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Prediction Model for Pregnancy Success in IVF Program in the Poor Prognosis Group

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ABSTRACT

Introduction: Infertility has become a severe problem for married couples who have hoped to have children after having sexual intercourse 1-3 times a week for 12 months without using contraception. WHO has reported that 1 in 7 couples have problems with pregnancy, whereas around 50-80 million married couples from all over the world have infertility problems. Both husband and wife factors are related to the potential for infertility that can occur, and various examinations in the IVF program are known to predict the outcome of the IVF program.
Methodology: This study aimed to predict the success of the IVF program, namely the achievement of clinical pregnancy based on IVF predictor factors in the poor prognosis group. This descriptive-analytic study uses total sampling and secondary data from medical records.
Results: Based on the logistic regression test results using the IBM SPSS (Statistical Package for the Social Science) 25 program it was obtained from various variables predicting clinical pregnancy factors, a significant research variable in predicting the success of the IVF program in the poor prognosis group was endometrial thickness p value = 0.001 (p = < 0.05) which stated that there was a relationship between endometrial thickness and the incidence of clinical pregnancy.
Conclusion: From the results of the bivariate test of factors predicting the incidence of pregnancy in the IVF program in the poor prognosis group, three variables are significant for the dependent variable, namely Endometrial Thickness, Number of Fertilized Oocytes, and Number of Top Quality Embryo Transfers; Results in the final model where one significant independent variable was obtained to predict the success of clinical pregnancy in the IVF program, namely Endometrial Thickness.

Keywords: *Infertility, prediction model, In Vitro Fertilization, Logistic Regression, Endometrial Thickness, Poor Prognosis, Clinical Pregnancy*

INTRODUCTION

Infertility according to the Indonesian Association of Reproductive Endocrinology and Fertilization (2013) is a condition where a couple is unable to have children. This condition is common and can be caused by female, male, or both factors. Infertility in men occurs due to poor sperm quality based on sperm quantity, motility, and morphology. Meanwhile, in women, the causes of infertility are divided into three groups, namely ovulation disorders, tube and pelvic disorders, and disorders of the uterus [1] [2]

According to the World Health Organization (WHO), it is estimated that 1 in 7 couples have problems with pregnancy, whereas around 50-80 million married couples from

around the world have infertility problems. Meanwhile, in Indonesia, the prevalence of infertility is ±12%-22% of reproductive age.[3] Around 50% of these couples are successfully helped to deal with secondary infertility problems; the rest have to adopt or live without a child. Women cause 40% of secondary infertility, 20% by men, and male and female factors cause the other 40%. Meanwhile, primary infertility is 8-12% (Ministry of Health of the Republic of Indonesia, 2014) [4]

Fertility in women begins to decline when they reach the age of 30. However, all women will experience a decrease in fertility. It is difficult to predict the rate of reproductive decline in each individual. This is associated with a decrease in the number of available egg cells due to the oocyte atresia process and a decrease in the quality of the egg cells. [5]

In vitro fertilization (IVF) is a process where egg cells are fertilized by sperm outside the body. The birth of the first baby using the IVF program, namely Louise Brown, on 25 July 1978, at Oldham Hospital, United Kingdom, marked the beginning of the success of the IVF program which has been carried out for more than 40 years. IVF technology has helped give birth to more than 8 million babies to date.[6][7] When it was first created, IVF was a method to increase fertility due to tubal damage that was difficult to repair, but now IVF has been used for almost all causes of infertility. The reason why married couples participate in the IVF program is generally because they want to have children and have tried everything they can to get pregnant but have been unsuccessful. With the development of IVF technology, it gives hope to many infertile couples to achieve their dream of having children.[6]

As IVF progressed, ovarian stimulation began, increasing the number of oocytes and pregnancy rates. Furthermore, with the development of IVF technology, it began to be complemented by several new technologies, including: ICSI techniques, Cryopreservation, Preimplantation Genetic Diagnosis (PGD) and several others.

