ORIGINAL ARTICLE

Hemodynamic Changes Before and After Resuscitation Comparative Study In Septic Shock

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Abstract

Background: ***Better management of pregnancy spacing is achieved with postpartum contraception, which is crucial for the health of the mother and child. Resuming ovulation prevention measures is the ideal first step. Because ovulation can happen before a woman's menstrual cycle resumes, using the right methods and timing for contraception is essential.***

*Aim and objectives****: In order to evaluate and contrast the efficacy of progestin-only pills (POPs) in causing uterine haemorrhage in nursing mothers.***

Patients and methods: ***From January 2024 to November 2024, 300 patients were observed in the Obstetrics and Gynaecology department of Al-Azhar University in Cairo at family planning clinics, Al-Hussein and Sayed Galal hospitals.***

Results: ***All three medications are effective, with no statistically significant differences in hemostatic duration or failure rates. Levonorgestrel showed a mean treatment duration of 7 days, Drosprinone 8 days, and Desogestrel 11 days. While Desogestrel required a longer treatment period, which could potentially impact patient compliance, it demonstrated a 0% failure rate along with Drosprinone. Levonorgestrel had a slightly higher failure rate of 1%, though this difference was not statistically significant.***

Conclusion: ***All three treatment modalities were effective in reducing abnormal uterine bleeding and improving Hb levels. Furthermore, the distribution of age, parity, previous contraceptive methods, and side effects was comparable among the treatment groups.***

Keywords: Uterine bleeding; Breast-feeding; Progestin-only pills

1. Introduction

Improved management of pregnancy spacing with postpartum contraception is crucial for maternal and infant health. Beginning the process of birth control before the next ovulation is ideal. Properly timed and methodical contraception is necessary since ovulation might happen before a woman's menstrual cycle resumes.[1]

One of the main functions of progesterone is to inhibit the ability to conceive. Their primary action is to stop ovulation from happening by blocking the process of follicular development. At the hypothalamus, progesterone negative feedback lowers the gonadotropin-releasing hormone's pulse frequency. As a result, less luteinizing hormone (LH) and follicle-stimulating hormone (FSH) will be secreted. Follicle development is required for a rise in oestradiol levels; otherwise, the follicle will not produce any.[2]

Although Progestin-Only Pills (POPs) are generally well-received because they do not interfere with breastfeeding, some women who take them may have painful and irregular menstrual flow. In order to effectively treat POP-induced uterine bleeding, a careful balancing act is required between the competing demands of preventing these bouts of bleeding and ensuring that nursing and effective contraception continue to have their many benefits.[3]

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There are a few drawbacks to POPs despite their many benefits, including being compatible with nursing and having a reduced risk of blood clots. Unlike combined oral contraceptives, these pills require regular dosing at the same time every day, so forgetting to take one might have serious consequences. Furthermore, spotting and breakthrough bleeding are among the irregular monthly bleeding patterns that some women may encounter when taking POPs.[4]

Although POPs have made great strides in the last several decades, they are still largely misunderstood and underutilised. Among Egyptian women of childbearing age, hardly 0.4% make use of them. This narrative review set out to do just that—describe the present framework of POPs within the spectrum of family planning strategies.[5]

The purpose of this research is to evaluate and contrast the efficacy of POPs-induced uterine haemorrhage in nursing mothers.

2. Patients and methods

From January 2024 to November 2024, 300 patients were observed in the Obstetrics and Gynaecology department of Al-Azhar University in Cairo at family planning clinics, Al-Hussein and Sayed Galal hospitals.

Sample size justification:

This study base on study carried out by Bjarnadóttir al.,[6] The following assumptions were taken into account while using Epi Info STATCALC to determine the sample size: a two-sided confidence level of 95%, with a power of 80%. & A 5% margin of error. Based on the results of the Epi-Info analysis, the maximum sample size was 300.

Inclusion criteria:

Age: in childbearing period (18-45) yrs; on progestin-only as a method of conception (typical user); females who have recently given birth (6 weeks- 6 months) postpartum; females with AUB during using their pills, and breastfeeding mothers.

Exclusion criteria:

US structural cause of bleeding as fibroids, polyps; any contraindications for POP; previous history of uterine bleeding disorders not related to postpartum; known bleeding disorders (e.g., von Willebrand disease); chronic medical conditions or comorbidities (e.g., clotting disorders, polycystic ovary syndrome), and finally multiple gestations or complications during pregnancy.

