Public Health of Indonesia
Ratrikaningtyas, P. D., et al. Public Health of Indonesia. 2018 September;4(3):100-107 **ISSN: 2477-1570**
http://stikbar.org/ycabpublisher/index.php/PHI/index

Original Research

PREVALENCE AND PATTERN OF UTERINE BLEEDING AMONG BREASTFEEDING WOMEN USING PROGESTERONE-ONLY PILLS

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Received: 2 July 2018 | Revised: 16 July 2018 | Accepted**:** 23 July 2018
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ABSTRACT
Background: *Progesterone*-Only Pill (POPs) is one of the ideal oral contraceptive methods for breastfeeding women. Discontinuation of POPs was mostly due to bleeding pattern disorders.
Objective: The purpose of this study is to identify the prevalence and pattern of uterine bleeding on breastfeeding women using contraceptive pills containing progesterone derivatives.
Methods: This study is a double blind block randomized controlled trial for the treatment group (*levonorgestrel* or *lynestrenol* pills) and non-randomized controlled trial for the control group, 6-8 weeks' postpartum women, 20 to 35-year-old, and breastfeeding. Monthly follow up was done for 6 months. Analysis was done using survival analysis, X^2, and Cox's Proportional Hazard.
Results: A hundred and seven women were involved with a drop-out rate of 17.8%. Subjects characteristics were ≤ 32-year-old, multiparous, ever used contraception with birth spacing of >60 months. Spotting and amenorrhea was the most common pattern. *Levonorgestrel* causes bleeding/menstrual resumption sooner in breastfeeding women than *Lynestrenol*.
Conclusion: The most common uterine bleeding on women using *Progesterone*-only Pills were spotting and amenorrhea. By recognizing such effects, for Indonesian women, POPs was expected to be produced in the country and can be included in the national family planning programs.

Keywords: progesterone-only pills, levonorgestrel, lynestrenol, bleeding patterns, breastfeeding

INTRODUCTION

Postpartum contraception is very important because it will increase the health of both mother and child by better managing pregnancy spacing (Phillips et al., 2015). Ideally, contraception starts before ovulation recurs. Ovulation may occur before the menstruation cycle returns so that it requires contraception with proper methods and time. Non-hormonal methods, including Lactation Amenorrheal Method (LAM), become the first choice for breastfeeding women because it does not affect lactation, health and growth of the child. However, due to some medical or personal reasons, many women prefer hormonal contraception. LAM is difficult to implement because the coverage of exclusive breastfeeding in Indonesia and the world is still low (Ichsan, 2015). Women practicing

exclusive breastfeeding in Indonesia was 40% (Susiloretni, Hadi, Prabandari, Soenarto, & Wilopo, 2015). WHO recommends exclusive breastfeeding coverage of up to 90% (Ichsan, 2015). The second preferred choice is the hormonal method which only contains progesterone because it is known that it does not have negative effects on lactation and the child, even allegedly increasing the volume of breast milk (Espey, Ogburn, Leeman, Singh, & Schrader, 2012; Phillips et al., 2015). Hormonal methods containing estrogen become the last choice because it is known that it decreases the production of breast milk, affects the duration of breastfeeding period, and has negative effects on infant growth (Espey et al., 2012).

Hormonal contraception was designed to change ovarian function, prevent ovulation by suppress endogenous menstrual cycle. Inhibition of ovulation, thickening of the endometrial and cervical mucus is largely the effect of progestin and depends on the amount of dose used (De Melo, 2010; Edelman, Cherala, & Stanczyk, 2010; Freeman & Shulman, 2010). Thickening of the cervical mucus is intended to inhibit sperm penetration (Zigler & McNicholas, 2017).

