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Individualized embryo transfer training: timing and performance

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STUDY QUESTION: How long is the individualized training and the stability of competence for the embryo transfer (ET) technique?

SUMMARY ANSWER: The embryo transfer technique is easy-to-learn, hardly unlearned, and training should be individualized by monitoring with learning curve-cumulative summation (LC-CUSUM) curves.

WHAT IS KNOWN ALREADY: Like many medical procedures, embryo transfer is an operator-dependent technique. Individualized or standardized training of these medical procedures should be monitored to determine when competence is acquired.

STUDY DESIGN, SIZE, DURATION: This prospective, monocentric study involving five embryo transfer trainees was carried out between August 2011 and November 2012.

PARTICIPANTS/MATERIALS, SETTING, METHODS: The study was carried out in a large private clinic. Five gynaecologist trainees during their first year of assisted reproduction subspecialty performed embryo transfer for patients undergoing either fresh IVF, oocyte donor IVF, or frozen embryo transfer. There were 586 embryo transfers performed in 96 sessions of 3–10 embryo transfers each. An embryo transfer was considered successful if it gave rise to a positive pregnancy test 14 days later. LC-CUSUM and cumulative summation (CUSUM) curves were used to determine when competence was acquired and whether it was maintained over time, respectively. The length of time between two consecutive sessions was assessed for an effect on consolidation of the acquired competence.

MAIN RESULTS AND THE ROLE OF CHANCE: We observed that all five trainees became proficient in embryo transfer by procedure 15 (after procedure 15, 9, 7, 13 and 9, respectively). Once competence was achieved, one of the five trainees showed a loss of proficiency. After having acquired competence, the median pregnancy rate per embryo transfer session was significantly lower when the interval between consecutive embryo transfer sessions was ≥ 10 days compared with < 10 days (20.0 versus 46.7%; $P = 0.006$).

LIMITATIONS, REASONS FOR CAUTION: The patient groups included in the study were heterogeneous (IVF, oocyte donor IVF and frozen embryo transfer) and their outcomes are very variable; thus the distribution and proportion of these groups can determine the timing of competence acquisition. Our data show that low numbers of embryo transfer are needed to acquire competence, but since a relative high percentage of embryo transfers in our practice are from oocyte donor IVF, extrapolation of the findings to other clinical context should be done with caution.

WIDER IMPLICATIONS OF THE FINDINGS: Personalized embryo transfer training is feasible and useful, allowing clinics, on one hand, to offer a maximum chances of pregnancy with fully trained personnel, and the other hand, to avoid the superfluous and costly overtraining of already proficient trainees. Furthermore, it is advisable to maintain a short interval of time between consecutive embryo transfer sessions after a trainee has acquired competence, to avoid a significant drop in the resulting pregnancy rate.

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Key words: embryo transfer / training / competence / LC-CUSUM / CUSUM

Introduction

Embryo transfer (ET) is the critical final step of the *in vitro* fertilization (IVF) process, and although its execution has changed greatly since the early days of ART, it is currently performed in a rather standardized fashion.

Embryo quality and patient characteristics notwithstanding, the main determinant of a successful embryo transfer is the operator ability to deposit the embryos where the chances of implantation are highest, without traumatizing the endometrium (Coroleu *et al.*, 2002). There are several reasons related to embryo transfer which might lead to a failure to implant: deposition of embryos in a suboptimal location, induction of uterine contractions (Fanchin *et al.*, 1998) and iatrogenic damage to the embryos. The presence of blood in the catheter, indicating a difficult embryo transfer, is also associated with lower pregnancy and implantation rates (Goudas *et al.*, 1998).

Proficiency in performing an embryo transfer, much like many other medical procedures, is traditionally assumed after the completion of a standardized training. The training might include theoretical explanations, witnessing a pre-set number of procedures, performing procedures under direct supervision, and performing sham procedures on dummies and animal models (Parra-Blanco *et al.*, 2013). However, all these methods do not take into account individual factors affecting the speed and stability in which a trainee reaches proficiency, potentially leading, on one hand, to wrongly assume proficiency or, on the other, to the superfluous and costly overtraining of already proficient trainees.

