

Do embryo transfer catheters affect pregnancy success?

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Ethics Committee Approval

Acibadem Mehmet Ali Aydınlar University Atakent Hospital ethic committee (date: 12.09.2019, number: ATADEK-2019-14/63). All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

Conflict of Interest

No conflict of interest was declared by the authors.

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Abstract

Background/Aim: In-vitro fertilization-embryo transfer requires meticulous technique. To minimize endometrial trauma and perform the procedure as delicately as possible, various catheters are used for embryo transfer. In this study, we aimed to determine whether pregnancy rate is affected by the softness of those catheters. A standard catheter is not preferred in clinics. We wanted to see how pregnancy success would be affected if we made the catheter a constant variable.

Methods: A retrospective cohort study was conducted with the participation of 149 patients in Acibadem University Atakent Hospital IVF Unit. We used Wallace (Smith Medical) semi-rigid catheters and Labotect (Labor-Technik-Göttingen) flexible catheters (divided into two groups). Patients between 28-35 years of age, with infertility without known causes or who had mild male factors and received Gn-RH antagonist treatment protocol were included in this study. Patients with azoospermic partners, tubal factors and severe ovarian failure were excluded.

Results: There were no statistically significant differences between the patients who got pregnant and those who did not in terms of age, basal FSH, duration of infertility, antral follicle count and endometrial thickness before transfer. The pregnancy rates after transfer in the semi-rigid (Group 1) and soft catheter (Group 2) groups were 43,5% and 56,5%, respectively ($P=0.108$).

Conclusions: In our study, the pregnancy rates were higher in transfers performed with a soft catheter. Soft catheter positively affects pregnancy success. However, it is difficult to say that this alone affects pregnancy success.

Keywords: Catheter, Embryo transfer, Pregnancy rate, Assisted reproductive medicine

Introduction

In-vitro fertilization-embryo transfer (IVF-ET) broke new ground in reproductive medicine, following its first use in 1978. Regarding the IVF-ET process, the most exciting part with the highest expectation is embryo transfer. In practice, embryo transfer is the stage that requires working most tactfully and meticulously [1].

To minimize endometrial trauma and perform the procedure as delicately as possible, various catheters are used for embryo transfer with ultrasonography. During the transfer, the main purpose is not contacting the uterine fundus, so a contraction is not triggered, and the endometrium is not damaged while advancing the catheter [2]. Although embryo transfer is considered the most critical process, the quality of the embryo, endometrial receptivity, and embryo transfer technique all play significant roles in pregnancy success [3]. In the first years of IVF treatments, the zygote was transferred into the fallopian tubes. Live birth occurred in 1983, following the transfer of fertilized sperm and oocyte to the fallopian tube [4]. In 1986, the first zygote from sperm and oocyte were transferred to the fallopian tube after in vitro fertilization. These methods were performed under laparoscopic observation by passing through the cervical canal with the aid of a modified catheter [5]. Although these methods have a more natural course, there are risks associated with anesthesia and laparoscopy [6].

A study evaluated the effects of soft, very soft, and rigid catheters in terms of their effects on the endometrium during a sham embryo transfer. The evaluation was made hysteroscopically, and soft and very soft catheters were observed to cause less trauma [7]. Further studies with catheters have also reported that flexible catheters cause less endometrial trauma [8,9]. For this reason, the ideal embryo transfer is that which reaches the uterine cavity causing the least physical trauma in the endocervix and endometrium. A meta-analysis comparing pregnancy rates between soft and hard catheters revealed a slight difference in clinical pregnancy rates [10].

Despite this meta-analysis result, the dexterity of the operator cannot be neglected. In a study, it was argued that not the softness of the catheter, but the application technique was associated with procedure success, and softer catheters were not superior to others for this reason [11, 12]. The catheter, which is not included in the treatment protocol for a successful procedure, is the most independent variable of IVF programs [13, 14].

In our study, we aimed to compare clinical pregnancy rates in a series of patients with no anatomical factors that would affect procedure success, enough ovarian reserve, and mild male factors, with regards to two diverse types of catheters, used by a single operator.

Materials and methods

The patients who visited Acıbadem Mehmet Ali Aydınlar University Atakent Hospital IVF Clinic (12.09.2019 ethic committee number: ATADEK-2019-14/63) were reviewed according to the below-mentioned inclusion and exclusion criteria, and their consents were obtained. A total of 149 cases were included in the study, which was conducted in accordance with the Helsinki declaration principles. Patients between 28-35

years of age with unknown infertility and mild male factors (except azoospermia) were included in the study. Patients whose partners were diagnosed with azoospermia, those with poor ovarian reserve and tubal factors were excluded. Antagonist protocol was administered to the patients participating in the study. The semi-rigid catheter was used in 74 cases and the soft catheter, in 75 cases. All transfers were made after fresh treatment cycles using 5th day embryos. Clinical pregnancy was considered the primary outcome and defined as the observation of a gestational sac along with the yolk sac or double decidual sac finding in transvaginal ultrasonography.

