Does Catheter Type Effect Pregnancy Rate in Intrauterine Insemination Cycles?

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Purpose: To determine if a soft insemination catheter increases pregnancy rates.

Methods: Seven hundred forty-seven consecutive intrauterine insemination (IUI) cycles in 364 women in a reproductive endocrinology office between October 1998 and March 2000. Patients with even birth years were inseminated with the Tomcat catheter, and those with odd birth year with the Wallace IUI catheter. Clinical pregnancy rates were compared.

Results: The Wallace catheter group included 180 women for 372 cycles and an overall pregnancy rate of 16.4%. The Tomcat catheter group included 184 women for 375 cycles and an overall pregnancy rate of 18.1%. This difference is not statistically significant ($P = 0.61$). Potential confounders were accounted for.

Conclusions: When comparing the softer Wallace catheter to the less pliable Tomcat catheter during IUI cycles, there was no significant difference in pregnancy rate when using a standard gentle technique that includes not touching the top of the fundus with the catheter.

KEY WORDS: Intrauterine insemination (IUI); catheter; Wallace; Tomcat; endometrium.

INTRODUCTION

There has been much discussion in the literature and in infertility clinics over the last several years regarding catheter type for IVF embryo transfer. This has led to the vast majority of IVF centers throughout the world switching to a soft transfer catheter to avoid endometrial trauma. Few studies have specifically addressed catheter type for the transfer of sperm to the uterine cavity, despite this being a far more commonly performed procedure. Lavie *et al.* suggested that the triple layer endometrial image, so commonly

identified at the time of ovulation, is disrupted in half of patients when using the stiff plastic Tomcat catheter for intrauterine insemination (IUI) (1). This image disruption was presumed to represent endometrial trauma. As this finding was much less common with the softer catheter, the implication was made that the softer catheter may lead to higher pregnancy rates after IUI. In the IVF situation, both soft catheter and atraumatic transfer have been associated with higher pregnancy rates (2,3).

In this study we ask whether a commonly used stiff catheter, the Tomcat, produces a similar pregnancy rate to the softer Wallace IUI catheter when used for IUI in a large prospective study.

MATERIALS AND METHODS

A trial was conducted over 18 months to assess the impact of the IUI transfer catheter on cycle pregnancy rates. Three hundred sixty-four women were enrolled in the study from October 1998 through March 2000 and a total of 747 COH-IUI cycles were

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performed. The catheter type was determined based on the participants year of birth. Two types of catheters were used, the Tomcat catheter (Sherwood Medical, St. Louis, MI) and the Wallace IUI catheter (Marlow, Willoughby, OH). One hundred eighty-four women (50.5%) with even birth years were inseminated with the Tomcat catheter, and 180 women (49.5%) with odd birth years underwent IUI with the Wallace catheter. In a power analysis conducted using an alpha of 0.05 and a beta of 0.20, we would need 156 IUI cycles in each study arm to statistically identify a 10% difference in pregnancy rate between the two groups. Study size was thus ample.

Patients were assigned to treatment with clomiphene citrate or gonadotropin based on their historical factors, laboratory results, and past treatment. Generally, three to four cycles of clomiphene citrate were employed before moving on to gonadotropins. Older patients were encouraged to use gonadotropins more quickly than younger patients. Patients undergoing gonadotropin cycles were monitored by intermittent ultrasound and serum estradiol testing, received hCG by injection upon visualizing a dominant follicle of 18 mm mean diameter, 36–38 h before the planned IUI. Patients undergoing clomiphene citrate were often monitored by ultrasound, and had inseminations timed 24 h after hCG administration. Patients not receiving ultrasound monitoring (clomiphene or natural cycle) had inseminations performed the morning after a spontaneous LH surge as detected by an over the counter test kit. Patients were encouraged to have sexual relations ad lib after the IUI was completed.