The aim of this study was to evaluate, using a personalized monitoring method, the learning curve in embryo transfer of untrained physicians, and the maintenance of embryo transfer proficiency over time.

Materials and Methods

Study design and ethical approval

This was a prospective study, designed to identify when a medical trainee becomes proficient at embryo transfer and how this proficiency is retained over time. The study was carried out between August 2011 and November 2012 at an ISO-certified private fertility clinic (ISO 9001:2008 for quality management). The embryo transfer training was conceived as part of an ongoing programme for quality improvement; therefore, external Ethics Committee approval for the study was not required. Nonetheless, ethical approval from the Institutional Review Board was obtained (TECUSUM280811) and informed consent was sought and obtained from the physicians involved.

Trainees' characteristics

We prospectively evaluated the training in embryo transfer of five gynaecologists during their first year of the assisted reproduction specialty. All trainees were medical doctors who had completed a further 4 years internship in Obstetrics and Gynaecology. Four of the five trainees started the assisted reproduction specialty in our facility immediately after the internship (Trainees A to D). The other (Trainee E) had a hiatus of 2 years between the end of the internship and the beginning of the assisted reproduction specialty. During this time, trainee E worked as general gynaecologist and obstetrician in a public hospital. All trainees had performed at least 20 intrauterine inseminations with the Intrauterine Insemination Memo catheter® (Gynetics, Lommel, Belgium) before embryo transfer training. None had ever performed an embryo transfer before their participation in the study.

Embryo transfer procedure and training

An experienced gynaecologist, who acted as the trainer, taught all trainees a theoretical (didactical, not hands-on) embryo transfer class prior to their participation in the study, followed by witnessing of at least 20 embryo transfer procedures. During the class, all trainees were instructed to perform embryo transfer according to the standard operating procedures of the clinic.

In general, the patient has to be in the dorsal lithotomic position (Egbase *et al.*, 2000). A sterile Collin vaginal speculum is inserted, and the cervix is cleaned with transfer culture media. If mucus is observed in the external os cervix, it can be aspirated with a sterile syringe to avoid interference with the delivery of the embryos inside the uterine cavity. The embryo transfer procedure is performed using a two-stage technique ('afterloading'), under trans-abdominal echographical visualization which is performed by a trained nurse. Briefly, an empty Wallace Sure Pro® (Smiths Medical, UK) catheter is introduced through the cervical canal until the entry of the uterine cavity, and it serves as a guide to a second catheter containing the embryos. Then, the embryos are deposited 15–20 mm to the fundal endometrial surface (Coroleu *et al.*, 2002). The catheter is maintained in the uterine cavity for about 10 s after the embryos are deposited (Wisanto *et al.*, 1989). The whole process is carried out under trans-abdominal ultrasound guidance, with the patient having a full bladder (Sundstrom *et al.*, 1984) which makes the entry of the catheter into the uterine cavity easier and reduces the incidence of use of a tenaculum or obturator (Lorusso *et al.*, 2005). Finally, the catheter is examined for retained embryos, which, if present, are retransferred.

Following the theoretical and observational training, the trainees started to perform embryo transfers by themselves, in sessions of 3–10 embryo transfer each. All embryo transfers at this stage were supervised (without intervention or theoretical counselling) by the trainer and registered in the database immediately after the procedure. Pregnancy outcomes were later recorded for each embryo transfer. A positive pregnancy test is defined as a plasma hCG value of >5UI/l 14 days after the embryo transfer.