Embryo transfer technique

With the patient in lithotomy position, the perineum, vulva, and vagina were cleaned with saline solution, after which a sterile cover was placed. The collum was monitored with the speculum and the vagina and collum were cleaned with EBSS (Earle's balanced salt solution, Sigma Aldrich). Then, the cervical mucus was cleaned with cotton tips and the outer sheath of the catheter was brought up to the internal os level under ultrasonographic guidance, and the embryo was delivered to the mid-cavitary region through the inner catheter.

Statistical analysis

Statistical analyses were performed with MedCalc 12.3 (MedCalc Software bvba). FSH levels, antral follicle count, infertility duration, pre-transfer endometrial thickness and clinical pregnancy rates were compared in both groups. Non-normally distributed data were presented as medians and compared with the Mann-Whitney U test. $P < 0.05$ was considered statistically significant.

Results

The 5th day embryos were transferred in fresh treatment cycles to 74 patients (divided into two groups) using a semi-rigid catheter (group 1) and to 75 patients, with a soft catheter (group 2). There were no statistically significant differences between the patients who got pregnant and those who did not in terms of age, basal FSH, duration of infertility, antral follicle count and endometrial thickness before the transfer (Table 1). The pregnancy rates after transfer with the semi-rigid (group 1) and soft catheter (group 2) groups were 43.5% and 56.5%, respectively ($P=0.108$) (Table 2).

Table 1: The classification of cases according to clinical pregnancy

	Clinically pregnant (n=97)	Clinically non-pregnant (n=52)	P-value*
Age	32 (28-35)	31 (28-35)	0.31
Basal FSH (mIU/ml)	5,5 (3-8)	5 (4-9)	0.95
Duration of Infertility (Years)	3 (1-9)	3 (1,5-25)	0.46
Antral Follicle Count	9 (5-15)	10 (6-15)	0.062
Pre-transfer endometrial thickness (mm)	10 (7-14)	9 (8-14)	0.38

* $P < 0.05$ is considered statistically significant.

Table 2: Comparison of pregnancy outcomes in terms of used catheter type

Catheter type	Clinical pregnancy achieved n (%)	Clinical pregnancy not achieved n (%)	P-value
Wallace (Group 1)	43 (43.5)	31 (56.5)	0.108
Labotect (Group 2)	54 (56.5)	21 (43.5)	
Total	97 (65.1)	52 (34.9)	

Discussion

The last stage of the IVF-ET process is embryo transfer. The use of a technique that will result in minimal tissue manipulation and endometrial trauma increases the chance of

success. There is evidence in the literature that the usage of soft transfer catheters results in higher pregnancy rates compared to rigid ones [8, 10].

Although it is known that many factors affect pregnancy rate, the catheter that will damage the endometrium the least is preferred. Cook and Wallace catheters were compared, and no difference was observed between pregnancy rates [15, 16].

Apart from the choice of catheter, it has been reported that ultrasound-guided embryo transfer does not cause a difference or adverse effect, but these studies were biased due to their retrospective design. A study by Drakeley [17] reported no difference between groups.

Although the patient's age, embryo quality, hormone profile, and treatment protocol have been standardized in all conducted studies, 9% report no additional information about the experience of the operator who made the transfer. This can lead to serious bias because experience is an important parameter in this process. Steps such as the clinical procedure, recommended treatment protocol and technique are important in terms of standardization of the transfer procedure. Experience and protocol standardization are vital to conduct more qualified studies with better results and increase the success of in vitro fertilization treatment.

In our clinic, we do not use rigid catheters unless we encounter problems with passing through the cervix. Therefore, we wanted to compare the two catheters (semi-rigid and soft) we use most in our clinic and evaluate pregnancy rates. Although there were no statistically significant differences, the clinical pregnancy percentage was higher in soft catheters compared to semi-rigid ones. The standardization of embryo quality, the day of transfer, reason of infertility, and age, all of which may affect clinical pregnancy rates, is the main strength of our study, while its retrospective design and sparse number of cases constitute its main limitations. Although factors such as physician experience, embryo quality, endometrium quality and preparation, and transfer technique are particularly important, preference of a catheter which causes the least trauma is a crucial factor in embryo transfer, which is the last step of in vitro fertilization.

Limitation

The standardization of embryo quality, the day of transfer, reason of infertility, and age, all of which may affect clinical pregnancy rates, is the main strength of our study, while its retrospective design and small number of cases constitute its main limitations.

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