A Comparative Study between Vaginal versus Oral Administration of Levonorgestrel as a Method of Emergency Contraception

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Abstract

Background: Access to emergency contraception and its need for increasing awareness and convenience are very important nowadays. Post-coital or emergency contraception is a simple, reliable and effective strategy. However, the complications associated with the emergency contraception are needed to be addressed before its full potential is realized.

Aim of Study: To compare between vaginal versus oral administration of levonorgestrel as a method of emergency contraception.

Patients and Methods: This was a prospective randomized comparative study, was carried at Al-Hussein University Hospital during period from February 2021 till August 2021. Sixty women with regular cycle admitted to Birth Control Unit at Al-Hussein University Hospital divided into 2 groups: 1st Group: 30 women who received levonorgestrel 1.5 mg as a single dose orally (two tablet of Contraplan II) and 2 nd Group: 30 women who received levonorgestrel 1.5mg as a single dose vaginally (two tablet of Contraplan II).

Results: There was high statistically significant difference between the studied groups as regard platelets, BT, CT and PT. The pregnancy rate was less in vaginal group with no statistically significant difference between the two groups. There was statistically significant difference between the studied groups as regard nausea, abdominal pain, headache and vomiting.

Conclusion: Among the Egyptian, the levonorgestrel-releasing intrauterine system (LNG-IUS) does not have any adverse effects on metabolic parameters, triglycerides (TGs), low-density lipoprotein (LDL) and blood sugar levels. Most of the studied patients were very or somewhat satisfied with methods and 30.43% were neutral or somewhat not satisfied the same result for recommend the method.

Key Words: Emergency contraception – Oral contraception – Levonorgestrel – Vaginal administration.

Introduction

EMERGENCY contraception (also known as postcoital contraception or the morning-after pill) refers to the use of drugs or devices as an emer-

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gency measure to prevent pregnancy. Emergency contraception (EC) is intended for use after unprotected intercourse or recognized contraceptive failure. It can reduce the risk of pregnancy by more than 75%. Research shows that EC prevents fertilization by delaying ovulation until viable sperm are no longer present in the upper female genital tract [1].

Emergency contraception refers to methods of contraception that can be used to prevent pregnancy after sexual intercourse. These are recommended for use within 5 days but are more effective the sooner they are used after the act of intercourse Emergency contraceptive pills prevent pregnancy by preventing or delaying ovulation and they do not induce an abortion. Emergency contraception cannot interrupt an established pregnancy or harm a developing embryo [2].

Emergency contraception (EC) is an effective way to prevent an unintended or unplanned pregnancy. EC is available in two forms in: A progestinonly method and a combined hormonal method, also known as the (Yuzpe regimen). EC has been proven to be most effective within 72h and up to 120h after unprotected sexual intercourse. To date, the progestin-only method is the preferred method of EC recommended to teens because it is known for higher efficacy and fewer side effects, and is, therefore, more widely accepted over the combined method [3].

Levonorgestrel (LNG) is a synthetic, biologically active progestogen, structurally related to 19-nortestosterone, which may be used alone or in combination with estrogens for the prevention of unintended pregnancies following unprotected coitus. LNG is only sought as a supportive method for irregular rather than regular use and LNG is intended to be used immediately after intercourse but prior to pregnancy has become recognized [4].

Levonorgestrel (LNG) contains a synthetic hormone-like substance called levonorgestrel. It prevents about 84% of expected pregnancies when you take it within 72 hours of having unprotected sex. It will not prevent a pregnancy every time and is more effective if you take it as soon as possible after unprotected sex. It is better to takeit within 12 hours rather than delay until the third day [5].

Oral contraceptives containing levonorgestrel suppress gonadotropins, inhibiting ovulation. Specifically, levonorgestrel binds to progesterone and androgen receptors and slows the release of gonadotropin-releasing hormone (GnRH) from the hypothalamus. This process results in the suppression of the normal physiological luteinizing hormone (LH) surge that precedes ovulation. It inhibits the rupture of follicles and viable egg release from the ovaries. Levonorgestrel has been proven to be more effective when administered before ovulation [6]. The elimination half-life of a 0.75mg dose of 1.5mg of levonorgestrel ranges between 20-60 hours postadministration [7].