Characteristics of embryo transfers

The embryo transfers included in the study were for IVF cycles with fresh or frozen embryo transfer, where the oocytes were from the patient or from a donor and were fertilized with intracytoplasmatic injection (ICSI). Percentages of each embryo transfer category for the first 50 procedures per trainee are presented in Table I. In most cases, two embryos were transferred during the embryo transfer (62% of IVF cases, 91% of oocyte donor IVF cases and 62% of frozen embryo transfer (FET) cases). A single embryo transfer (SET) was performed in those cases where there was a medical or obstetric contraindication for twin pregnancy or on request by the patient, and three-embryo transfer (TET) was performed for a few patients undergoing IVF-ICSI with their own oocytes. During fresh embryo transfer cycles, embryos were transferred on Day 2 or 3 following fertilization or on Day 5 or 6 if the patient had three or more previous IVF cycle failures. For FET, embryos were transferred 1 day after thawing if they were frozen on Day 2–3, or on the same day as thawing if they were frozen at Day 5 or Day 6.

Endometrial preparation

Endometrial preparation differed within the embryo transfer categories. In cases of embryo transfer after a fresh IVF cycle with a patient own oocytes, the only treatment was luteal phase support with progesterone (400 mg/12 h) (Utrogestan®, SEID or Progeffik®, Effik Laboratory) vaginally administered from the day of oocyte retrieval. In cases of embryo transfer with donated oocytes where the oocyte recipient had residual ovarian function, the recipient hypophysis was suppressed by administration of GnRH agonists. (Triptoreline, 3.75 mg, Decapeptyl® 3.75 mg, Ipsen Pharma); in addition, there was a phase of endometrial estrogenic preparation where estradiol valerate was administered orally in increasing doses, from 2 to 6 mg per day (Progynova®, Bayer Health Care or Provames®, Sanofi-Aventis) or estradiol hemihydrate was given transdermally from 75 to 150 µg (Estradot®, Novartis Pharma or Vivelledot®, Novartis Pharma). In cases of FET,

Table I Percentages of embryo transfer categories for the first 50 procedures per trainee.

	Trainee A	Trainee B	Trainee C	Trainee D	Trainee E
ET (*n*)	50	50	50	50	50
IVF donor (*n*,%)	27 (54%)	32 (64%)	23 (46%)	22 (44%)	36 (72%)
IVF (*n*,%)	4 (8%)	4 (8%)	3 (6%)	3 (6%)	8 (16%)
FET (*n*,%)	19 (38%)	14 (28%)	24 (48%)	25 (50%)	6 (12%)

ET, embryo transfer; IVF donor, *in vitro* fertilization with donated oocytes; IVF, *in vitro* fertilization; FET, frozen embryo transfer.

the endometrial preparation was the same as that for IVF with donated oocytes, but progesterone was started 3 or 5 days before the embryo transfer, depending on the stage of the embryo at the time of freezing. Estrogen and progesterone treatment was continued until the pregnancy test 14 days after the embryo transfer, and, in case of a positive result, until Week 12 of pregnancy.

Statistical analysis

Learning to perform embryo transfer: LC-CUSUM analyses

To monitor the individual achievement of embryo transfer proficiency, we employed the cumulative summation (CUSUM) test for learning curves (LC-CUSUM). The CUSUM test, originally developed for the production industry, detects if a process is 'out of control' following a mathematical model. The CUSUM test detects 'out of control' performances; then outside of these periods, in-control performance is assumed. The aim of CUSUM test is to identify the need to suspend a process when it is 'out of control', that is, outside of a predefined level of acceptance. LC-CUSUM is a modification of the CUSUM method designed to determine when a pre-set level of competence is achieved, reducing the risks of incomplete training when new operators perform complex procedures (Biau *et al.*, 2008). When an operator begins a new procedure, by definition, the process is 'out of control' until the trainee reaches the level of competence. LC-CUSUM monitors the process while it is 'out of control' until it becomes in control. The LC-CUSUM has already been used in several medical procedures like orotracheal intubation (Correa *et al.*, 2009), endoscopic retrograde cholangiopancreatography (Biau *et al.*, 2008), vitrification of embryos (Dessolle *et al.*, 2009), embryo transfers (Dessolle *et al.*, 2010) and ultrasound diagnosis in obstetrics (Balsyte *et al.*, 2010).