Anti-Müllerian Hormone (AMH) also known as Müllerian inhibiting substance is a glycoprotein which is part of the transforming growth factor β (TGF-β) superfamily.8 AMH plays a significant role in cell growth and differentiation. AMH reflects the number of growing follicles, therefore Anti-Mullerian Hormone (AMH) levels can be used as an accurate predictor of ovarian reserve and ovarian stimulation response in In Vitro Fertilization.[9]

Antral follicles are small with a diameter of 2-8 mm found in the antral phase and can be detected via transvaginal ultrasound at the beginning of menstruation. A high Antral Follicle Count (AFC) value indicates a higher ovarian reserve and, thus, a higher chance of pregnancy.[10] The AFC value decreases with age, but some other hereditary or genetic factors can also cause a decrease in the value.[11]

Most published studies show that infertile patients have a higher prevalence of follicular decline associated with age. If this statement is considered accurate, it is estimated that low AMH and AFC levels in infertile women influence the success of the IVF program. The AMH and AFC cut-offs are included in the Bologna criteria to determine whether a patient is included in the good prognosis or poor prognosis group, accompanied by patient criteria in age and number of oocytes produced in the previous cycle. This research aims to predict the success of the IVF program in the poor prognosis group.

Research Problem

Based on the description in the background above, the problem can be formulated as follows:

1. What is Clinical Pregnancy's success rate in the IVF program's poor prognosis group based on the Bologna criteria?
2. What predictive factors are significant in predicting clinical pregnancy success in the IVF program?

Research Purposes

Research regarding the prediction model for pregnancy success in the IVF program in the Poor Prognosis group based on the Bologna criteria has two research objectives, namely the general and specific research objectives.

General purpose

This research aims to determine the characteristics of patients undergoing the IVF program at one of private IVF clinic in Jakarta.

Special purpose

1. To predict the success of the IVF program, namely Clinical Pregnancy, based on IVF predictor factors in the Poor Prognosis group.
2. For the practical benefits of decision-making on Assisted Reproductive Technology (ART), especially in estimating the expected possible IVF results in the IVF program.

Benefits of research

For Educational Institutions

1. It is hoped that the results of this research can be added to the literature so that it becomes reference material that can later be used in conducting further research.
2. Hopefully, this research can increase scientific insight regarding predicting pregnancy success through the IVF program in the Poor Prognosis group.

For Researchers

1. Increase knowledge in the field of Research Methodology as capital for further research.
2. Increase knowledge, experience, and information regarding predictions of pregnancy success in the IVF program in the Poor Prognosis group.

For Society

1. Provide information regarding predictions of pregnancy success in the IVF program in the Poor Prognosis group.
2. It is hoped that the results of this research can be used as a reference source for further research regarding the prediction of pregnancy success with the IVF program in the Poor Prognosis group.
3. It is hoped that this research can be used to predict pregnancy success in the IVF program in the Poor Prognosis group.

Research Hypothesis

Ho: There is no relationship between the predictive factors for IVF success and the occurrence of successful pregnancy in the In Vitro Fertilization (IVF) program.

Ha: There is a relationship between the predictive factors for IVF success and the occurrence of successful pregnancy in the In Vitro Fertilization (IVF) program.

MATERIALS & METHODS

Method

Research Design

This research is non-experimental research with a retrospective analytical descriptive design using secondary data taken from the medical records in one of private IVF clinic in Jakarta from January 2017 – December 2019.

Location and Time of Research

This research was conducted at Morula IVF Jakarta, The BIC, Jl. Teuku Cik Ditiro No.12, RT.8/RW.2, Gondangdia, Menteng, Central Jakarta. This research will be carried out for approximately two months, from December 2020 to January 2021, by taking existing medical record data from January 2017 to December 2019.

Population and sample

The study population was all medical records of women with a history of infertility and undergoing the IVF program at Bunda International Clinic Morula IVF for the period January 2017 – December 2019. The sample for this study was part of the

population that met the inclusion and exclusion criteria.

Determination of Sample Size

A sample is part of a population that has the same characteristics as the population. Sampling is the method used to obtain a sample that suits the overall research object. In this study, researchers used a total sampling method, where the sample size is part of the population that meets the Inclusion Criteria.

Research Criteria

Inclusion Criteria

- Patients undergoing fresh embryo transfer in the IVF program at Bunda International Clinic Morula IVF from January 2017 – December 2019
  Patients who meet the poor prognosis criteria according to the Bologna criteria:
- Patients aged □ 38 years.
- Patients with AMH examination results ≤1.1 ng/ml.
- Patients with AFC examination results ≤7.
- Patients with Basal Estradiol test results □ 80 pg/ml.
- Patients with Basal FSH test results □ 12 IU/ml.
- Patients with oocyte quantity from the previous stimulation cycle as a response ovarian value (<3 oocytes)

Exclusion Criteria

- Patients undergoing oocyte or embryo donation
- Patients undergoing frozen embryo transfer
- Patients who do not meet the poor prognosis criteria.

Research Variables

The variables used based on type are:

Independent Variables

The independent variables from this research are factors predicting successful pregnancy in the in vitro fertilization (IVF) program.

