JMSCR Vol||04||Issue||12||Page 14787-14791||December 2016

www.jmscr.igmpublication.org
Impact Factor 5.244
Index Copernicus Value: 83.27
ISSN (e)-2347-176x ISSN (p) 2455-0450
crossref DOI: https://dx.doi.org/10.18535/jmscr/v4i12.77

IGM Publication
Journal Of Medical Science And Clinical Research
An Official Publication Of IGM Publication

Clinical Pregnancy Rate in Intra Uterine Insemination (IUI) is not Affected by the type of Catheter Used

Authors
Ashraf Hany Abdelrahman[1], HadeerAly Abbassy[2]
[1]Department of Obstetrics & Gynecology (Shatby IVF-ICSI Unit) Alexandria University, Egypt
Madina IVF-ICSI Center, Alexandria, Egypt
[2]Department of Clinical Pathology Alexandria University, Egypt
Madina IVF-ICSI center Alexandria, EGYPT
Email: *hadeerabbassy@gmail.com*
Corresponding Author
Ashraf Hany Abdelrahman
416 El Horria Road, Roushdy Alexandria, Egypt
Email: *ashrafhany3000@yahoo.com*

ABSTRACT
Objective: *To compare the clinical pregnancy rate of IUI with the Gynetics catheter (Gynetics Medical Products, Hamont-Achel, Belgium) or the Labotect catheter (labotect insemination catheter, Germany).*
Design: *Prospective, randomized study.*
Setting: *Infertility unit at Alexandria university hospital (Shatby IVF-ICSI LAB), and Madina IVF-ICSI Center.*
Patient (s): *Two hundred infertile couples undergoing IUI treatments.*
Intervention(s): *Patients were randomly assigned to undergo IUI treatment with either the Gynetics catheter (100 patients) or the Labotect catheter (100 patients).*
Main Outcome Measure(s): *Primary outcome measure was the clinical pregnancy rate.*
Result (s): *The use of the Gynetics catheter resulted in similar pregnancy (33% vs. 33%) and clinical pregnancy rates (20% vs. 19%) as compared with the Labotect catheter.*
Conclusion (s): *There was no significant difference in pregnancy rates with use of either the Gynetics catheter or the Labotect catheter.*
Key Words: *Catheter type in IUI & pregnancy rate.*

INTRODUCTION

IUI is one of the treatments for infertility, and it is still a widely used and cost-effective therapy. The aim of IUI with washed spermatozoa is to bypass the cervical mucus barrier and increase the sperm concentration at the site of fertilization. The pregnancy rate per IUI cycle varies between 6% and 22% [1–4]. The prime factors affecting the efficiency of IUI treatments are the woman's age, cause of infertility, sperm quality, and ovarian stimulation [1,4 – 6]. During the IVF treatments, the type of ET catheter has proved to have a considerable effect on treatment outcome [7,8]. The explanation for this difference is still unclear, but it might be associated

with the traumatic effects of the catheter during introduction into the uterine cavity [9,10], This has led to the vast majority of IVF centres throughout the world switching to a soft transfer catheter to avoid endometrial trauma. Data are limited regarding comparisons between different types of IUI catheters, and the results do not confirm the hypothesis that the use of an insemination catheter with a soft tip has any beneficial effect on the outcome of IUI [11,12]. Different varieties and types of IUI catheters are commercially available. They differ in length, calibre, location of the distal port (end or side-loading), and degree of rigidity and malleability. All of them must meet the following criteria: (I) they are easy to use, (II) they are semi rigid devices that follow the curvature of the uterus and decreases trauma to the cervix and endometrium, (III) they are made of nontoxic material, and (IV) the intrauterine tip of the catheter occupies a small volume, to decreases reflux of the inseminated sample [13]. It is important for the injected contents to be retained within the uterine cavity to maximize the chances of sperm getting to the site of fertilization.

The aim of this study was to compare the effect of two different types of catheters on pregnancy rates

MATERIAL AND METHODS

A trial was conducted over 12 months to assess the impact of the IUI transfer catheters on cycle pregnancy rates. Two hundred married women were enrolled in the study from July 2014 through July 2015 and a total of 200 COH-IUI cycles were performed.

The study was approved by the medical ethics committee and informed consents were obtained from all participants involved in the study. All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008.

Randomization: All patients were prospectively randomized into two groups: 100 were inseminated with the Gynetics catheter (Gynetics Medical Products, Hamont-Achel, Belgium) and 100 with the Labotect catheter (labotect insemination catheter, Germany)

Randomization was achieved by a computer-generated randomization table, which was known by the staff of the andrology laboratory only.

Patients were assigned to treatment with gonadotropin for 7-10 days based on their historical factors, laboratory results, and past treatment. They were monitored by intermittent ultrasound and serum oestradiol testing, received hCG by injection upon visualizing a dominant follicle of 18 mm mean diameter, 36–38 h before the planned IUI.

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 minutes to the 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.