For LC-CUSUM analyses, we adhered to current methodological recommendations (Biau and Porcher, 2010). The LC-CUSUM score was calculated at each procedure (t) as: $\mathrm{St} = \min(0, \mathrm{St} - 1 + \mathrm{Wt})$, with $W = \log((1 - p_0)/(1 - p_0 - d))$ for a success, and $W = \log(p_0/p_0 + d)$ in case of failure; $p_0 =$ acceptable failure rate; $d =$ acceptable deviance from acceptable performance to be detected. St was plotted on the y-axis against the successive procedures on the x-axis. As long as the score remains in the continuation region, namely between the x-axis and the decision limit (h_{LC}), performance cannot be considered as acceptable and monitoring continues. With an accumulation of successes, the score decreases until it crosses the limit h_{LC} where competency is declared. LC-CUSUM incorporates a holding barrier at 0 that cannot be crossed and the score remains at 0 even if the trainee accumulates successive failures; this allows the test to be responsive to the current performance of the trainee. The acceptable (process in control) and unacceptable (process out of control) failure rates were set a priori at 0.6 and 0.8 by a panel of experts in embryo transfer, according to the overall success rates at our institution and to what has been previously used in previous publications on the same issue (Dessolle *et al.*, 2010). The acceptable deviance from acceptable performance to be detected (d) was set a 0.1. Under both scenarios (in and out of control), a simulation of 10 000 replicates of 50 procedures was carried out to select the h_{LC} value optimizing error rates: an h value of 1.5 resulted in a risk of 3.1% of declaring competency in a 'out of control' scenario [false discovery rate (FDR))] and a risk of 77.4% of declaring competency in a 'in control' scenario [true discovery rate (TDR)].

Maintaining embryo transfer proficiency: CUSUM analyses and effect of time intervals

Once the trainees demonstrated competence, their performance was monitored with a CUSUM test. The CUSUM sequentially tests the null hypothesis that the process is in control (acceptable failure rate) against the alternative hypothesis that the process is out of control (unacceptable failure rate). Graphically, the CUSUM score increases with accumulation of failures until it crosses the limit h_c where unacceptable performance is declared. For CUSUM, a limit of $h = 3.6$ was chosen on 10 000 simulated replicates so that the risk of declaring unacceptable performance when performance is in fact acceptable (error type I) was 7.4% and the risk of not declaring unacceptable performance when performance is really unacceptable (error type II) was 11.9% over 50 procedures.

To analyse the stability of embryo transfer proficiency over time, we investigated whether the time interval between two consecutive sessions has an impact on performance. For each session, the pregnancy rate was calculated as the ratio between the number of pregnancies and the number of embryo transfers performed. The difference in the success rate by the time interval between sessions (<10 days and ≥ 10 days) was univariately analysed by non-parametric Mann–Whitney U-test. The chosen cut-off, 10 days, is arbitrary, but it represents a whole week including the consecutive weekends without performing embryo transfer, a time relevant to describe a vacation or holiday times in most countries.

Furthermore, in order to analyze the effect of both time interval between embryo transfer sessions and the source of embryos (fresh versus frozen) on the pregnancy rate of each trainee, we used mixed (random and fixed) regression models, whereby data were hierarchically structured into two levels corresponding to the session (first-level) and to the women within each session (second-level). The interval between sessions was defined as a first-level variable (the coefficient was only allowed to vary between sessions) and the embryo origin (frozen versus fresh) was defined as a second-level variable (the coefficient was allowed to vary between individuals). The statistical software MLwIN 2.02 (©Centre for Multilevel Modelling, Institute of Education) was used for this analysis.

