasible and highly acceptable to allow midwives to carry out ETs.

Materials and methods

Stimulation

Pituitary-gonadal suppression was achieved with a GnRH agonist (buserelin, Suprecur®, Hoechst, Frankfurt-am-Main, Germany) or an antagonist (Cetrotide®, Asta Medica). Controlled ovarian hyper-stimulation was induced using recombinant follicle-stimulating hormone (FSH; Gonal F®, Serono Nordic, Stockholm, Sweden, or Puregon®, Organon, Oss, the Netherlands). Ovulation was induced by human chorionic gonadotrophin (hCG; Profasi®, Serono or Pregnyl®, Organon) when the largest follicles had reached a diameter of at least 18 mm. The oocytes were retrieved by transvaginal ultrasound-guided follicle aspiration 37 h later.

In the midwife ICSI group there was one instance of IVM, involving short-term stimulation with low-dose Gonal-F® (Serono) without agonist or antagonist treatment, to recover immature oocytes. The decision to perform insemination by standard IVF or by ICSI was based on sperm quality. On the day of oocyte aspiration the subjects were randomized, by using sealed envelopes, to ET by either a midwife or a gynecologist. Before ET, the couples were informed as regards their embryo quality and possibility of embryo cryopreservation, as well as whether the ET was to be performed by a midwife or a gynecologist.

Embryo culture

Oocytes and embryos were cultured in IVF-medium (Vitrolife®, Gothenburg, Sweden). Insemination was performed in the afternoon of the day of oocyte aspiration. In most cases ET was performed on day two after ovum pick up (OPU). Embryo quality and selection for ET was evaluated by using an original scoring system (7, 8). Briefly, a maximum score of 3.5 was given to embryos when no factors reducing embryo quality were observed. For each of the following factors, 0.5 was subtracted from the embryo score: > 10% fragmentation, > or < 4 cells on day 2, or > or < 8 cells on day 3, uneven size of blastomeres, nonspherical blastomeres, cytoplasmic anomalies, uneven cell membranes and a large perivitelline space. Embryos with multinucleated blastomeres were avoided whenever possible.

ET procedure

All subjects for ET presented with a full urinary bladder to reduce the angle between the cervix and the uterus and to allow visualization in ultrasonographic scanning. Abdominal or vaginal ultrasonography was performed to check the position of the uterus, the size of the ovaries and for possible fluid in the pouch of Douglas. A self-holding speculum was applied and the cervix was wiped with Heps-buffered medium containing human serum albumin (Gamete, Vitrolife Gothenburg, Sweden). A mock transfer was in most cases performed with a soft test-catheter (K-soft 5002 Cook, Queensland, Australia). Catheters used for ET were Wallace 1816 N (Sims Portex Ltd, Kent, UK) (midwife n = 25, gynecologist n = 20) and Emtrac 4219 Delphin (Gynétics Medical Products N.V., Hamont-Achel, Belgium) (midwife n = 19, gynecologist n = 15). In cases of difficult passage through the cervical canal a K-jet 3205 (Cook, Queensland, Australia) (midwife n = 7, gynecologist n = 14) was used. Twice in the gynecologist group a TDT catheter (Frydman, Neuilly, France) was used. With ultrasound guidance (9, 10), one or two embryos were placed in the middle of the uterine cavity. Afterwards, the catheter was flushed and checked for remaining embryos. In cases of unsuccessful transfer by midwife a gynecologist, present in the unit at all times, was called.

The women were instructed to carry out a pregnancy test (urine test kit) 20 days after OPU. For luteal phase support, vaginal progesterone (400 micrograms) was applied three times a day from day two after OPU until the pregnancy test. All pregnancies were later confirmed by vaginal ultrasonography and only clinical pregnancies with gestational sacs were counted, i.e. a visible intrauterine sac with amniotic fluid, a yolk sac and a fetus with a heart beat.

