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A Comparison of the Incidence of Natural Pregnancy and Ovulation Induction in Patients of Post Laparoscopic Neosalpingostomy on Patients with Stage III-IV of hydrosalpinx

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Abstract

Objective : Comparing the accomplishment of pregnancy in 2 groups of post-neosalpingostomy patients who successfully conceived with ovulation induction clomiphene image compared to natural pregnancy.

Methodology : We performed a quasi-experimental design in infertility patients with bilateral hydrosalpinx with non-patent tubes according to the American Fertility Society classification of adhesion. All patients underwent a laparoscopic neosalpingostomy procedure and were then able to induced ovulation compared to natural pregnancies.

Results : Natural pregnancy success was found to be lower than pregnancies that occurred with ovulation induction, with a fairly high percentage of pregnancies that continue to even months, namely 54%. Meanwhile, only 5% of the total population experienced an ectopic pregnancy. Patients aged > 35 years had a lower pregnancy rate in both the natural and induced pregnancy groups and they also have a higher abortion rate than those aged < 35 years.

Conclusion : Laparoscopic neosalpingostomy for hydrosalpinx with the damage of grades III and IV has a high success rate of pregnancy. It can be one of the main options in infertility patients before IVF.

Key words : Natural pregnancy, Pregnancy with ovulation induction, hydrosalpinx, Laparoscopic Neosalpingostomy.

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INTRODUCTION

Infertility still becomes a health problem in the world, including in Indonesia. Infertility, although it has no effect on physical activity and is not life-threatening, it has a major impact on family life for many couples because it results in medical problems, and also economic and psychological problems. Infertility is defined as failure to conceive after 12 months without regular protection of sexual intercourse in the absence of reproductive pathology^{1, 2}

Infertility can be caused by women, men, or both. However, from the number of infertile couples that exist, most of the causes come from female factors. A woman can be infertile because of increased risk factors. These factors are very diverse, including age, occupation, stress level, body mass index related to nutritional status, and reproductive organ abnormalities, such as the presence or absence of disorders of ovulation, tubal and pelvic disorders, and uterine disorders.^{3, 4, 5}

Abnormalities factors of female reproductive organs are also causing infertility. Based on the results of the study, it is determined that women with reproductive organ disorders are more at risk of infertility compared to ones who do not have reproductive organ disorders. The problem of closed fallopian tubes accompanied by swelling of the fallopian tubes or hydrosalpinx becomes the cause of the embryo damage in the form of embryotoxic and mechanical disturbances in the movement of the ciliary hairs from the fallopian tubes.⁶⁻⁸

It is advised to perform corrections in the form of peritubal adhesiolysis, fimbrioplasty and neosalpingostomy in the case of obstruction of the fallopian tubes with hydrosalpinx which is performed laparoscopically. It is also recommended to be performed in patients who wish to conceive naturally. Neosalpingostomy technique is a strategic alternative for patients who are not willing to undergo salpingectomy and still want a normal pregnancy process without assisted technology, such as IUI or IVF.⁹⁻¹¹

The purpose of this study was to compare the rate of pregnancy in patients who conceived naturally and those who successfully induced ovulation after undergoing laparoscopic neosalpingostomy for hydrosalpinx.

METHODS

This research is an quasi-experimental design. It was conducted at Anugerah Women & Children Hospital in Semarang Indonesia, from January 2014 to December 2019 that approve by Ethical Clearance for Research by Health Research Ethic Committee no 380/EC/KEPK.FK-UNDIP/X/2021. Patients are divided into 2 groups of hydrosalpinx. The first group consists of patients who are not willing to be given ovulation induction, while the second group is patients who receive ovulation induction therapy in the form of 10 mg of clomiphene citrate (the tablet of Pinfetil 50 mg, Novell pharmaceutical laboratories) 2 tablet for 5 days taken from 2nd day til 6th day of cycle and 1 tablet of estradiol valerate 2 mg (The white tablets of Progynova, BAYER) 2 tablets daily for 5 days taken from 8th day till 12th day of the cycle,

The patients will be monitored for 3 cycles with the same therapy. They are monitored according to the egg monitoring protocol via transvaginal ultrasound and on day 12 for monitoring of follicle size and endometrial thickness and 3 months without therapy. Thus, the total number of patients is monitored for 6 months from the start of the intervention.