Results

Overall, 586 consecutive embryo transfer grouped in 96 sessions were analyzed. The mean number of embryo transfer per session was 6 (range 1–10). Successful and failed embryo transfers were plotted for each of the 5 trainees using LC-CUSUM curves for the learning period, and CUSUM curves for the follow-up period, up to a total of

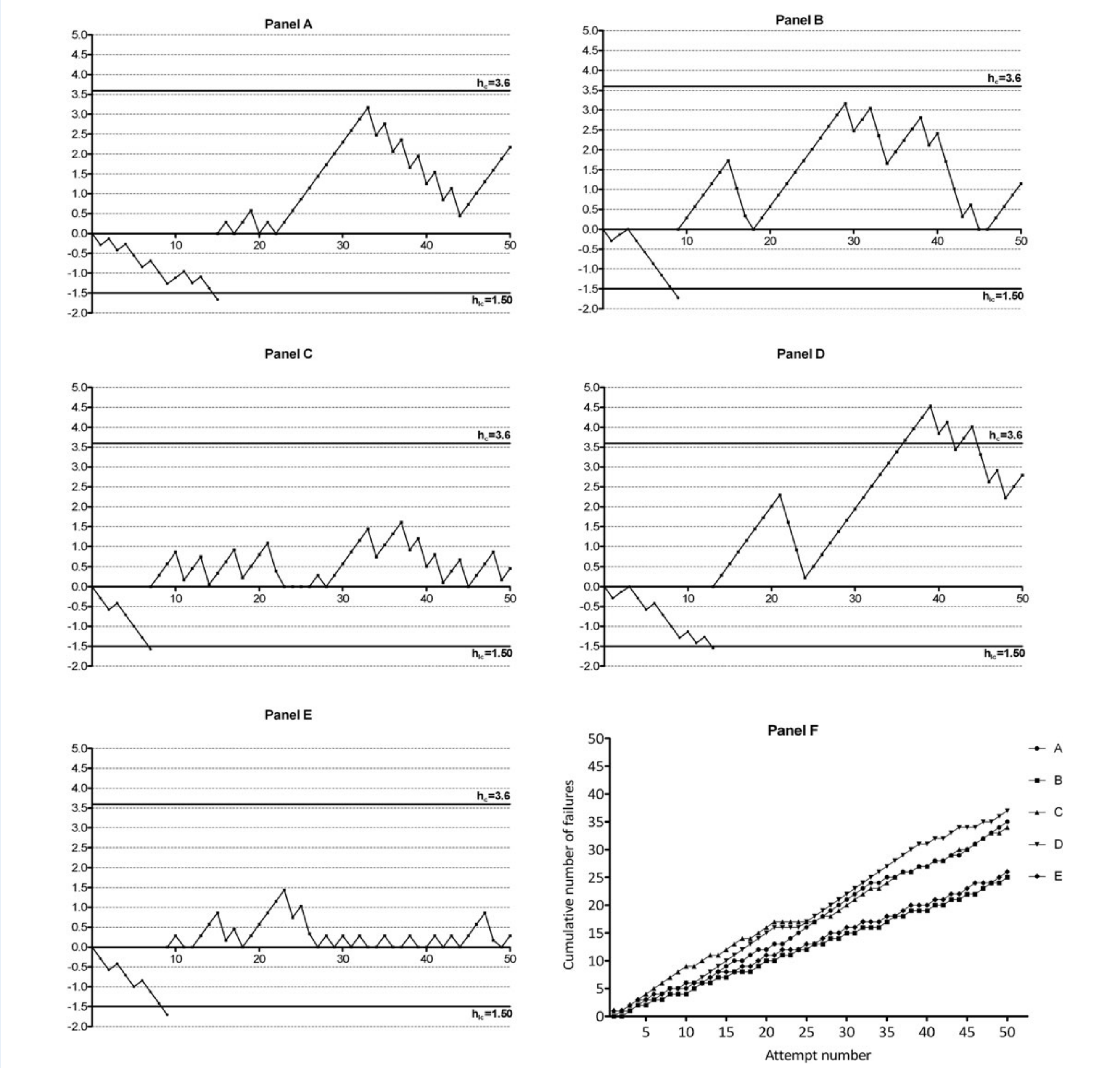

Figure 1 LC-CUSUM and CUSUM curves are shown for five gynaecologist trainees learning embryo transfer. In the LC-CUSUM curve (the first part of the graph, going downwards), while the line remains between 0 and the lower limit h, the trainee is considered not competent. When the line crosses the lower limit h, the trainee is considered competent. For the CUSUM curve (the second part of the graph, going upwards), while the line remains between 0 and the higher limit h, the procedure is considered 'in control'; if the line crosses the upper limit h (see **D**), the procedure is considered 'out of control'.