Dependent Variable

The dependent variable of this research is the occurrence of clinical pregnancy from in vitro fertilization (IVF) therapy.

Ethical Clearance

This research has been approved by the Ethics Committee of the Faculty of Medicine, Indonesian Christian University No.23/Research Ethics/FKUKI/2020.

Research Instruments

The research instrument used in this study was medical records of patients undergoing IVF therapy.

Research Procedure

Collecting Data

Data was collected in the Bunda International Clinic Morula IVF medical records section. Next, medical record data corresponding to the research variables will be recorded. All data obtained will be filtered again according to the Inclusion Criteria and Exclusion Criteria that have been determined so that data can be produced that will be used in the results of this research.

Data Processing Methods

Data that has been collected through medical records is processed by entering it in table form in Microsoft Excel and processing it using the IBM SPSS (Statistical for Social Science) 25 for Windows program.

RESULT AND DISCUSSION

Research result

In research conducted in the period January 2017 to December 2019, the number of infertility cases was found to be 344 cases. Data taken by sampling totaled 344 cases of infertility diagnoses that were included in the inclusion criteria for this study and were used as samples.

The data collected in this study were from patients with poor prognosis according to the Bologna criteria. The data used were duration of infertility, BMI, basal FSH, basal Estradiol, basal Progesterone, Endometrial thickness, quality embryo transfer, Total embryo transfer, Day embryo transfer,

Fertilization, and Clinical pregnancy. The data collected is then analyzed to determine factors that can predict the occurrence of clinical pregnancy in the IVF program at Bunda International Clinic Morula IVF Jakarta.

Table 1. Normality Test Result

Variable	P value
Durasi Infertilitas	0.006
BMI	0.000
FSH Basal	0.001
Estradiol Basal	0.000
Progesterone Basal	0.000
Endometrial Thickness	0.000
Number of Fertilized Oocyte	0.000
Number of Top Quality Embryo Transfer	0.000
Total Embryo Transfer	0.000

From the results obtained from the data normality test using the Kolmogorov-Smirnov test method (more than 50 samples), it was found that there was a sig value. < 0.05 for all variables tested; this indicates that the data distribution is abnormal. So with this, the prerequisite tests for parametric tests are not met on numerical variables, so we will use a non-parametric statistical test, namely the Mann-Whitney test and for categorical variables we will use the Chi-Square test.

Univariate Analysis

Univariate analysis was carried out to determine the distribution of research subjects who succeeded in achieving pregnancy by calculating the frequency and percentage of each research variable. The analysis results will provide a general picture by describing each variable used in the research, namely by looking at the frequency distribution in table form. If the data distribution is normal, then the data that must be included in the table is the mean and standard deviation. Still, in this study all the data distributions obtained were not normal so what was included in the table was the median and interquatile range.

Data analysis includes the variables duration of infertility, BMI, basal FSH, basal Estradiol, basal Progesterone, Endometrial thickness, Top quality embryo transfer, Total embryo transfer, Day embryo transfer, Number of Fertilized Oocytes with Clinical pregnancy in patients undergoing the IVF program. The results obtained from the research are listed in the table below.

Table 2. Data Distribution Based on Duration of Infertility, BMI, basal FSH, basal Estradiol, basal Progesterone, Endometrial thickness, Top quality embryo transfer, Total embryo transfer, Day embryo transfer, Number of Fertilized Oocytes, and Clinical Pregnancy in In Vitro Fertilization Program Patients

Prediction Factors	Frequency	Median and interquartile range	Min-Max Value
Infertility Duration	334	8,00±8,00	0,6-20
BMI	325	24,21±4,94	17,4-38,4
FSH Basal	320	8,39±3,46	2-20
Estradiol Basal	324	34,7±23,97	5-253
Progesterone Basal	313	0,20±0,27	0,05-2,85
Endometrial Thickness	328	10,0±2,30	3,1-23
Number Of Fertilized Oocyte	344	2,00±2,00	1-14
Top Quality Embryo Transfer	344	1,00±1,00	0-2
Total Embryo Transfer	344	1,00±1,00	1-3
Day Embryo Transfer			
D3	214(65,1%)	-	-
D5	120(34,9%)	-	-

Based on the data in table 2, it can be seen that the data obtained according to the prediction factors for the duration of infertility contained 334 data the largest data obtained was 20 years and the smallest data obtained was six months. There are 325 BMI prediction factors; the largest data obtained is 38.4, and the smallest is 17.4. There are 325 BMI prediction factors; the largest data obtained is 38.4, and the smallest is 17.4.