The aim of the present study was to compare between vaginal versus oral administration of levonorgestrel as a method of emergency contraception.

Patients and Methods

This was a prospective randomized comparative study, was carried at Al-Hussein University Hospital during period from February 2021 till August 2021.

Sixty women with regular cycle admitted to Birth Control Unit at Al-Hussein University Hospital divided into 2 groups: 1 st Group: 30 women who received levonorgestrel 1.5mg as a single dose orally (two tablet of Contraplan II) and 2 nd Group: 30 women who received levonorgestrel 1.5mg as a single dose vaginally (two tablet of Contraplan II).

Inclusion criteria: Women with regular menstrual cycle, reproductive age, normalbody mass index, and negative pregnancy test.

Exclusion criteria: Females want to get pregnant, female had any contraindications to hormonal contraception, such as abnormal liver function, clotting disorders, or personal or family history of thromboembolic events, and contraindications of levonorgestrel: Hypersensitivity to the active substances was not being given with undiagnosed vaginal bleeding nor to those with history or current high risk of arterial disease.

Method of randomization: Randomization was ensured using closed sealed envelope with the method containing letter "O" indicating oral Contraplan II, letter "V" indicating vaginal Contraplan II.

An approval of the study was obtained from Zagazig University academic and ethical committee. Every patient signed an informed written consent for acceptance of the operation.

All patients were subjected to:

- a- Complete history was taken with special emphasis on:
- Personal history.
- Complaint of each woman in the study: Period of infertility, type of infertility whether primary or secondary, hirsutism and acne.
- Menstrual history: With emphasis on menstrual dating and regularity.
- Obstetric history: History of similar condition (recurrent abortion).
- Contraceptive history: Type and duration.
- Past history of any medical problem.
- Family history of infertility or consanguinity.

b- Clinical examination:

- Physical examination included General examination: Weight, Height, BMI, Abdominal examination, Local (Pelvic) examination.
- Investigations:
- Complete blood picture.
- Urine analysis.
- Coagulation profile including bleeding time (BT), Clotting time (CT), Prothrombin time (PT) and activity.
- Liver function test including liver enzyme, serum bilirubin, HBV, and HCV.
- Kidney function tests including blood urea, and serum creatinine.
- Routine ultrasound examination.
- The drug used in the research levonorgestrel (trade name Contraplan II 0.75mg/tablet) is approved by the Egyptian Ministry of Health.
- Follow-up:
 - Pregnancy test was applied after two weeks from administration of levonorgestrel.
 - Researching any side effect of the drug.

Statistical analysis:

Analysis of data was done using Statistical Program for Social Science version 20 (SPSS Inc.,

Chicago, IL, USA). Quantitative variables were described in the form of mean and standard deviation. Qualitative variables were described as number and percent. In order to compare parametric quantitative variables between two groups, Student t-test was performed. Qualitative variables were compared using chi-square (X^2) test or Fisher's exact test when frequencies were below five. Pearson correlation coefficients were used to assess the association between two normally distributed variables. When a variable was not normally distributed, Ap-value <0.05 is considered significant.

Results

There were no statistically significant difference between the studied groups as regard demographic data and general examinations (Table 1).

Table (1): Comparison between the studied groups as regard demographic data and general examinations.

	Oral (n=30) 27-35 31.53±2.76		Vaginal (n=30) 28-35 31.67±2.47		p
Age (years): Range Mean ± SD					0.844
Parity: Nulliparous Multiparous	No. 7 23	% 23.3 76.7	No. 4 26	% 13.3 86.7	0.317
Previous abortion: No Yes	26 5	86.7 13.3	24 7	80.0 20.0	0.488
Surgical history: Non CS	15 15	50.0 50.0	10 20	33.3 66.7	0.190
Comorbidity: Non Diabetes	24 3	80.0 10.0	25 2	83.3 6.7	0.896
Hypertension	3	10.0	3	10.0	
Systolic BP: Range Mean ± SD	110-140 125.67±12.23		110-150 126±13.03		0.919
Diastolic BP: Range Mean ± SD	70-90 75.67±6.26		70-90 76.33±5.56		0.664
Pulse: Range Mean ± SD	71-98 83.83±8.76		70-98 81.6±7.85		0.303
Temp: Range Mean ± SD	36.5-37.5 36.99±0.32		36.5-37.5 36.9±0.34		0.279

There were no statistically significant difference between the studied groups as regard anthropometrics and CBC (Table 2).