50 embryo transfers for each trainee. Figure 1A–E shows each of the individual graphs.

Learning to perform embryo transfer

The first 53 embryo transfers of the study were needed to construct the individual learning curves. The five trainees achieved competence in embryo transfer after procedure 15, 9, 7, 13 and 9, respectively, as observed in their respective LC-CUSUM curves. Therefore, by procedure 15 (after 4 embryo transfer sessions) all trainees had learned to perform embryo transfer.

Maintaining embryo transfer proficiency

The follow-up period consisted of the 533 transfers performed immediately after the learning period, grouped in 84 sessions. Trainee A performed 143 embryo transfers in 22 different sessions, trainee B performed 140 embryo transfers in 23 different sessions, trainee C

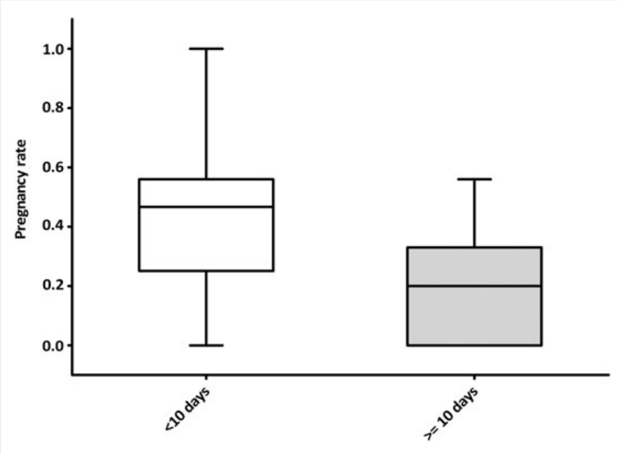

Figure 2 Distribution of pregnancy rate per session by time interval between consecutive sessions.

performed 88 embryo transfers in 14 different sessions, trainee D performed 130 embryo transfers in 20 different sessions and trainee E performed 31 embryo transfers in 5 different sessions. The mean pregnancy rate per session was 35.7% (SD = 0.27). The mean proportion of FET per session was 30% (SD = 0.4).

Four out of five trainees maintained an in-control performance level during the follow-up period, but trainee D who showed a CUSUM curve out of control twice, indicating loss of performance. This could be explained in two ways. First, trainee D performed a higher proportion of FET (with lower pregnancy rates than fresh embryo transfer) than the other trainees. The adjusted mean effect of a FET was a reduction by 34% [OR 0.66 (95% CI 0.53–0.82)]. Second, the interval of time within embryo transfer sessions may have a negative effect on embryo transfer performance (see below).

Stability of embryo transfer proficiency over time

As shown in Fig. 2, if the interval between two consecutive sessions was ≥10 days, the pregnancy rate was 20.0%, compared with 46.7% if the interval between two consecutive sessions was <10 days. The adjusted mean effect of a 10-day interval on the likelihood of pregnancy was a reduction by 12% [OR: 0.88 (95% CI 0.78–0.99)].

Discussion

Medical procedures must adhere to pre-set quality standards, which guarantee that patients are receiving acceptable treatment and, at the same time, allow improvements in medical practice and rationalization of the cost effectiveness of healthcare. Quality management should include close supervision of medical trainees when learning new procedures. Common strategies to this end involve a first period observing how the procedure is executed by a trained physician and a second period performing mock procedures with dummies or in animal models, prior to applying the procedure to patients. These strategies usually assume that proficiency is attained after a pre-set number of observations/procedures. For example, Papagerorgiou *et al.* set the number of procedures needed to acquire competence in embryo transfer at 25, but obtained pregnancy rates lower than expected and only after 40–50 procedures did all trainees achieve pregnancy rates similar to their trainers (Papageorgiou *et al.*, 2001).