Methods:

Complete history taking, including biographical details, any complaints, obstetric details, menstruation history, previous medical and surgical records, and family medical history; obtaining informed consent from all patients; thorough medical evaluation, including patient history, current vitals (temperature, pulse, respiration rate, blood pressure, etc.), body mass index (BMI), laboratory testing, local examination, and ultrasound.

Three different treatment groups were randomly assigned to the patients:

Group A (100 patients) (levonorgestrel pills):

A 0.03 mg tablet of Levonorgestrel (MICROLUT®, scherring) was administered to the patients. Take one pill everyday at the same time every day without interruption, even during menstruation.

Group B (100 patients) (Desogestrel pills):

Patients were given 0.075 mg Desogestrel tab (CERAZETTE®, Organon). One pill daily, at the same time each day, starting from the first day of the period.

Group C (100 patients) (drospirenone pills):

Patients were administered 4 mg of drospirenone (DROSPINETTA). One pill for 24 days of 28 cycles, at the same time each day. Stop for 4 days leading to withdrawal; cyclic bleeding is not used during menstruation.

Patients of the 3 groups were regularly monitored for: reduction in uterine bleeding (measured by assessing blood loss (by napkins: number of napkins changed by day, 3=moderate), hemoglobin levels); adverse effects, such as gastrointestinal symptoms or allergic reactions; response to treatment. Patients have had a scheduled follow-up visit to assess treatment response and side effects. We continued monitoring until the bleeding was adequately controlled.

Ethical considerations:

The Research Ethics Committee gave its stamp of approval after reviewing the procedure. Prior to patients being enrolled in the trial, their informed consent was acquired. Participants were given the option to resign from the study at any time without repercussions from their management, and all data was handled confidentially.

Data analysis:

We used the SPSS application (Version 25) for Windows to code, process, and analyse the data that we collected. Medians, ranges, percentages, standard deviations, and means were among the descriptive statistics computed. For continuous variables, we compared normally distributed means using independent t-tests. Additionally, for non-normally distributed data, the Mann-Whitney U test was employed to examine median differences, and for categorical data, the chi-square test was employed. For the dependent groups, we utilised the t-test and the Wilcoxon probability test. To be deemed statistically significant, a p-value must be less than 0.05.

Outcome measurements:

Primary outcomes include treatment response

(i.e., decreased serviette use), haemostatic measure length, and treatment failure. Medications' side effects and patients' happiness are secondary outcomes.

3. Results

Table 1. Patient demographics that were part of the study.

	LEVONORGESTREL GROUP A		DESOGESTREL GROUP B		DROSPRINONE GROUP C		P - VALUE
	n	%	n	%	n	%	
AGE (YEARS OLD)							
MEAN ± SD	33.5 ± 2.4		35.2 ± 3.6		31.4 ± 3.5		0.34
NUMBER OF LIVE BIRTH (PARITY)							
PRIMIPAROUS	36	36%	43	43%	37	37%	0.434
MULTIPAROUS	64	64%	57	57%	63	63%	

Regarding the age of the studied patients, the mean age of group A was 33.5 ± 2.4 years, the mean age of group B was 35.2 ± 3.6 years, while the mean age of group C was 31.4 ± 3.5 years, with no statistically significant differences, p = 0.34.

Regarding the number of live births, for 3 groups, primiparous patients were 36%, 43% and 37% respectively, while the multiparous were 64%, 57% and 63% respectively, with no statistically significant difference, p = 0.4, (table 1).

Table 2. Effectiveness of treatment.

	LEVONORGESTREL GROUP A		DESOGESTREL GROUP B		DROSPRINONE GROUP C		P - VALUE
	n	%	n	%	n	%	
NUMBER OF NAPKINS CHANGED BY DAY AND PERCENTAGE OF IMPROVEMENT							
PRE	4	75%	3	66.6%	4	75%	0.001
POST	1		1		1		
PRE HB (MEAN ± SD)							
	11.0 ± 0.3		10.9 ± 0.4		10.8 ± 0.8		0.84
POST HB (MEAN ± SD)							
	12.5 ± 0.6		12.6 ± 0.8		12.1 ± 0.9		0.39

Regarding the effectiveness of the treatment in diminishing the abnormal uterine bleeding in breastfeeding women who receiving progestin-only pills, the average number of napkins changed before treatment was 4 napkins per day for group A, after treatment, number of napkins was 1, in group B before treatment was 3 napkins per day, after treatment, became 1 napkin, in group C was 4 napkins per day, after treatment,1 napkin per day. There was significant improvement toward only one napkin per day at first week in all 3 groups, p = 0.001.