Table (2): Comparison between the studied groups as regard anthropometrics and baseline CBC.

	Oral	Vaginal	
	(n=30)	(n=30)	p
Weight:			
Range	59.5-85	60-84.5	0.991
Mean \pm SD	70.4 ± 5.8	70.42 ± 6.24	
Height:			
Range	157-173	157-173	0.304
Mean \pm SD	164 ± 5.17	165.33 ± 4.77	
BMI:			
Range	23.7-29	23.1-28.7	0.365
Mean \pm SD	26.16 ± 1.72	25.74 ± 1.81	
Нь:			
Range	11.1-13.5	11-13.5	0.974
Mean \pm SD	12.32 ± 0.83	12.33 ± 0.77	
WBCs:			
Range	4.7-7.3	4.8-7.8	0.701
Mean \pm SD	6.04 ± 0.87	6.13 ± 0.94	
Plts:			
Range	151-269	151-268	0.597
Mean ± SD	213.3±36.4	217.97±31.34	

There was no statistically significant difference between the studied groups as regard coagulation profile. There was a statistically significant difference between the studied groups as regard plasma level of levonogestrel (Table 3).

Table (3): Comparison between the studied groups as regard baseline coagulation profile and plasma level of levonogestrel.

	Oral (n=30)	Vaginal (n=30)	p
Coagulation profile: <i>BT (mins)</i> :			
Range Mean ± SD	1.1-1.4 1.21±0.1	1-1.4 1.19±0.09	0.974
CT (mins): Range Mean ± SD	4.5-7.5 6.13±0.91	4.4-7.4 5.76±0.85	0.701
PT (Sec): Range Mean ± SD	10-12.8 11.43±0.91	10.1-12.9 11.36±0.81	0.597
Plasma level of levonogestrel (mg): Peak level 1-4 hours: Range Mean ± SD	42-100 73.17±20.39	5-19 11.33±4.38	<0.001
Time of peak (mins): Range Mean ± SD	61-178 103.77±32.45	202-315 260.1±35.58	<0.001
Half time level: Range Mean ± SD	7-30 20.77±7.13	2-11 6.63±2.44	<0.001

There was a statistically significant difference between the studied groups as regard platelets, BT, CT and PT (Table 4).

Table (4): Comparison between patients' data before and at follow-up as regard Lab.

	Before (n=60)	After (n=60)	p
Hb:			
Range	11-13.5	10.8-13.9	0.413
Mean ± SD	12.33 ± 0.79	12.36±0.82	
WBCs:			
Range	4.7-7.8	4.3-8.1	0.489
Mean \pm SD	6.09±0.9	6.12±0.99	
Plts:			
Range	151-269	153-279	< 0.001
Mean ± SD	215.63±33.76	220.95±33.65	
BT (mins):			
Range	1-1.4	0.8-1.3	< 0.001
Mean \pm SD	1.2 ± 0.1	1.11 ± 0.13	
CT (mins):			
Range	4.4-7.5	3.8-7.2	< 0.001
Mean \pm SD	5.94±0.89	5.67±0.92	
PT (Sec):			
Range	10-12.9	9.9-12.7	< 0.001
Mean \pm SD	11.39±0.85	11.26±0.84	
AST:			
Range	10-40	7-44	0.965
Mean \pm SD	26.4±9.71	26.42±9.94	
ALT:			
Range	12-45	10-47	0.283
Mean \pm SD	27.02 ± 10.08	27.43 ± 9.85	
Serum bilirubin:			
Range	0.6-1.2	0.5-1.3	0.132
Mean ± SD	0.94 ± 0.17	0.95±0.17	
Serum creatinine:			
Range	0.7-1.2	0.6-1.3	0.727
Mean ± SD	0.97±0.17	0.96 ± 0.2	
Urea:			
Range	7-30	5-31	0.360
Mean ± SD	18.27±6.94	18.03 ± 6.95	

The pregnancy rate was less in vaginal group with no statistically significant difference between the two groups. There was a statistically significant difference between the studied groups as regard nausea, abdominal pain, headache and vomiting (Table 5).