Thanks to LC-CUSUM curves, we can know precisely when a trainee becomes proficient. Our study shows that embryo transfer is relatively fast to learn, with <20 procedures needed to acquire competence in all cases. The lower number of procedures we needed to achieve competence compared with the study of Papageorgiou and colleagues could be in part explained by the use of biochemical pregnancy rates to construct our curves instead of clinical pregnancy rates. Another difference that may influence the results was that, unlike the reported study, we included both fresh and frozen embryo transfers as well as transfers of embryos from donor oocytes. Furthermore, the theoretical embryo transfer class given before the beginning of training, specifically designed by each clinic, could determine different levels of basal embryo transfer knowledge.

Tailored learning using LC-CUSUM curves is a worthy alternative to performing a fixed number of procedures, as it avoids unnecessary waste of time and resources, and ensures that the competence has been acquired. A pioneering study in the use of LC-CUSUM curves for monitoring embryo transfer learning (Dessolle *et al.*, 2010) found that a variable number of embryo transfer, from as little as 11 to as many as 99, was necessary to achieve competence. This finding also contrasts with the 7–15 procedures required in our study, but corroborates that the learning curve to perform embryo transfer proficiently is variable among gynaecologists who have received the same theoretical information and have similar clinical experience in reproduction. As explained above, there are various potential explanations for the differences, including the number of oocyte donation cycles in our study, whose better pregnancy rates could have accelerated the LC-CUSUM progression to competence. Also, despite the fact that the acceptable and unacceptable performance rates and acceptable deviation were similar, the error risks were different in the previous study (1.50 in our study versus 1.86 in Dessolle *et al.*, 2010).

Since the embryo transfer technique does not depend on the origin of the embryo (i.e. proceeding from the patient's oocytes or donor oocytes) or its nature (frozen or fresh), LC-CUSUM in embryo transfer should ideally include only one ART method to ensure a reasonable event rate, consistent across trainees, to warrant reliable analysis and comparisons between trainees. The heterogeneity in the techniques included (IVF, IVF with oocyte donors, FET) is a significant weakness of the presented study.

The effect of time intervals between embryo transfer sessions has been explored with other experienced physicians not participating in this study, and pregnancy rates have remained stable even after time intervals >30 days between consecutive embryo transfer sessions (data not shown), suggesting that the effect of the interval between consecutive embryo transfer sessions is only significant soon after the acquisition of competence. Perhaps the most important finding in our study is the identification of a link between the evolution of the pregnancy rate and the time interval between embryo transfer sessions. During the period immediately following the acquisition of competence, while a physician competence is in a phase of consolidation, 10 days or more between consecutive embryo transfer sessions will affect the pregnancy rate. This information should be taken into account when planning embryo transfer training periods during the year, as well as when allocating time off after embryo transfer training has been completed. An uninterrupted training is ideal to achieve embryo transfer proficiency faster, and this should be continued after acquiring embryo transfer competence.

In conclusion, embryo transfer is an easy-to-learn technique which can be faithfully monitored using LC-CUSUM and CUSUM tools during the acquisition and the maintenance of competence. During the training period, differences between trainees should be minimized to standardize the embryo transfer procedure (using same origin and nature of embryos). Just after achieving competence, we recommend embryo transfer sessions to be close (with an interval of <10 days) to prevent a decrease in pregnancy rates.

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Authors' roles

M.J.L. and D.G.: study design, data analysis and manuscript preparation. A.R. and M.C.: study design and data collection. R.V.: data analysis, study supervision, expert knowledge, manuscript preparation. V.V.: study supervision, expert knowledge, manuscript preparation.

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Conflict of interest

None declared.

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