Bivariate Analysis

Bivariate analysis was carried out on two correlated variables. Analysis of the relationship between predictive factors and pregnancy success in the IVF program. Each independent variable was subjected to bivariate analysis with the dependent variable.

Table 3. Results of Bivariate Analysis of Factors Predicting Pregnancy Success in the IVF Program on the occurrence of Clinical Pregnancy

Variable	*Clinical Pregnancy*		P value
	Yes	No	
Infertility Duration	8.00±8.50	8.00±8.00	0.946
BMI	2.83±5.09	24.31±4.98	0.490
FSH Basal	8.16±3.42	8.41±3.47	0.527
E2 Basal	32.0±27.96	35.14±22.63	0.465
P4 Basal	0.20±0.24	0.20±0.29	0.407
Endometrial Thickness	11.0±2.30	9.80±2.50	0.000
Number Of Fertilized Oocyte	3.00±2.00	2.00±1.75	0.002
Top Quality Embryo Transfer	1.00±1.00	1.00±1.00	0.053
Total Embryo Transfer	2.00±1.00	2.00±1.00	0.339
Day Embryo Transfer			0.485
D3	43(19,2%)	181(80,8%)	
D5	27(22,5%)	93(77,5%)	

In table 3 is the median and interquatile range data (because the data distribution is not normal according to the Kolmogorov-Smirnov normality test) and n(%) for categorical data such as day embryo transfer. And the p value results are obtained using the Mann Whitney test and categorical variables will use the Chi Square test to determine bivariate results so that variables can be selected that can be included in multivariate analysis.

Bivariate test results can show the probability of an event where if the p-value (sig.) > 0.05, then H0 is accepted, meaning that statistically, there is no significant relationship between the independent and dependent variables. Conversely, if the p-value (sig.) < 0.05, then H0 is rejected, meaning there is a significant relationship between the independent and dependent variables.

In the bivariate analysis three variables will be included in the multivariate test, namely the Endometrial Thickness variable with a p value of 0.000 which has data of 11.0±2.30 (median and interquartile range) in patients who get clinical pregnancy results and 9.80±2.50 in patients who don't get it. The multivariate analysis included a number of Fertilized Oocytes with a p-value of 0.002 with a data distribution of 3.00±2.00 in patients who achieved clinical pregnancy and 2.00±1.75 in patients who did not achieve clinical pregnancy results. Top Quality Embryo Transfer with p value of 0.053, the median and interquartile range data for patients who succeeded in achieving clinical pregnancy was 1.00±1.00 and for patients who did not achieve clinical pregnancy results of 1.00±1.00.

The percentage of IVF patients who underwent embryo transfer on day 5 (D5) was more significant than patients who underwent embryo transfer on day 3 (D3). The results obtained from 224 patients who underwent embryo transfer on day five showed that 22.5% successfully achieved clinical pregnancy. Meanwhile, in patients who underwent embryo transfer on day 3, 19.2% were successful in obtaining a clinical pregnancy.

Multivariate Analysis

If the bivariate results produce a p-value <0.25, the variable immediately enters the multivariate stage. For independent variables whose bivariate results produce a p-value> 0.25 but are substantially important, these variables can be included in the multivariate model.

After the analysis results are obtained, the variables that will enter the multivariate analysis, namely the logistic regression test, need to be selected. The variables included in the multivariate analysis were variables which in the bivariate analysis had a p value of ≈ 0.25, namely Endometrial Thickness, Number of Fertilized Oocytes, and Number of Top Quality Embryo Transfers.

Logistic Regression Analysis

Table 4. Binary Logistic Regression Test Results

		B	S.E.	Wald	df	Sig.	Exp (B)	95% C.I.for EXP(B)	
								Lower	Upper
Step 1[a]	Endometrial Thickness	.200	.057	12.353	1	.000	1.221	1.092	1.365
	Number of fertilized oocyte	.083	.073	1.263	1	.261	1.086	.940	1.254
	Number of top quality embryo transfer	.318	.214	2.194	1	.139	1.374	.902	2.092
	Constant	-4.030	.695	33.598	1	.000	.018		

Based on table 4, the results of the analysis of variables with a p value > 0.05 are Endometrial Thickness with a p value = 0.000, Number of Fertilized Oocytes with a p value = 0.261, and Number of Top Quality Embryo Transfers with a p value = 0.139. The variable with the largest p value in the table will be excluded from the model. According to the results obtained, the largest p value is Number of Fertilized Oocytes, so the next modeling variable Number of Fertilized Oocytes is removed from the model.