The baseline Hb levels for the 3 groups were 11.0 ± 0.3, 10.9 ± 0.4, and 10.8 ± 0.8 g/dl with no statistically significant differences between the 3 groups, after one month of treatment, the mean Hb levels rose significantly for the 3 groups as the mean level was 12.5 ± 0.6, 12.6 ± 0.8 and 12.1 ± 0.9 g/dl, with no statistically significant difference between the type of treatment, p = 0.39, (table 2; figure 1).

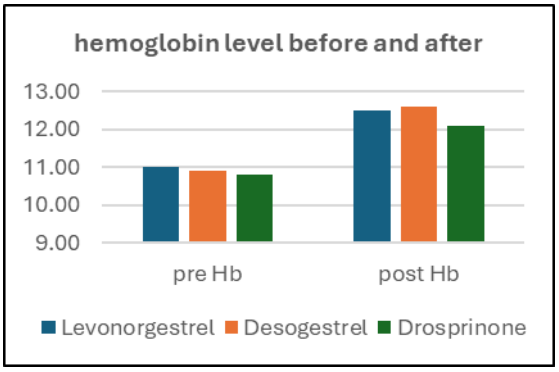

Figure 1. Levels of Hb before and after treatment.

Table 3. Effectiveness of treatment by failure rate.

	LEVONORGESTREL GROUP A	DESOGESTREL GROUP B	DROSPRINONE GROUP C	P - VALUE
	n	n	n	
FAILURE RATE (PREGNANCY).				
N / %	1 (1%)	0 (0)	0 (0)	0.54

Table 4. Side effects of used treatment.

	LEVONORGESTREL GROUP A		DESOGESTREL GROUP B		DROSPRINONE GROUP C		P- VALUE
	n	%	n	%	n	%	
DIZZY / HEADACHES	5	5%	5	7%	7	7%	0.23
NAUSEOUS / VOMIT	1	1%	2	2%	1	1%	0.13
CHEST PAIN	1	1%	1	1%	0	0.0	0.58
VAGINAL DISCHARGE	0	0.0	2	2%	2	2%	0.32
FACIAL SPOTS / PIMPLES	2	2%	0	0.0	0	0.0	0.11
WEIGHT CHANGES	3	3%	1	1%	0	0	0.32
OTHER DISORDERS	6	6%	5	5%	8	8%	0.74

Regarding the side effects of the 3 groups, group A experienced 5% of dizziness or headache, 1% of Nausea or vomiting, 2% of facial pimples, 3% for WT changes and 6% other nonspecific disorders. On the other hand, the group B experienced 7% dizziness, 1% chest pain, 2% vaginal discharge, 1% WT changes and 5% other disorders. Regarding the third group, they experienced 7% dizziness, 1% nausea or vomiting, 2% vaginal discharge, and 8% other disorders, with no statistically significant difference regarding the 3 types of treatment, (table 4).

4. Discussion

he most prevalent adverse effect of hormonal contraception is abnormal uterine haemorrhage. This kind of bleeding is usually harmless, yet it still worries a lot of women. Hormonal contraception is often stopped by women due to negative effects like irregular bleeding. Of the 1,657 women who began using oral contraceptives (OCPs), 32% stopped using them after six months, with side effects accounting for 46% of the withdrawals.[7]

The present investigation found no statistically significant variations in the age distribution among the three categories (p=0.34). We also did not find any statistically significant variations in the parity distribution (p=0.4). The results provide more evidence that our comparative study was valid since they imply that the three treatment groups were similar in age and parity.

Additionally, when looking at the patients' prior methods of contraception, there were no statistically significant differences (p=0.3) across the three groups. The percentages of IUD, injection, and other contraceptive methods were comparable among the groups. This indicates that the distribution of previous contraceptive methods was balanced across the treatment groups.