The chi-square test and Fisher’s exact test were used in statistical comparison of the groups. A p-value of < 0.05 was considered statistically significant.
Questionnaire

After ET, the subjects were asked to anonymously fill in a questionnaire regarding their experiences of the treatment. The questionnaire contained five questions. The first asked if it was their first ET or not. The next question concerned their experience with the midwife/gynecologist during the ET. The third question was about the information concerning embryos for ET and embryos for possible cryopreservation. The two last questions regarded what to do until the pregnancy test and how to carry it out.

The questionnaire was based on a scale from 1 to 4: 1 = poor; 2 = acceptable; 3 = good; 4 = excellent.

Results

One hundred and two subjects participated in the study, and after randomization there were 51 in each group. No significant differences were observed regarding age, IVF/ICSI, average number of all oocytes and average number of all oocytes fertilized. The average embryo score was similar in both groups, as was the average number of embryos for ET. There were no differences in agonist vs. antagonist cycles between the two groups. No significant differences were observed in clinical pregnancy rates between the midwife and gynecologist groups, 31% vs. 29%, respectively (Table I).

A gynecologist was called twice, when the embryo transfer attempt by a midwife was unsuccessful. In one case there was difficulty in passing the cervix, and in the other case the subject had a double uterus, with two cervical canals, of which one was blind.

The questionnaires were answered by 44 subjects in the midwife group, and by 30 subjects in the gynecologist group. Most subjects responded to the questions with scores of 3 = good and 4 = excellent. Of those who responded, 19 in the midwife group and 18 in the gynecologist group were undergoing their first ET, while 25 in the midwife group and 12 in the gynecologist group had already undergone it. There were no differences regarding experiences with the gynecologist or midwife during ET information regarding embryos for ET or cryopreservation, or information regarding the pregnancy test (Table II).

Discussion

Some of the midwives in our IVF Unit have had several years of education and experience of abdominal and diagnostic ultrasonographic examinations in the Obstetric Unit of the University Hospital. These midwives are also allowed to carry out vaginal ultrasonographic examinations, which is an advantage in the current circumstances. Monitoring of the ovaries before OPU, and early pregnancy scanning approximately 6 weeks after ET, is performed by midwives. Education and experience of ultrasound examinations are very important in this context; for instance, before ET, the position of the uterus, the size of the ovaries, possible fluid in the pouch of Douglas, and where the catheter tip is situated during embryo transfer must be checked (9,10). The midwives who perform intrauterine insemination (IUI) also have to examine the ovaries before insemination, checking that there are no more than two developing follicles and checking for an anti- or retroflexed uterus. Intrauterine insemination is a good training procedure for ET. A Swedish midwife is familiar with inserting a self-retaining vaginal speculum visualizing the cervix before introducing an intrauterine device for prevention of pregnancy. The procedure is similar when performing ET. Continuous experience in abdominal and vaginal ultrasonography is important as regards successful ETs.

Introducing the couple to the IVF Unit, with information on the IVF procedure, the injection technique, assistance during OPU and ET, and counseling, both by telephone and directly, has always by tradition been the work of a midwife. In the majority of units oocyte recovery and embryo transfer have been performed by a gynecologist. In the UK two studies have been published regarding nurses/midwives performing ET (5, 6). In Oxford, 771 ETs were reported. Nurses had performed 679/771 (88%) and doctors 68/771 (9%).

The clinical pregnancy rate after transfer by a nurse was 36.2% and the pregnancy rate after transfer by a doctor was 29.4%. In Birmingham during 1996/1997, a clinical pregnancy rate/ET of 29.4% was reported when performed by nurses, and it was 31.8% when performed by doctors. These pregnancy rates in the two studies were similar. Our study confirmed those results, with the clinical pregnancy rate/ET performed by a midwife (31%) and by a gynecologist (29%) being similar. The total number of ETs was too low to show a statistical difference, but the equal numbers show good feasibility of ET by midwives.

Embryo transfer performed by midwives is a good development for the midwives themselves and for IVF Units in countries such as Sweden and UK where the midwives have an education for carrying out procedures independently. Most important is proper training and education in
performing ET, with backup by a gynecologist always being available in the IVF clinic.