Progesterone Only-Pill (POPs) or minipill is a birth control pill which only contains progestin in low dosages, is proven to be reversible and effective for breastfeeding women (Phillips et al., 2015). *Levonorgestrel* (LNG) and *Lynestrenol* are synthetic progestin commonly used. Unfortunately, menstrual irregularity and menstrual pattern disorders are often the primary causes to discontinue using it (d'Arcangues, Jackson, Brache, & Piaggio, 2011; Freeman & Shulman, 2010; Kaneshiro, Edelman, Carlson, Nichols, & Jensen, 2012). Twenty percent of women using POPs have amenorrhea, 40% have regular bleeding and the remaining 40% have irregular bleeding (Busby, 2016). Twenty percent women using POPs experienced amenorrhea, 40% had irregular bleeding and 40% had unscheduled bleeding (Busby, 2016). Breastfeeding women in the Family Planning program do not have choices in hormonal pills. All types of POPs distributed in Indonesia have not been part of the Family Planning program due to their relatively high prices. This study is aimed at identifying the effects of progesterone pill on the bleeding pattern in breastfeeding women in Indonesia.

METHODS

Study design

This study was a *double-blind block randomized control trial* for treatment group (which received LNG or *Lynestrenol* pill) and a *non-randomized control trial* for control group (which used IUD). Subjects were observed up to 6 months. Follow-up visit was performed at every 26 days - 1 month. Each follow-up visit included physical examination for subject and her baby, give the new blister pills and daily cards, as well as interviews; consisting of questions about the use of pills, observations of adverse events, history of menstruation or bleeding outside the menstrual period in the previous month, and breastfeeding process. The flow of the study is shown in Figure 1.

Sample and setting

This study was conducted at six health care centers, in two district of Yogyakarta province, Indonesia, from June 2012 to July 2013. Subjects were women aged 20-35 years, 6-8 weeks of postpartum, still breastfeeding, willing to use Progesterone Only Pills or used IUD, met the inclusion and exclusion criteria. The dependent variable was bleeding pattern, the independent variables were the use of LNG pill, *Lynestrenol* pill, and IUD, and confounding variables were body mass index/ BMI, breastfeeding compliance, and status.

Data analysis

Data analysis consisted of univariate analysis by considering frequency distribution and percentage; bivariate analysis using survival analysis, and multivariate analysis using Cox's Proportional Hazard Regression with Time-Varying covariate, with a significance level of $p<0.05$ and 95% Confident Interval (CI).