The semen specimens were collected the morning of the insemination in sterile specimen containers. The specimen was then kept at room or body temperature and delivered within 30 min to Baystate's Reproductive Biology Lab for preparation. The sample was layered onto three-layer Isolate gradients that were centrifuged for 20 min at 330g. The pellet and lowest layer were washed and the final pellet was resuspended in 0.4–0.6 mL of medium. The samples were stored at room temperature until used for the IUI.

At the time of insemination, this specimen was drawn up into the desired IUI catheter, which was attached to a standard 1 cc syringe. Care was taken to avoid obtaining air in the column of sperm. Transfers were performed in the dorsal lithotomy position using a suitable speculum. A single toothed tenaculum was used to facilitate the procedure in less than 1% of cases. The cervical mucus was removed with absorbent swabs. The catheter tip or introducer was

curved manually to imitate the curve of the uterine cervix. The catheter was then inserted carefully into the uterine cavity, and the semen was expelled when the catheter was felt to be in the uterine cavity. Care was taken to avoid hitting the top of the fundus with the catheter. The transfers were carried out by one of the three board certified reproductive endocrinologists or under their direct supervision by one of the third year Ob/Gyn residents rotating on the service.

We identified the following variables as potential confounders in the two groups: age, parity, body mass index, ovulation induction agent, primary cause of infertility, and number of cycles. Each potential confounder was evaluated using chi-square tests for nominal variables and unpaired *t* tests for continuous variables. The major outcome investigated in this study was cycle pregnancy rates. Clinical pregnancy was defined by ultrasonic evidence of a gestational sac. After accounting for the above confounders, the cycle pregnancy rates were calculated in the two different catheter groups and analyzed for significance using the Analyse-It and Epi Info programs.

RESULTS

After 747 treatment cycles, there were 129 clinical pregnancies established with ultrasound evidence of a gestational sac for an overall pregnancy rate of 17.3%. Patient number (184 vs. 180), number of IUI cycles (375 vs. 372), and pregnancies (68 vs. 61), were similar between the two catheter groups, Tomcat versus Wallace, respectively. There were no statistically significant differences in the pregnancy rate per cycle or pregnancy rate per patient for the two catheter groups (Table I). Distribution of various types of ovulation induction agents was similar between the two catheter groups (Table II). The etiologic factors contributing to infertility were also distributed evenly between the two catheter groups (Table III). Both catheter types resulted in high patient satisfaction and a low incidence of complaints of pain or bleeding.

Table I. Number of Procedures, Patients, and Pregnancy Rates for the Two Catheter Groups

	Catheter vs. outcome		
	Tomcat group	Wallace group	<i>P</i> value
IUI procedures	375	372	—
Patients	184	180	—
Pregnancies	68	61	—
Cycles/patient	2.0	2.1	0.84
Pregnancy rate/cycle	18.1%	16.4%	0.61

Table II. The Proportion of Ovulation Induction Agent Used in Each Catheter Group^a

OI agent	OI agent vs. catheter			
	Tomcat group (%)	Tomcat pregnancy rate	Wallace group (%)	Wallace pregnancy rate
Clomid	53	17.5	59	15.1
Gonadotropins	44	13.8	39	17.4
Natural	3	0/14	2	1/6

^a Distribution of ovulation induction agents are similar between catheter groups, $P = 0.37$. There was no significant difference in pregnancy rate between catheter groups based on ovulation induction agent.

DISCUSSION

This study was designed to compare the pregnancy rates with the Wallace catheter to those achieved with the less expensive Tomcat catheter. The cost of the Tomcat catheters is less than \$1, while the Wallace catheters is nearly \$5 each. The stiffer plastic construction of the Tomcat catheter enables it to maintain shape and mimic the cervical/uterine contours, which allows for ease of control and maneuverability. The Wallace catheter is coaxial with a softer inner catheter inside a stiffer outer catheter that can be curved to facilitate cervical bends, if the inner catheter cannot be advanced initially.