The gynecologists have to continue to carry out a part of the ETs in order to be able to perform difficult transfers. On the other hand, according to our experience, midwives also learn to carry out difficult ETs when gaining experience. Our study was a prospective randomized study, because we thought that randomization was the most objective method to share the patients between the gynecologists and the midwives. In such an approach we did not need a power to show differences between pregnancy rates at the level of, for instance, 5%, for which 400 cycles in each arm would have been needed. To show that it is feasible that midwives can carry out ETs, the number of ETs in our study can be regarded as sufficient. This study shows that ET by an experienced midwife can be performed without compromising clinical pregnancy rates. This is in agreement with reports from the UK (5, 6). Our study also shows that subjects are satisfied with a midwife performing ETs (Table II).

Table I. Subject characteristics and outcome of treatment in the two groups

<table>
<thead>
<tr>
<th></th>
<th>Midwife group</th>
<th>Gynecologist group</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>51</td>
<td>51</td>
</tr>
<tr>
<td>Mean age ± SD</td>
<td>32.8 ± 3.3</td>
<td>33.1 ± 3.8</td>
</tr>
<tr>
<td>No. of IVF cycles</td>
<td>22 (43%)</td>
<td>30 (59%)</td>
</tr>
<tr>
<td>No. of ICSI cycles</td>
<td>29 (57%)</td>
<td>21 (41%)</td>
</tr>
<tr>
<td>Agonist cycles</td>
<td>35 (69%)</td>
<td>39 (76%)</td>
</tr>
<tr>
<td>Antagonist cycles</td>
<td>15 (29%)</td>
<td>12 (24%)</td>
</tr>
<tr>
<td>Average no. of all oocytes</td>
<td>IVF 14.2 ICSI 13.9</td>
<td>IVF 14.8 ICSI 11.2</td>
</tr>
<tr>
<td>Average no. of all fertilized</td>
<td>IVF 5.4 ICSI 7.6</td>
<td>IVF 9.5 ICSI 5.4</td>
</tr>
<tr>
<td>Average score of all embryos</td>
<td>IVF 2.3 ICSI 2.2</td>
<td>IVF 2.2 ICSI 2.2</td>
</tr>
</tbody>
</table>

Table II. Scores in the questionnaire

<table>
<thead>
<tr>
<th>Questionnaire answers</th>
<th>Midwife group</th>
<th>Gynecologist group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous ET</td>
<td>25 subjects</td>
<td>12 subjects</td>
</tr>
<tr>
<td></td>
<td>1 = 0</td>
<td>1 = 0</td>
</tr>
<tr>
<td></td>
<td>2 = 0</td>
<td>2 = 0</td>
</tr>
<tr>
<td></td>
<td>3 = 0</td>
<td>3 = 3 (10%)</td>
</tr>
<tr>
<td></td>
<td>4 = 44 (100%)</td>
<td>4 = 27 (90%)</td>
</tr>
<tr>
<td></td>
<td>1 = 0</td>
<td>1 = 0</td>
</tr>
<tr>
<td></td>
<td>2 = 0</td>
<td>2 = 2 (6%)</td>
</tr>
<tr>
<td></td>
<td>3 = 4 (9%)</td>
<td>3 = 11 (37%)</td>
</tr>
<tr>
<td></td>
<td>4 = 40 (91%)</td>
<td>4 = 17 (57%)</td>
</tr>
<tr>
<td>Information on embryos for ET</td>
<td>IVF 1.6 ICSI 1.6</td>
<td>IVF 1.7 ICSI 1.7</td>
</tr>
<tr>
<td>Information on the period before the pregnancy test</td>
<td>1 = 0</td>
<td>1 = 0</td>
</tr>
<tr>
<td>Information on the pregnancy test</td>
<td>1 = 0</td>
<td>1 = 0</td>
</tr>
</tbody>
</table>

Scale 1–4: 1 = poor; 2 = acceptable; 3 = good; 4 = excellent.

ET = embryo transfer.
development can successfully perform embryo transfers without compromising pregnancy results. In the future we are going to extend the program by letting midwives carry out all ETs.

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References


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