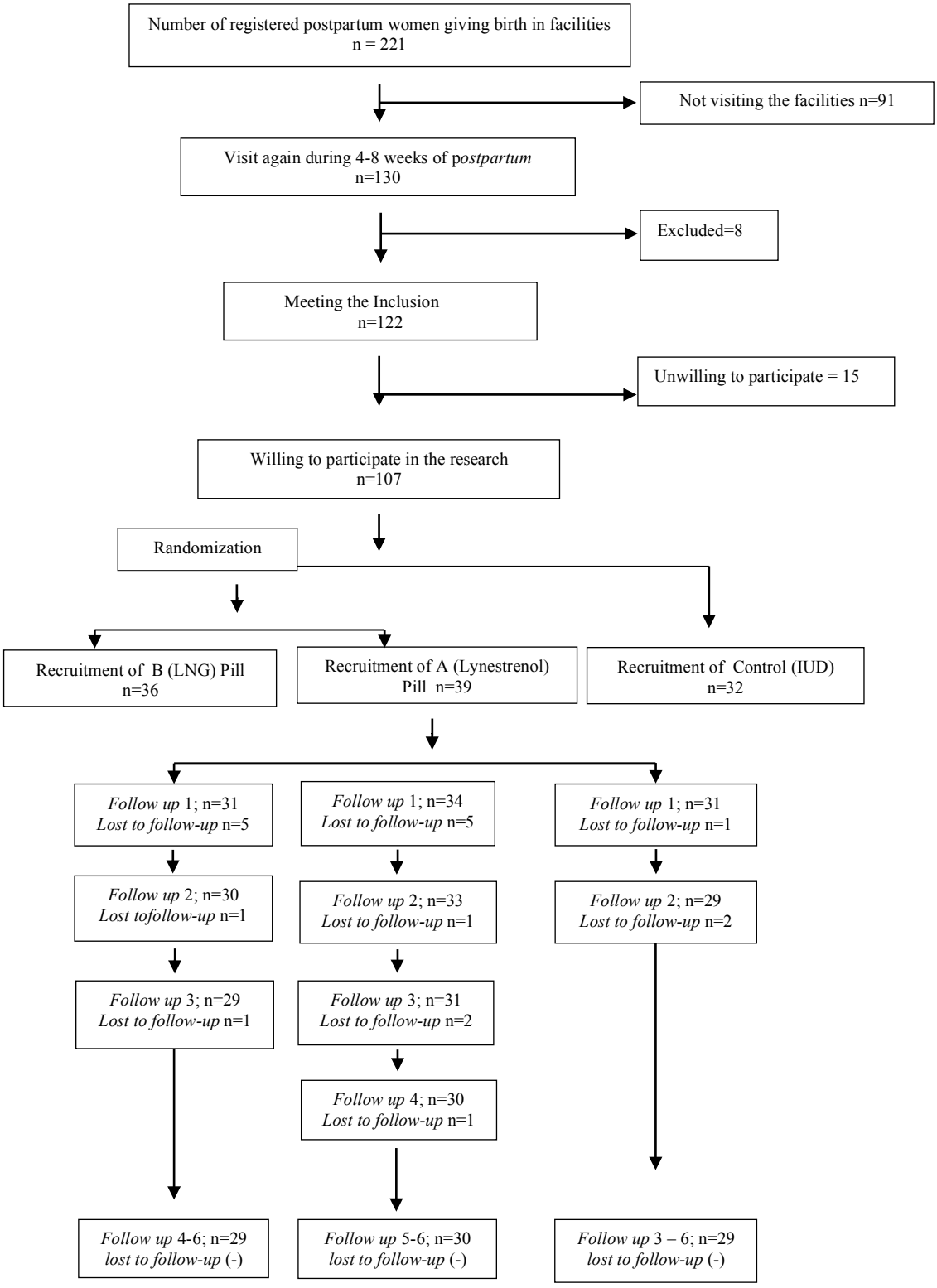

Figure 1 Recruitment and Follow up Diagram

Ethical consideration

This research has obtained an Ethical Clearance Certificate from Medical Research Ethics Commission, Faculty of Medicine, Public Health and Nursing, Universitas Gadjah Mada with Ref: KE/FK/484/EC reference number dated July 5th 2012.

RESULTS

The number of subjects at the beginning of the study was 107 women and decreased to 88 until research completed. **Table 1** shows the characteristics of subjects.

Table 1 Characteristic of Socio Demographic and Reproductive Health

Variable	Type of Contraception						Total		*p*
	LNG Pill		*Lynestrenol* Pill		IUD/Control				
	n	%	n	%	n	%	n	%	
Age (years old)									
≤ 32	23	63.9	31	79.5	26	81.3	80	74.8	0.18
> 32	13	36.1	8	20.5	6	18.8	27	25.2	
Education									
Primary	16	44.4	12	30.8	11	34.4	39	36.5	0.54
Secondary	17	47.2	24	61.5	16	50.0	57	53.3	
Higher	3	8.3	3	7.7	5	15.6	11	10.3	
Occupation									
Housewife/not working	25	69.4	28	71.8	25	78.1	78	73.0	0.47
Employee	9	25.0	8	20.5	7	21.9	24	22.4	
Self-employed	2	5.6	2	5.1	0	0	4	3.74	
Farmer	0	0	1	2.6	0	0	1	1.0	
Number of Live Birth (parity)									
Primiparous	13	36.1	17	43.6	12	37.5	42	39.3	0.78
Multiparous	23	63.9	22	56.4	20	62.5	65	60.8	
Birth Spacing (months)									
13 – 24	3	13.0	3	13.6	4	20.0	10	15.4	0.71
25 – 36	2	8.7	0	0	2	10.0	4	6.2	
37 – 48	2	8.7	5	22.7	2	10.0	9	13.9	
49 – 60	4	17.4	4	18.2	5	25.0	13	20.0	
>60	12	52.2	10	45.5	7	35.0	29	44.6	
Last type of contraception used									
IUD	0	0.0	1	5.6	3	15.8	4	7.4	0.47
Injection	12	70.6	9	50.0	8	42.1	29	53.7	
Pill	3	17.7	5	27.8	3	15.8	11	20.4	
Condom	2	11.8	3	16.7	4	21.1	9	16.7	
Others	0	0.0	0	0.0	1	5.3	1	1.9	
Height (mean ± SD)	153.0 ± 6.0		152.8 ± 5.3		153.8 ± 5.8		153.2 ± 5.6		0.73
weight (mean ± SD)	53.5 ± 7.6		52.6 ± 9.8		55.5 ± 10.6		53.8 ± 9.3		0.43

