Comparative Study between two Types of Embryo Transfer Catheters
(A Randomized Controlled Trial)

Thesis

Submitted for Partial Fulfillment of the M.D. Degree in Obstetrics and Gynecology

By

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List of Abbreviations

Abb.	Full term
ART	*Assisted Reproductive Technology*
BMI	*Body Mass Index*
CI	*Confidence Interval*
DOR	*Diminished Ovarian Reserve*
E2	*Estradiol*
FR	*French Size*
HCG	*Human Chorionic Gonadotropin*
LEEP	*Loop Electrocautery Excision Procedure*
MAC	*Monitored Anesthesia Care*
OD	*Ovarian Dysfunction*
POR	*Poor Ovarian Reserve*
PR	*Pregnancy Rate*
RCT	*Randomized Controlled Trial*
RR	*Relative Risk*
SPSS	*Statistical Package for Social Sciences*
TDT	*Tight Difficult Transfer*

ABSTRACT

Background: embryo transfer is a crucial step in IVF-embryo transfer treatment cycles, but it is probably the' most inefficient. Ovarian stimulation, oocytes retrieval, fertilization and embryo culture have been extensively studied and are performed under tight control, while improvements in embryo transfer are less often considered. There are many factors, in addition to the embryo quality, that have been shown to influence the success of embryo transfer, such as the technique used, the experience of the operator, and the difficulty of the procedure.

Aim of the Work: to compare the efficacy of the embryo transfer catheters: Wallace® and Prince® in an IVF program of a tertiary referral university center.

Patients and Methods: a randomized controlled research trial conducted at private IVF unit and the unit of Reproductive Medicine of Ain Shams University. Study subjects have been recruited from an IVF management cycle. The research study has been conducted from January 2016 till September 2019.

Results: the current research study investigated four types of embryonic catheters Wallace, Prince with and without mandrel and Labotech most of the research study findings didn't reveal any statistical significant differences by statistical analysis in which basic features and ovarian stimulation features didn't differ between research groups categorized according to the type of catheter implemented.

Conclusion: another issue that should be considered in future research is the integration of uterine volume, cervical position, uterine axis as factors affecting the choice of the type of catheter that could aid in proper performance of this meticulous art of embryonic transfer besides differences in experience and practice performed by the reproductive clinician should be put in consideration. Future research studies should consider multicentric fashion of research with great consideration of age, BMI, ethnicity, infections (causing cervical edema) as factors affecting the anatomic integrity and position therefore affecting the ease of the embryonic transfer process.

Keywords: Embryo Transfer Catheters - Dimished Ovarian Reserve - Ovarian Dysfunction

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Introduction

Embryo transfer is a crucial step **in IVF-embryo transfer** treatment cycles, but it is probably the most inefficient ***(Buckett, 2006).***

Ovarian stimulation, oocytes retrieval, fertilization and embryo culture have been extensively studied and are performed under tight control, while improvements in embryo transfer are less often considered. There are many factors, in addition to the embryo quality, that have been shown to influence the success of embryo transfer, such as the technique used, the experience of the operator, and the difficulty of the procedure ***(Mcllveen et al., 2005).***

Several studies have shown increases in clinical pregnancy rate (PR) resulting from improvements in the various aspects of embryo transfer, including cervical cleaning, a full bladder, dummy transfer, pretreatment cervical dilatation in difficult cases, and ultrasound guidance ***(Buckett, 2006)***.

It has also been suggested that catheter' choice influences pregnancy rates ***(Meriano et al., 2000)***, and several surveys in the UK and Australia have shown that embryo transfer catheters rank high as an important independent factor in the- success of an IVF program ***(Abou-Setta et al., 2005)***.

A systematic review has suggested that, the ideal embryo transfer catheter should avoid any trauma to the endocervix and/or

the endometrium as it is introduced into the uterine cavity ***(Abou-Setta et al., 2005)***.

In the search for the ideal catheter, many large retrospective studies ***(Burke et al, 2000; Choe et al., 2001; Wood et al., 2002***).

Sallam etal., (2003)have looked into the catheter typeused, and have reported higher PR with soft catheters such as the Cook (Conk Medical, USA), and the Wallace (Marlow Technologies, USA) compared with firm ones such as TDT (Laboratoire. CCD, France), Frydman (Laboratoire CCD), Tomcat (Kendell-Health care, USA), Tefcat (Kendell Healthcare, MA, USA), and Rocket (Rocket Medical, UK) ***(Bucket, 2006)***. However, there are also several reporats of the choice of catheter not influencing PR ***(Unman et al., 2000; Karande et al., 2002; De Placido et al., 2002)***.

It was, therefore, decided to evaluate the performance of the Wallace, Labotech and Prince catheters in a prospective randomized controlled trial (RCT) using clinical PR asthe main outcome measure, in continuing efforts to determine the optimal embryo transfer device.

Embryo transfer can lead to the success or failure of an assisted reproductive technology (ART) cycle ***(Hearns-Stokes et al.,2000).***

One factor in ET that has been identified as a variable that can positively or negatively affect pregnancy rate (PR) is the type of transfer catheter used ***(Meriano J et al.,2000).*** Ithas been reported that more flexible catheters, such as the Edwards-Wallace, result in

significantly higher PRs than the more rigid Frydman Tight Difficult Transfer (TDT) (Fertility Technologies, Natick, MA) catheters ***(Wood et al.,2000)***. In 2001, Boone et al. demonstrated a trend toward improved PRs with the Edwards- Wallace (Cooper Surgical, Shelton, CT) catheter compared with the Cook Soft-Pass (Cook Urological, Spencer, IN) catheter ***(Boone et al.,2001).*** In a -recent article by ***Mcllveen et al.,the Cook K-Jet*** was compared with the und when comparingAWallace. No differenceEdwards-Wallace. No difference in PR was found when comparing the two catheters ***(Mclllveen et al., 2005)***.

Aim of the work

Aim of this study is to compare between two types of embryo transfer catheters in an IVF program of a tertiary referral university center and private IVF center.

1. Research hypothesis:

Null Hypothesis: Prince® Embryo transfer catheter will not affect the Live Birth Rate

2. Research Question:

Will the newly invented Prince® embryo transfer affect the Live Birth rate?

3. Primary outcome:

The main outcome measure in this study is the Live Birth rate.

4. Secondary outcomes:

(a) Implantation rate.

(b) Biochemical pregnancy rate.

(c) Clinical pregnancy rate.

(d) Miscarriage rate.

(e) Ongoing pregnancy

(f) Visibility of the catheter under ultrasound

(g) Number of retained embryos post transfer

(h)Whether change of catheter was required

(i)Patient discomfort during the procedure.