Table 5. Binary Logistic Regression Test Results After the Number of Fertilized Oocyte Variable is removed

		B	S.E.	Wald	df	Sig.	Exp (B)	95% C.I.for EXP(B)	
								Lower	Upper
Step 1[a]	Endometrial Thickness	.197	.057	11.965	1	.001	1.217	1.089	1.361
	Number of top quality embryo transfer	.379	.209	3.296	1	.069	1.460	.970	2.198
	Constant	-3.824	.665	33.071	1	.000	.022		

After the Number of Fertilized Oocytes are released, we see changes in the OR values for the Endometrial Thickness and Number of Top Quality Embryo Transfer variables.

Table 6. Comparison of changes in OR values with/without the Number of Fertilized Oocyte (NOFO) variable

Variable	OR NOFO exist	OR NOFO does not exist	OR Change
Endometrial Thickness	1.221	1.217	0%
Number of top quality embryo transfer	1.374	1.460	0,6%

Pay attention to the OR value after the Number of Fertilized Oocyte (NOFO) variable is removed. Then compare the changes that occur in the OR value to the OR value from the first logistic regression test.
With the OR comparison results, it can be seen that there is nothing > 10% and therefore it is excluded from the model. Next, the variable with the largest p value, Number of Top Quality Embryo Transfer, was thus removed from the model and the results were as follows.

Table 7. Binary Logistic Regression Test Results After the Number of Top Quality Embryo Transfer Variables were removed

		B	S.E.	Wald	df	Sig.	Exp (B)	95% C.I.for EXP(B)	
								Lower	Upper
Step 1[a]	Endometrial Thickness	.200	.058	11.996	1	.001	1.221	1.091	1.368
	Constant	-3.415	.624	29.990	1	.000	.003		

After the Number of Top Quality Embryo Transfer is issued, we see the change in the OR (Exp(B)) value for the Endometrial Thickness variable with the following results

Table 8. Comparison of changes in OR values with/without the Number of Top Quality Embryo Transfer variable

Variable	OR Top Quality ET exist	OR Top Quality ET does not exist	OR Change
Endometrial Thickness	1.217	1.221	0%

From the OR comparison analysis, it turns out that the Endometrial Thickness OR value shows a change of <10%, thus the Number of Top Quality Embryo Transfer variable is removed from the model.

Table 9. Final Model Table

		B	S.E.	Wald	df	Sig.	Exp (B)	95% C.I.for EXP(B)	
								Lower	Upper
Step 1[a]	Endometrial Thickness	.200	.058	11.996	1	.001	1.221	1.091	1.368
	Constant	-3.415	.624	29.990	1	.000	.003		

From the multivariate analysis, it is known that the variable that is significantly related to the incidence of Clinical Pregnancy is the endometrial thickness variable. The results of the analysis showed that the Odds Ratio (OR) of the endometrial thickness variable was 1.2, meaning that every increase in endometrial thickness would increase the incidence of pregnancy by 1.2 times.

In table 9 there is an Exp(B) column which means the exponential value from column B. The Exp(B) value in logistic regression is the same as the odds ratio (OR) value. In the endometrial thickness line, the OR was 1.221 (95% CI 1.09-1.36). Because there is no number 1 in the confidence interval range, the OR is said to be significant. We can conclude that the endometrial thickness variable is significantly related to the incidence of clinical pregnancy as a predictive factor.

The results of the logistic regression test on endometrial thickness showed a p value = 0.001 (p = <0.05) which stated that there was a relationship between endometrial thickness and the incidence of clinical pregnancy.

The equation obtained from logistic regression is

$y = a + \beta 1X1 + \ldots\ldots + \beta iXi$

a = constant; β = coefficient; X = independent variable

The constant value is the value in column B in the constant row of -3.415. The independent variable is in the leftmost column, namely Endometrial Thickness. The coefficient value for the independent variable (Endometrial thickness) is the value in column B in the Endometrial Thickness row, namely 0.200. With this information, you can create a logistic regression equation.

$y = a + \beta 1X1 + \ldots\ldots + \beta iXi$

$y = a + \beta 1X1 = -3.415 + 0.200$ x Endometrial Thickness

CONCLUSION

Based on the research results above, researchers can conclude that:

1. According to the results of the bivariate test, there are three variables that are significant for the dependent variable, namely Endometrial Thickness, Number of Fertilized Oocytes, and Number of Top Quality Embryo Transfers.
2. Results in the final model where one significant independent variable was obtained to predict the success of a clinical pregnancy in the IVF program at Bunda International Clinic Morula IVF, namely Endometrial Thickness.

Declaration by Authors

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