Insemination Procedure

The IUI was performed with the patient in the dorsal lithotomy position. A speculum was placed inside the patient's vagina, and the portio vaginalisuteri was cleaned with a sterile swab. Either the Gynetics catheter or the Labotect catheter was attached to a syringe, and the sperm suspension was loaded into the catheter. The catheter was gently inserted through the cervix into the uterine cavity, and then the sperm suspension was slowly expelled through the catheter. After the sperm suspension was injected into the uterus, the catheter was slowly removed. The patient remained in the dorsal lithotomy position for 10 minutes and rested in a sitting position for 30 minutes after IUI.

The transfers were carried out by a certified reproductive endocrinologists (Doctor degree) 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, duration of

infertility, basal hormones on the 2nd day of the cycle (FSH, LH, E_2), ovulation induction agent, estradiol (E_2) at the day of hcg, and chemical and clinical pregnancy rates.

STATISTICAL ANALYSIS

Each potential confounder was evaluated using unpaired t tests for continuous variables. The major outcome investigated in this study was chemical and clinical pregnancy rate. 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 analysed for significance using MaxStat Pro Version 3.60 copyright 2015.

RESULTS

So After 200 treatment IUI cycles, there was a total of 39 clinical pregnancies using the two different types of catheters established with ultrasound evidence of a gestational sac for an overall pregnancy rate around 20% of using each type of catheter. There were no statistically significant differences regarding the chemical and clinical pregnancy rateas shown in table (BHCG 33 %vs 33% and clinical pregnancy 20% vs 19%). Distribution of various types of ovulation induction agents (HMG ampules used for induction) were comparable between the two catheter groups as shown in the Table (1). The rest of parameters regarding as shown in table (1) the age, basal hormonal patterns at the 2nd day of the cycle and duration of infertility were comparable between the two catheters used and finally both catheter types resulted in high patient satisfaction and a low incidence of complaints of pain or bleeding.

DISCUSSION

Intrauterine insemination combined with controlled ovarian hyperstimulation is a commonly used and cost-effective method for the treatment of infertility. It is mainly used to treat male factor, cervical factor, or unexplained infertility cases. The pregnancy rate per cycle varies extremely: very low (4%) or high (40%) pregnancy rates have been published [14, 15]. The great variation in pregnancy rate by IUI treatment might be due to different characteristics of the study populations, different ovarian stimulation protocols, and different insemination technique.

In our study, the pregnancy rate was comparable in the two groups. These data confirm the results from the published randomized studies [11,16] and suggest that the consistency of the catheter is not a major determining factor in clinical outcome after IUI.

Why does catheter consistency have a positive impact on clinical outcome after IVF with embryo transfer [17] but not after IUI? First, the effect of catheter tip on uterine contractility can be hypothesized to be more important at or around the time of implantation (embryo transfer) than at the time of ovulation (IUI). Indeed, after IUI, sperm is known to reach the peritoneal cavity very soon, but embryo implantation in the uterus occurs only about 7 days after fertilization. In contrast, after embryo transfer, the embryo will float around before implantation or will be opposed to endometrial cells without firm attachment for a few days (embryo transfer day 2 or day 3) or will implant within 1 day (embryo transfer day 5 or day 6). Therefore, the implantation rate per embryo may be reduced if the embryo transfer catheter causes direct damage to embryo (s) and/or endometrial lining or if the embryos are expelled through the cervix or via the Fallopian tubes. It has been recognized over the last years that the technique of embryo transfer is very important, and attention is needed for all details with respect to patient installation, preparation, catheter insertion under ultrasound guidance, etc [18]. Second, any potential negative effect of a hard-tip catheter used for IUI may be overcome by the sheer volume of inseminated sperm (0.5 ml), at least 10 times higher than the suspension fluid for embryos (0.04 ml). In that context it is interesting to note that there is randomized evidence that IUI with a much higher volume (up to 4 ml) of inseminated sperm is more successful than classical IUI using 0.5 ml [17,19]. 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, duration of infertility, E2 at the day of hcg, and ovulation induction agents used.

CONCLUSION

Our randomized study has confirmed our hypothesis that catheter type does not affects clinical pregnancy rate after IUI. Furthermore, our results indicate that low-dose hmg ovarian stimulation in combination with IUI leads to an acceptable clinical pregnancy rate per cycle (20%) .