Group A had an average height of 153.0 ± 6.0 cm, group B of 152.8 ± 5.3 cm, and group C of 153.8 ± 5.8 cm, with a p-value of 0.84 for mean height and weight, respectively, in this study. In contrast, group A had an average weight of 63.5 ± 7.6 kg, group B of 62.6 ± 9.8 kg, and group C of 65.5 ± 10.6 kg, with a p-value of 0.39. In terms of anthropometric dimensions, none of the three groups differed significantly from one another.

Ratrikaningtyas et al.,[8] the purpose of this study was to determine how often and what causes uterine haemorrhage in breastfeeding mothers who take oral contraceptives that contain progesterone. It is purportedly linked to steroid absorption by adipose tissue or dilution factors related to blood volume; however, they found that bigger women had lower levels of Levonorgestrel (LNG) than lighter women. This is why heavier women often have amenorrhoea, whereas lighter women have irregular and frequent periods of bleeding. Women with a higher body mass index (BMI) should not take LNG as a form of contraception because it has the potential to interfere with their menstrual cycle.[9]

In the current study, there was a significant improvement in the average number of napkins changed per day after treatment (p = 0.001). Breastfeeding mothers who took progestin pills alone showed a decrease in uterine haemorrhage after undergoing any of the three procedures. While we did not find any statistically significant changes (p = 0.39), we did find that the mean haemoglobin (Hb) levels increased significantly across the board after the first month of treatment. This suggests that all three treatment modalities were effective in improving Hb levels.

When comparing our results with those of previous studies, several investigations have reported a significant reduction in uterine bleeding following treatment with levonorgestrel implants.[10,11] The consistent findings across these studies and our own research strengthen the evidence for the efficacy of progestin-only pills in managing abnormal uterine bleeding.

Researchers found that bleeding was the most common reason women stopped using levonorgestrel implants in a trial involving nearly 500 women. The correlation between discontinuation and either increased or decreased bleeding, rather than irregular or unpredictable bleeding, was stronger in this study.[12]

These findings align with our observation that all three medications were effective in reducing uterine bleeding among breastfeeding women who were on progestin-only pills. The significant improvement in the number of napkins changed per day post-treatment in our study corroborates the effectiveness of these medications in managing abnormal uterine bleeding.

A study conducted by Ashraf et al.,[13] conclusions indicate oral norethisterone is inferior to intrauterine devices (IUDs) containing Levonorgestrel.

Research shows that 35% of women who discontinue POPs cite blood-related problems and abnormal bleeding as the reason.[14]

Our results indicate that all three medications are effective, with no statistically significant differences in hemostatic duration or failure rates. Levonorgestrel showed a mean treatment duration of 7 days, Drosprinone 8 days, and Desogestrel 11 days. While Desogestrel required a longer treatment period, which could potentially impact patient compliance, it demonstrated a 0% failure rate along with Drosprinone. Levonorgestrel had a slightly higher failure rate of 1%, though this difference was not statistically significant.

Comparing these findings with existing literature reveals both consistencies and variations. Sakurai[15] reported no failure rate for Levonorgestrel. Notably, this study contributes new data on Drosprinone as a POP for managing uterine bleeding, an area with limited existing research. The treatment durations observed were generally longer than those reported in some previous studies, such as Abdel-Aleem et al.,[11] which found a median of 4 days to stop bleeding with Levonorgestrel.

In our study, the percentages of side effects were comparable among the three groups, with no statistically significant differences observed. Side effects such as dizziness, headache, nausea or vomiting, and vaginal discharge were reported in varying frequencies, but none of the treatments demonstrated a significantly higher incidence of side effects.

Our findings align with the results of several other studies that have investigated the side effects of progestin-only pills.[16] These studies have reported similar percentages of side effects, indicating that the occurrence of adverse events is consistent across different populations.

In the current study, the percentages of side effects were comparable among the three groups, with no statistically significant differences observed. Side effects such as dizziness, headache, nausea or vomiting, and vaginal discharge were reported in varying frequencies, but none of the treatments demonstrated a significantly higher incidence of side effects.

4. Conclusion

All three treatment modalities were effective in reducing abnormal uterine bleeding and improving Hb levels. Furthermore, the distribution of age, parity, previous contraceptive methods, and side effects was comparable among the treatment groups.

Disclosure

The authors have no financial interest to declare in relation to the content of this article.

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