Basal transvaginal ultrasonography (TVS) on day 2 of the menstrual cycle was done for all patients before starting, Serial TVS started at cycle day 8 for assessment of follicular growth (number and diameter of follicles) and endometrial thickness and was continued at 1–3 day interval till a mean follicular diameter (mean of two orthogonal diameter measurements) reaching ≥ 18 mm

The inclusion criteria in this study are patients who have undergone laparoscopic neosalpingostomy surgery due to phimosis in both fallopian tubes with damage of grade III and grade IV. They are monitored in 2 groups and are willing to perform teleconsultation. In addition to the wives' factors, the husbands' factors in the form of normal sperm according to WHO criteria are also necessary.

Exclusion criteria are patients who are not willing to be monitored by the teleconsultation system. They wish to directly carry out pregnancy therapy with assisted technology with abnormal sperm factors. If more than 6 months after the intervention in the 2 groups, group 2 is still not pregnant, then the patients will be included in the exclusion criteria because the patient will be recommended to get pregnant using assisted technology. The case population in this study are all women who checked themselves for infertility cases at Anugerah Women & Children Hospital in Semarang Indonesia. The control population was ones who have problematic infertility and are examined at the infertility clinic at Anugerah Women & Children Hospital in Semarang Indonesia. The research subjects in the case group are women who experience primary infertility with both non-patent tubal hydrosalpinx stage III and IV, which are confirmed by supporting examination, namely HSG. The study subjects for the control group are infertile women who have undergone laparoscopic neosalpingotomy without ovulation induction [natural cycle]. They are compared with patients who receive ovulation induction in the form of 10 mg of clomiphene citrat which is given on the 2nd day of menstruation and 2 mg of estradiol valerate on 8th day of cycle, according to inclusion criteria. The success of Operating Procedure opening the fimbria in the hydrosalpinx, according to the classification defined by Donnez and Casanaz-Roux, from preoperative HSG examination [table 1], is influenced by the degree of adhesion according to the American Fertility Society classification of adhesion.¹²

Table 1 shows the classification of the degree of closure of the fimbria in the fallopian tube according to Donnez and Casanaz-Roux. In grade 1, the end of the fimbria is closed, but on a hysterosalpingography (HSG) test, both tubes are patent. At grade 2, both fimbriae are completely closed and the results of HSG show that both tubes are non-patent. At grades 3 and 4, it is accompanied by widening of the fallopian tubes. Meanwhile, in grade 5, there is thickening of the fallopian tube wall which causes the loss of the folds of the entire ampulla of the fallopian tube.

Table 1. Classification of Distal tubal Occlusion by Donnez and Casanaz-Roux

No	Degree of damage	Remark
1	Degree I	Phymotic Ostium with preserved tubal patency
2	Degree II	Total Distal Tubal Occlusion Without Ampullary Dilatation
3	Degree III	Ampullary Dilatation inferior to 2.5 cm; ampullary fold well-preserved
4	Degree IV	Hydrosalpinx simple, Dilatation more than 2.5 cm' Well Preserved ampullary fold
5	Degree V	Thick-walled hydrosalpinx; absence of ampullary Folds

In table 1, we can see the report during laparoscopic neosalpingostomy based on *American Fertility Society Classification of Adhesion*, in which the level of adhesion is higher. This is why adhesion is divided into mild, moderate, and severe criteria.¹³

The closing of the distal portion of the fimbria or phimosis of the fimbria with or without hydrosalpinx is caused by a chronic pelvic infection that will lead to adhesions. During laparoscopic, adhesiolysis is performed to release all parts of fallopian tube from the adhesion followed by gently holding the distal part of the tube with phimosis. An opening of a tube with phimosis is performed. This action is done by using 40 watt monopolar needle with “pure cut” setting without coagulation effect until phimosis is opened.