Table 2 Results of χ^2 analysis of subjects' complaints based on the type of pills during observation

Type of Pill	LNG		*Lynestrenol*		IUD/Control		Total		X^2	*P*
Complaint	N	%	n	%	n	%	n	%		
Dizzy/headaches	15	42.9	19	50.0	3	7.7	37	33.0	17.79	0.00*
Nauseous/ vomit	6	17.1	1	2.6	1	2.6	8	7.1	7.68	0.02*
Chest pain	1	2.9	1	2.6	0	0.0	2	1.8	1.09	0.58
Vaginal discharge	0	0.0	2	5.3	17	43.6	19	16.9	30.47	0.00*
Facial spots / pimples	2	5.7	0	0.0	0	0.0	2	1.8	4.48	0.11
Weight changes	3	8.6	1	2.6	0	4.1	4	3.6	4.08	0.00*
Changes in menstrual patterns	13	36.1	3	8.1	5	12.8	21	18.8	10.77	0.01*
Spotting	10	28.6	14	36.8	14	35.9	38	33.9	0.66	0.72
other disorders	6	16.2	5	13.9	8	20.5	19	17.0	0.60	0.74

Spotting, dizziness/headache, and changes in menstrual patterns were 3 complaints of most subjects. Most complaints to the subjects of LNG pills and *Lynestrenol* pill were dizziness/headache, while the IUD was vaginal discharge (**Table 2**). Of the 19 subjects (17.8%) who dropped out, 5 (4.7%) stated health reason of and 14 (13.1%) for personal reasons; 7 (19.4%) used LNG pill, 9 (23.1%) used *Lynestrenol* pill, and 3 (9.4%) used IUD. In regard to health reason, among LNG pill users, 2 subjects (5.6%) complained about nausea and vomiting and 1 (2.8%) always felt the pain of both legs after 1 hour taking the pills, while 1 *Lynestrenol* pill user and 1 IUD user complained about changes in the menstrual pattern (2.6% and 3.1%). In regard to personal reason, the respondent worked through the night was the most common reason (3.7%) making it difficult to join the next follow-up.

Bleeding patterns (amenorrhea, spotting, and abnormal bleeding) at each follow-up visit indicated that amenorrhea occurred along the period of observations and was the most common bleeding pattern experienced by subjects (between 57.9%-75.0%). Analysis using the Kaplan-Meier curves indicated a biggest survival time of 25% for the bleeding/menstrual resumption among variables was IUD (week 13), BMI ≥18.5 kg/m^2 (week 13), status of compliance (week 10), and exclusive breastfeeding (week 13). The value of Hazard Ratio, IUD, BMI ≥18.5 kg/m^2/good nutrition, the status of non-compliance, and non-exclusive breastfeeding had a greater probability of causing bleeding/menstrual to resume than the comparative variable. The results were not statistically significant.

Table 3 The results of the analysis of survival time and the statistical test of Cox's Proportional Hazard Regression

Variable		*Survival time*			HR	95% CI	*P*
		25%	50%	75%			
Contraception							
IUD		13.8	17.0	-	1	1	0.16
LNG Pill		11.3	-	.	0.72	0.31 - 1.64	
Lynestrenol Pill		-	-		0.41	0.15 - 1.06	
BMI(kg/m^2)							
<18.5	IUD	8.3	8.3		1	-	0.46
	LNG Pill	-	-	.	.	-	
	Lynestrenol Pill	8.7	-	.	0.40	0.02 - 6.48	
≥18.5	IUD	13.8	17.0	-	0.96	0.12 - 7.34	
	LNG Pill	11.3	-	.	0.69	0.08 - 5.47	
	Lynestrenol Pill	-	-	.	0.39	0.04 - 3.38	
Compliance							
Compliant	LNG Pill	26.8	-	.	2.62	0.23 - 29.07	0.28
	Lynestrenol Pill	-	-	.	1	1	
Non compliant	LNG Pill	10.4	25.6	.	5.81	0.71 - 47.39	
	Lynestrenol Pill	8.7	-	.	3.97	0.23 - 29.07	
Breastfeeding Status							
Exclusive	IUD	10.0	17.0	-	1	-	0.15
	LNG Pill	-	-	.	0.16	0.02 - 1.28	
	Lynestrenol Pill	9.1	-	.	0.48	0.10 - 2.27	
Non-exclusive	IUD	13.8	16.3	-	0.83	0.30 - 2.29	
	LNG Pill	10.4	25.6	-	1.06	0.39 - 2.83	
	Lynestrenol Pill	-	-	.	0.33	0.10 - 1.12	