The softer Wallace catheter is reported to have advantages over stiff plastic catheters such as the Tomcat. It is theorized that the softer and more pliable construction of the Wallace catheter may be less traumatic to the endometrium, and therefore reduces the number of subendometrial transfers in the IVF

situation (4). This may also be important for causing endometrial trauma during IUI. It is also thought that the introducer used with the Wallace may decrease the amount of mucus and vaginal contaminants carried into the uterus on the inner catheter, hence improving fecundity rates. Positive bacterial cultures from embryo transfer catheter tips have been negatively associated with pregnancy rate (5). The Tomcat catheter has been reported to disturb the appearance of the three layer endometrium during the IUI procedure more commonly than the Wallace catheter, 50% versus 12.5% (1). This may have an effect on pregnancy rates. Additionally, patients are more likely to report pain or bleeding with the Tomcat catheter (1).

Given this information, we conducted our study and failed to identify a statistical difference in pregnancy rates between the two catheter groups. Statistical analysis showed us that our two groups were matched with respect to age, body mass index, parity, number of cycles, causes of infertility, and ovulation induction agents used. Randomization by birth year is an imperfect technique; however, it is highly convenient in a busy office practice and seems to have been effective. Though other confounders may indeed exist, the process of randomization would likely have eliminated these also. Power calculations show adequate sample size.

This study did not attempt to control for total motile sperm, original or post wash, for each IUI procedure. The effectiveness of IUI is likely a continuum over a range of sperm parameters, with motility of <30%, concentration of <5 million/mL, <10 million total motile sperm, and abnormal strict morphology associated with reduced IUI effectiveness (6–8). However, these associations are not uniformly agreed upon as a recent prospective randomized study concluded that IUI was equally effective in male factor and in idiopathic infertility (9). Addressing these concerns statistically is a very difficult issue. In general, male factor patients with total motile sperm count of <10 million are quickly referred for IVF services as this is cost-effective (6) and a covered benefit of most insurance providers in the state of Massachusetts. Thus with such a low prevalence of severe male factor infertility in this IUI population, we allowed randomization to minimize the effect of this potential confounder on pregnancy rate by catheter type. The randomization technique, odd versus even year of birth, produced a similar proportion of male factor infertility in each group.

The technique used when performing IUI may be important. Ultrasound guided transfers for IVF do

Table III. The Distribution of Etiologic Factors for Infertility in the Catheter Groups, and Pregnancy Rate/Cycle for Each Etiologic Factor^a

Etiologic factor	Cause of infertility vs. catheter			
	Pregnancy rate	Tomcat group	Wallace group	<i>P</i> value
Mean age	—	34.0	33.5	0.29
Mean BMI	—	25.7	25.5	0.28
Mean parity	—	0.3	0.3	1.00
Ovulatory	20%	32%	32%	0.95
Idiopathic	25%	18%	18%	0.97
Male factor	12%	21%	14%	0.24
Uterine factor	16%	11%	9%	0.47
Pelvic factor	15%	11%	15%	0.30
Tubal factor	6%	7%	11%	0.21
Cervical factor	75%	1%	1%	1.00

^a The distribution of etiologic factors was not significantly different between catheter groups.

increase the ability of the physician to be gentle, even with difficult transfers and this has been suggested to improve IVF pregnancy rates (3). Because ultrasound guided IUI could not logistically be provided to all IUI procedures in this study, it was not included. Hearn-Stokes reports variation in IVF pregnancy rates dependent upon provider performing the embryo transfer (10). This variable was not specifically addressed in this study of IUI catheters. Because our IVF program emphasizes atraumatic transfer of gametes or embryos regardless of catheter used, it is possible that our gentle IUI technique may have overcome the deficiencies of a particular catheter.

In conclusion, this large study of IUI procedures using two different catheter types fails to show an advantage of the soft catheter over the stiffer catheter when a gentle technique avoiding contact with the uterine fundus is employed.

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