ACKNOWLEDGMENT

The authors thanks Madina IVF-ICSI Lab Team and Shat by IVF-ICSI Team, for there valuable Lab support. Prof Fayek

Table (1):

	Gynetics catheter Nu= 100	Labotect catheter Nu= 100	P value
age in years	30.11 ± 2.34	30.10 ± 2.34	0.9777
Duration of infertility in years	4.6 ± 0.8	4.6 ± 0.9	0.9380
Basal FSH IU/ml at day 2of cycle	6.1 ± 0.6	6.1 ± 0.7	0.9676
Basal LH IU/ ml at day 2 of cycle	6.2 ± 0.7	6.0 ± 0.7	0.0583
Basal E_2 (pg/ml) at day 2 of the cycle	40.1 ± 7.8	38.7 ± 7.3	0.1621
Number of hmg ampules	9.5 ± 1.0	9.7 ± 1.0	0.3642
E_2 (pg/ml) at the day of hcg	660.8 ± 47.4	662.1 ± 46.0	0.8558
% B HCG	33	33	1
% Clinical pregnancy	20	19	0.8426

P value less than 0.05 is considered significant

REFERENCES

1. Campana A, Sakkas D, Stalberg A, Bianchi PG, Comte I, Pache T, et al. Intrauterine insemination: evaluation of the results according to the women's age, sperm quality, total sperm count per insemination and life table analysis. Hum Reprod 1996;11:732– 6.
2. Alborzi S, Motazedian S, Parsanezhad ME, Jannati S. Comparison of the effectiveness of single intrauterine insemination (IUI) versus double IUI per cycle in infertile patients. FertilSteril 2003;80:595–9.
3. Depypere H, Milingos S, Comhaire F. Intrauterine insemination in male subfe-rtility: a comparative study of sperm preparation using a commercial percoll kit and conventional sperm wash. Eur J Obst Gyn Repr Biol 1995;62:225–9.
4. Hughes EG. The effectiveness of ovulation induction and intrauterine insemination in the treatment of persistent infertility: a meta-analysis. Hum Reprod 1997;12:1865–72.
5. Noujua-Huttenen S, Tomas C, Bloigu R, Tuomivaara L, Martikainen H. Intrauterine insemination treatment in subfertility: an analysis of factors affecting outcome. Hum Reprod 1999;14:689 –703.
6. Omblet E, Vandeput H, Van de Putte G, Cox A, Janssen M, Jacobs P, et al. Intrauterine insemination after ovarian stimulation with clomiphene citrate: predictive potential of inseminating motile sperm count and sperm morphology. Hum Reprod 1997;12:1458–63.
7. Meriano J, Weissman A, Greenblatt EM, Ward S, Casper RF. The choice of embryo transfer catheter affects implantation after IVF. FertilSteril 2000;74:678 – 82.
8. Van Weering HGI, Schats R, McDonell J, Vink JM, Vermeiden JPW, Hompes PGA. The impact of the embryo transfer catheter on the pregnancy rate in IVF. Hum Reprod 2002;17:666 –70.
9. Kovacs GT. What factors are important for successful embryo transfer after in vitro fertilization? Hum Reprod 1999;14:590 –2.
10. Goudas VT, Hammitt DG, Damario MA, Session DR, Singh AP, Dumesic DA. Blood on the embryo transfer catheter is associated with decreased rates of embryo implantation and clinical pregnancy with the use of in vitro fertilization-embryo transfer. Fertil Steril 1998;70:878 – 82.
11. Smith KL, Grow DR, Wiczyk HP, O'Shea DL, Arny M. Does catheter type affect pregnancy rate in intrauterine insemination cycles? J Assist Reprod Genet 2002;19:49 –52.

12. Spiessens C, Demaeght O, Debrock S, Meeuwis L, Bakelants E, Meuleman C, et al. The type of catheter has no impact on the pregnancy rate after intrauterine insemination: a randomized study [abstract]. Hum Reprod 2003;18S1:75.
13. Lavie O, Margalioth EJ, Geva-Eldar T, Ben-Chetrit A. Ultrasonographic endometrial changes after intrauterine insemination: a comparison of two catheters. FertilSteril 1997;68:731– 4.
14. Karlström PO, Bergh T, Lundkvist O. A prospective randomized trial of artificial insemination versus intercourse in cycles stimulated with human menopausal gonadotropin or clomiphene citrate. FertilSteril 1993;59:554 –9.
15. Fanchin R, Olivennes F, Righini C, Hazout A, Schwab B, Frydman R. A new system for fallopian tube sperm perfusion leads to pregnancy rates twice as high as standard intrauterine insemination. FertilSteril 1995; 64:505–10.
16. 16 . Miller PB, Acres ML, Proctor JG, Higdon HL. Flexible versus rigid intrau-terine insemination catheters: a prospective, randomised, controlled study. FertilSteril 2005;83:1544-1546. 3rd and Boone WR.
17. NICE guideline. National Institute for Clinical Excellence; 2004. Fertility: assess-ent and treatment for people with fertility problems. Clinical guideline 11.February.
18. Schoolcraft WB, Surrey ES, Gardner DK. Embryo transfer: techniques and variables affecting success.
19. https://www.ncbi.nlm.nih.gov/pubmed/1170 4102FertilSteril. 2001 Nov;76(5):863-70.
20. Mamas L. Higher pregnancy rates with a simple method for fallopian tube sperm perfusion, using the cervical clamp double nut bivalve speculum in the treatment of unexplained infertility: a prospective randomised study. Hum Reprod1996; 11:2618-2622.