Cross-slices were performed with a monopolar needle under the guidance of a laparoscopic camera until the distal part of the tube was opened and the fimbriae were visible. This procedure was called a salpingostomy. To ensure that there is no re-closing of the phimosis, suturing is continued using 6-0 monofilament threads in 4 corners of the opened fimbria which is called a Bruhat procedure or fimbrioplasty. This procedure of salpingostomy and fimbrioplasty is called neosalpingostomy.^{14,15}

RESULTS

All of the study lasts for 5 years, the participants were monitored through a teleconsultation system about menstrual patterns, fertile period schedules until the occurrence of pregnancy. Repeating HSG examination was performed one month after surgery to make sure that the laparoscopic neosalpingostomy is succeed. After confirming that the fallopian tubes are open from the HSG after surgery, the patient during menstruation is asked to come to the infertility polyclinic to get advice from the doctor for a pregnancy program. When the woman is successful in getting pregnant it will be recorded whether the pregnancy happened naturally, or through ovulation induction. They were also asked about the duration interval between laparoscopy and pregnancy, gestational age and gestational period. They were also invited to attend the hospital's antenatal care to confirm the pregnancy. Participants who are not pregnant are invited to visit the polyclinic to discuss further steps such as the need for pregnancy with assisting technology.

The main result is the pregnancy happened in the span of 6 months after HSG confirmed or 7 months after performing the laparoscopic neosalpingostomy. Meanwhile, the level of the live birth rate was defined as the proportion of women with the births of live fetus and the ongoing pregnancy rate was defined as the proportion of women with pregnancies beyond 24 weeks of gestation or more.

The secondary result is the rate of clinical pregnancy of the women's proportion with the observed fetus heart rate in ultrasound scan, and miscarriage is defined as the proportion of women with miscarriage in their less than 20 week-pregnancy. Abnormal laparoscopic findings and surgery-related complications are also analysed. Technique of data analysis is using univariate, bivariate and multivariate analysis. Univariate analysis is aimed to describe each characteristic data. Statistically, data is described in the term of deviation standard, or frequency (the number of cases) and if necessary,

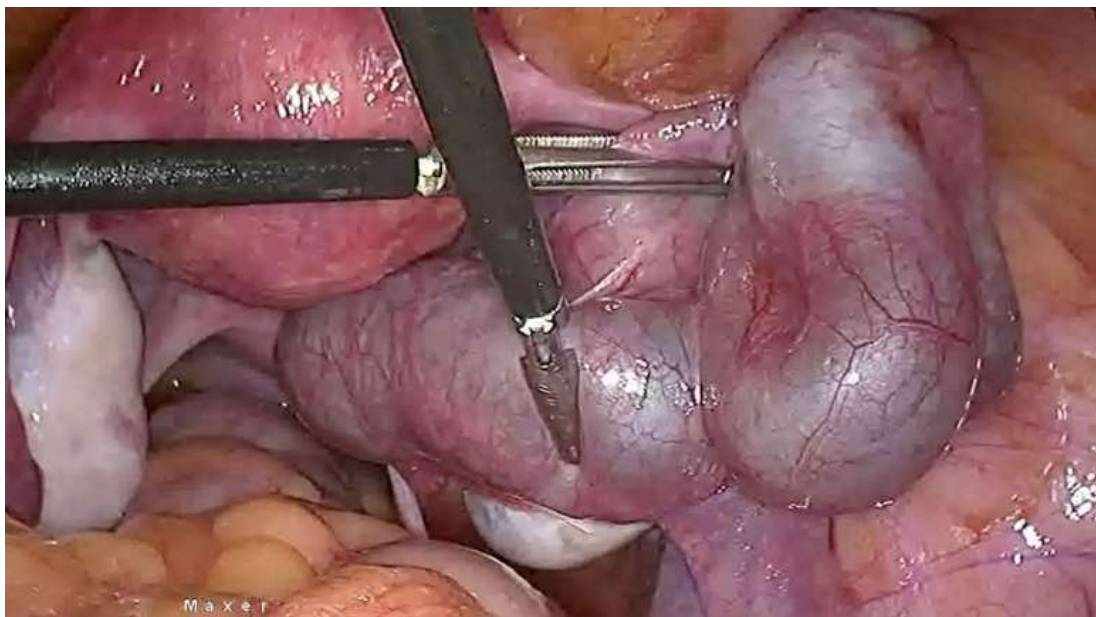


Figure 1. laparoscopic view due to phimositis in both fallopian tubes with damage of grade III and grade IV

the percentage. Bivariate analysis is aimed to analyze the connection of two variables using stata with chi square test.