HR=Hazard Ratio, CI=Confident Interval

Stratified analysis was performed to further analyze the effects of BMI, compliance status, and breastfeeding status on bleeding pattern based on the type of contraception. The results of BMI analysis indicated that in the category of poor nutrition and good nutrition IUD made menstruation faster to reoccur (HR=1 and HR=0.96 respectively), in the category of compliant and non-compliant, LNG had greater probability of 2.62 and 5.81 times

(HR=2.62 and HR=5.81), while for the exclusive breastfeeding status-IUD and nonexclusive breastfeeding-LNG had greater probability (HR=1 and HR=1.06 respectively) (**Table 3**).

The results of multivariable analysis, with and without compliance, indicated that there was no significant effect of the use of LNG pills, *Lynestrenol* pill, and IUD, BMI, compliance and status breastfeeding on the bleeding/menstrual resumption in breastfeeding women (**Table 4**).

Table 4 Results of analysis of *Cox's Proportional Hazard with Time-Varying Covariate*

Variable	Model 1 HR (95% CI)	Model 2 HR (95% CI)	Model 3 HR (95% CI)
Usage			
IUD	1	1	1
LNG Pill	0.71 (0.30-1.63)	0.71(0.30-1.62)	0.72 (0.31-1.64)
Lynestrenol Pill	0.38 (0.14-1.02)	0.38 (0.14-1.01)	0.41 (0.15-1.06)
BMI (kg/m^2)			
≥ 18.5	1.04 (0.23-4.59)		
<18.5	1		
Breastfeeding Status			
Non-exclusive	1.32 (0.61-2.82)	1.32 (0.62-2.80)	
Exclusive	1	1	
-2 log likelihood	237.61	237.61	238.15
N	88	88	88

HR=Hazard Ratio, CI=Confident Interval

Bleeding patterns shown in this study were amenorrhea, spotting, and irregular bleeding. Amenorrhea occurred throughout the observation. Amenorrhea and inter-menstrual bleeding are bleedings which are commonly experienced by breastfeeding women who use POPs. Clinically, IUD, the variables of BMI 18.5kg/m2 (good nutrition), status of non-compliance and non-exclusive breastfeeding affected the bleeding or menstrual resumption compared to the comparative variables, although statistically not significant.

DISCUSSION

This study shows that the use of progesterone pill (hormonal) was likely to cause amenorrhea rather than IUD (non-hormonal). The use of hormonal contraceptive was likely to cause amenorrhea rather than non-hormonal, especially in breastfeeding women. Baby sucking during breastfeeding increases prolactin levels, which allegedly interfere with the release of the Gonadotrophic Releasing Hormone (GnRH) by the hypothalamus by increasing the production of hypothalamic β-endorphin. Disorders of the release of GnRH affect the release of Luteinising Hormone (LH) from the pituitary that play a role in the maturation of follicles in the ovaries so that ovulation does not occur (Edelman et al., 2010). In breastfeeding women, mini pills cooperate with prolactin to suppress ovulation process, which effectively enhances the protection (Speroff & Darney, 2010). IUD works mainly by preventing fertilization of the egg by the sperm.

The results of the study showed women with higher BMI of good nutritional status had HR=1:20, that 1.2 times of the probability of bleeding or menstruation to recur. BMI is known to affect amenorrhea. Women with malnutrition experienced amenorrhea longer than those with good nutrition (Dwivedi & Dixit, 2012). There were two mechanisms that might cause this condition: lack of nutrition directly affects female reproductive system and cause delays in the menstrual resumption; and indirectly through the process of breastfeeding, women with malnutrition will produce a little amount of milk so their babies will suck more intensely to get adequate nutrition. Women with heavier weight have lower level of LNG than women who are lighter; it is allegedly related to steroid absorption by fat tissue or dilution factors associated with blood volume.