Patients' characteristics that meet the proper criteria has been outlined in table 1 and table 2. There are 72 patients who are included in the inclusion criteria, but there are two of them losing the follow up, therefore the total number of the patients in the inclusion criteria is 70 infertile patients who meet the proper criteria and who are then analyzed.

Table 2. Characteristics of Patients' Age, Age of Marriage and Maternity

		Total Number	Percentage	Mean
Age	<35	16	27 %	32,5
	>35	56	78 %	38,7
Infertility Age	<5 year	13	18%	3,7
	>5 year	59	82%	8,2
Pregnancy Status	Abortion	16	22 %	
	Ectopic	4	5 %	
	Full Term	38	54 %	
	No Pregnancy	12	17 %	
Maternity Method	Normal Delivery	9	23 %	
	C-Section	29	76 %	
Degree of Hydrosalpinx	Grade III	49	70 %	
	Grade IV	21	30 %	

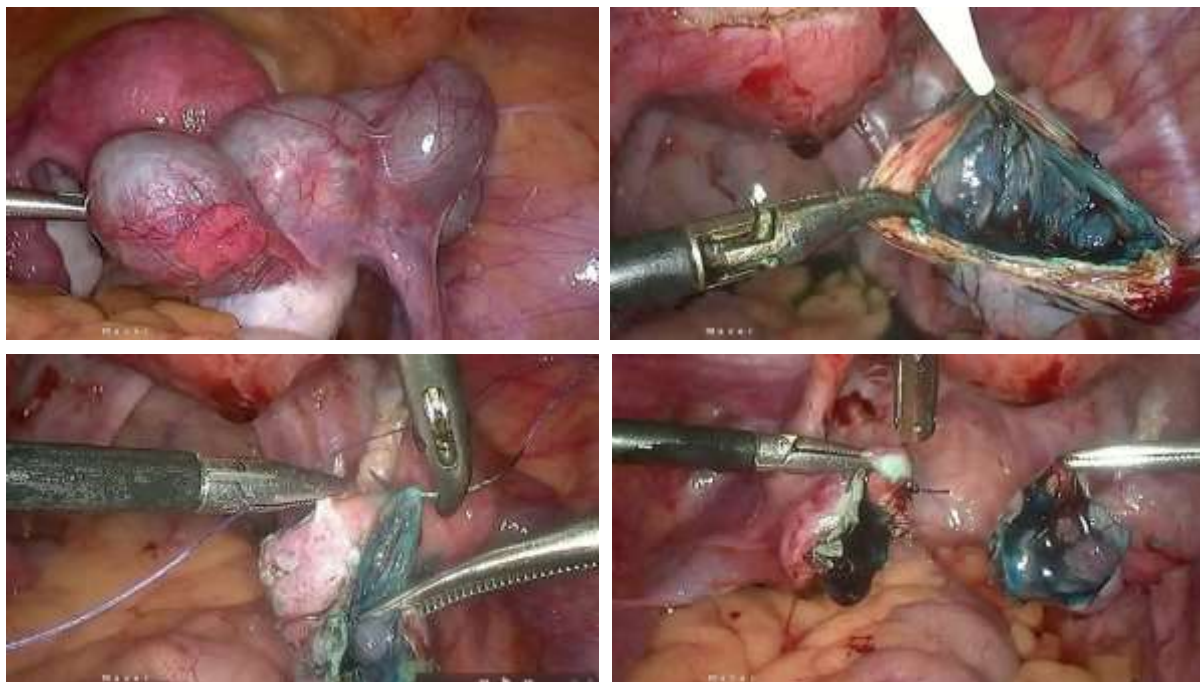


Figure 2. The figure shows picture a in which the distal of fallopian tube is closed (phimos), the procedure of how the fimbrial end opened, laparoscopy neosalpingostomy by stitching the fimbrial end and methylene blue dye test to make sure the opened tube.

The pregnancy of the both group of patients with the high treatment is 83% happening in the span of 7 months after laparoscopic neosalpingostomy , in which 41 patients are successfully pregnant though without ovulation induction. However, there are only 38 patients who can continue the pregnancy completely and there are 76% of them delivering the babies using caesarean section due to medical indication.

Tabel 3. Pregnancy percentage in the span of 7 motnhs after Laparoscopic Neosalphingostomy

	Pregnancy Output									
	abortion		ectopic		Full term		No pregnancy		Total	%
	n	%	n	%	n	%	n	%		
Method of pregnancy										
CC + EE	8	50	1	25	23	60.5	9	75	41	100.0
Natural cycle	8	50	3	75	15	39.4	3	25	29	100.0

CC : Clomiphen Citrat
EE : Estradiol Valerat

Although there is no significant difference in table 4 ($p < 0.01$) from 70 patients with infertility due to hydrosalpinx on pregnancy, but the relative ratio of age over 35 years old, compared with the ectopic pregnancy, is quite high with the big range of confidence interval (CI).

Table 4.The Comparison of mother's age > 35 years old with the pregnancy status

	<i>p</i> Value	RR	CI 95%
Age compared with abortion	0.35	1.53	0.85-2.75
Age compared with ectopic	0.45	2.33	0.42-12.91
Age compared with term pregnancy	0.24	1.29	0.98-1.68

Meanwhile, in table 5, it seems that the chance in a complete-month pregnancy due to ovulation induction is 0.71% with low range of confidence interval. Ectopic in hydrosalpinx tends to be high with the number of relative risk of 1.43.

Table 5. The comparison of pregnancy with the ovulation induction

	<i>p</i> Value	RR	CI 95%
Ovulation Induction compared with abortion	1.00	0.80	0.18-3.53
Ovulation Induction with ectopic	0.25	1.43	0.95-2.14
Ovulation Induction with term pregnancy	1.00	0.71	0.16-3.02

DISCUSSION

Infertility due to the phymosis of fallopian tube along with the swelling of fallopian tube or hydrosalpinx is confirmed causing the damage for embryo in the form of embryotoxic and mechanical disturbance in the movement of ciliary hair from fallopian tube happens to be 20-30% of one of women infertility causes. Laparoscopic neosalphingostomy is reported to be one of the factors causing ectopic pregnancy.^{16,17} In this study, it is found that 4.1% from the total of patient population although it is confirmed one month after the procedure that both tubes are patent from HSG. Ectopic pregnancy is

also affected by the adhesion which involves not only fimbria but also other organs in adnexa. Laparoscopic adhesiolysis procedure is reported to be more superior than laparotomy, both for moderate and heavy adhesion. Corrective actions in the form of peritubal adhesiolysis, fimbrioplasty and neosalpingostomy by laparoscopy are indeed an option for patients who choose the process of pregnancy without assisted technology such as IVF.^{18, 19,20}

Although there is no significance in this study, 82.8% success of pregnancies both natural and induced ovulation are found for 7 months after laparoscopic neosalpingostomy in patients with an average infertility period of 8.2 years. Compared with previous studies in which 60% of pregnancies occurred after fimbrioplasty, this surgical technique can be an option for patients who desire pregnancy.

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Conflicts of interest

There is no conflict of interest in this study

CONCLUSIONS

The closing of distal part from the oviduct or fimbriae phimosis is one of the infertility causes. The procedure of laparoscopic neosalpingostomy on patients with non-patent HSG with hydrosalpinx damage grade III and IV still becomes one procedure that can be recommended to patients before they perform assisted pregnancy procedure.

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