Therefore, they tend to have irregular and frequent bleeding, while women with lighter weight tend to experience amenorrhea (Shoupe, Ballagh, & Mishell Jr, 1992). This can be taken into consideration when giving contraception that LNG should not be given to women with heavier weight or BMI because it would tend to disrupt the bleeding pattern.

This study shows that non-compliant subjects 2.85 times faster probability to experience the bleeding or menstrual resumption. This is related to the theory that indiscipline, either postponement or discontinuation of 1 or 2 days, will decrease its effectiveness and can cause menstrual disorders, including irregular bleeding, short or very long menstrual cycle, spotting, very long period of menstruation or not having menstruation at all (Bachmann & Korner, 2007).

The analysis of this study indicates that the status of non-exclusive breastfeeding is not likely to cause the bleeding or menstrual resumption by 1.14 times faster than exclusive breastfeeding. Exclusive breastfeeding is known to prolong the duration of amenorrhea in breastfeeding women. The increase in prolactin levels during breastfeeding process will decrease with the weaning or introduction of supplementary food and will cause ovulation in 14-30 days (King, 2007).

The stratification analysis indicated that IUD and LNG pill cause the bleeding/menstrual resumption sooner in breastfeeding women than *Lynestrenol* pills. Bleeding happens because IUD could be a reaction of the endometrium due to the insertion of IUD. Pharmacologically, LNG has stronger androgenic properties than *Lynestrenol* so that it tends to cause bleeding. A dose of LNG do not proven to be able to eliminate the unscheduled bleeding on women who start to use a continuous oral contraceptives pills (Kaneshiro et al., 2012). Study by LNG implant user showed an abnormal fragility on the endometrial vessel (Dinh, Sriprasert, Williams, & Archer, 2015).

The results of multivariable analysis showed that there was no significant difference in the effects of the use of contraceptives (LNG pill, *Lynestrenol* pill, and IUD), BMI, compliance, and breastfeeding status on the bleeding/menstrual resumption in breastfeeding women. However, further study with longer follow up period is required to investigate the long-term effect of POPs use on breast milk quality and maternal health.

Knowledge, information, religion, perceptions, socio-economic status, ethnicity and age are factors that influence contraceptive choice (Belfield, 2009). Women need to understand that bleeding disorders experienced when using hormonal contraceptives do not endanger health. Before giving education about bleeding disorders, health workers need to explain in advance the normal menstrual cycle. The knowledge about menstruation need to be improved since previous study found that more than half women did not know about the normal menstruation cycle (Gustina & Djannah, 2015). In addition, a better understanding of the work of progesterone in the body can enhance its safety and effectiveness in medical interests (Taraborrelli, 2015). It is unfortunate that this progestin contraception is not much in demand. As a second-line method after combination pills, sterilization and IUD, this method is preferable because it does not contain estrogen. Thus, it is expected that POPs which contains *Levonorgestrel* (LNG) or *Lynestrenol* can be produced in generic manner in the country and can be used as a national program for breastfeeding women.

CONCLUSION

Levonorgestrel pill caused the bleeding or menstrual resumption sooner in breastfeeding women than *Lynestrenol* pill. There was no difference in the effects of the use of birth control pills that contain *Lynestrenol* and LNG as well as the IUD, BMI, compliance, and breastfeeding status on the bleeding pattern and the bleeding/menstrual resumption in breastfeeding women. Suggestions that can be

offered are as follows: 1) Socializing the use of progestin pill containing *Levonorgestrel* and *Lynestrenol* including the possible side effects through Communication, Information, and Education to prospective acceptors; 2) In case of a future study, participant retention strategies will need to be considered to reduce the number of lost to follow up subjects in order to increase the quality of the study.

ACKNOWLEDGEMENTS

The authors would like to thank PT Harsen Laboratories which has provided the investigational drugs, also for Universitas Gadjah Mada which has provided funding and facility support to this study.

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Cite this article as: Ratrikaningtyas, P. D., Rosdiana, D., Wilopo, S. A. (2018). Prevalence and pattern of uterine bleeding among breastfeeding women using progesterone-only pills. *Public Health of Indonesia*, *4*(3):100-107.