Table (5): Comparison between the studied groups as regard pregnancy and complications.

	Oral (n=30)		Vagina (n=30)		
	No.	%	No.	%	p
Early pregnancy:					
No	27	90.0	29	96.7	0.301
Yes	3	10.0	1	3.3	
Complications:					
Nausea	18	60.0	6	20.0	0.002
Abdominal pain	20	66.7	11	36.7	0.020
Fatigue	11	36.7	11	36.7	1.0
Headache	23	76.7	10	33.3	0.001
Breast tenderness	10	33.3	14	46.7	0.292
Vomiting	8	26.7	2	6.7	0.038
Diarrhea	6	20.0	6	20.0	1.0

Discussion

This study showed that there was no statistically significant difference between the studied groups as regard demographic data.

Kesim et al., [8] found that baseline characteristics such as mean age, body mass index and exposure to tamoxifen therapy were similar in both groups.

In the study done by Singh et al., [9], they found that in anthropometric data, significant reduction from baseline was seen in case of both BMI and waist circumference at 6 months. Other parameters did not show any significant change.

Saif Elnasr et al., [10] showed that there was no significant difference between both groups regarding age, parity, residence and educational level.

This study cleared that there was no statistically significant difference between the studied groups as regard anthropometrics.

Rezk et al., [11] reported that there was no statistically significant difference between the studied groups as regard anthropometrics (height, weight, BMI and WC).

This study demonstrated that there was no statistically significant difference between the studied groups as regard CBC. This table shows that there was no statistically significant difference between the studied groups as regard follows-up of CBC.

Cavrois et al., [12] showed that Monocytes, despite their relatively low abundance in blood (5.5%), accounted for 12.2% of fused cells; pDCs

represented only 0.2% of immune cells in blood but 2.3% of fused immune cells.

This study illustrated that there was no statistically significant difference between the studied groups as regard Coagulation profile. There was no statistically significant difference between the studied groups as regard follow-up of Coagulation profile.

Middeldorp et al., [13] showed that Compared with the pretreatment value, the plasma concentrations of factors II, VII, X, and fibrinogen significantly increased during use of both the levonorgestrel and desogestrel-containing OC's (Table 1). The plasma concentrations of factor VIII increased, and of factor V decreased, changes which only reached statistical significance during the use of the desogestrel-containing OC. The most prominent increases for both tested OC's were observed for factors VII, II, X and fibrinogen.

This study showed that there was no statistically significant difference between the studied groups as regard baseline Lab (as AST and ALT).

Cheema and Gupta [14] showed that Levonorgestrel IUD use is contraindicated in patients with ongoing liver injury or tumors. We report for the first time acute liver injury related to a levonorgestrel-releasing IUD. Our diagnosis is based on temporal association with acute liver injury after placement of the levonorgestrel IUD and marked improvement of the liver enzymes after its removal in the absence of any other alternative etiology. All likely etiologies as suggested by liver biopsy were excluded. The patient started feeling better symptomatically over the next few weeks after IUD removal. She had no abdominal pain, her appetite was back, and icterus was much improved. They showed a significant downward trend in transaminase and bilirubin levels of over the next 2 months.

In study by Ng et al., [15] they found no significant changes in the HDL/TC ratio and the mean HDL/LDL ratio. In both groups, the mean HDL/TC ratio remained above 0.2, and the mean HDL/LDL ratio was above 0.3 at all sampling times.

This study showed that there was high statistically significant difference between the studied groups as regard plasma level of levonogestrel.

Gainer et al., [16] showed that LNG milk concentrations paralleled those of plasma but were lower than plasma concentrations, with an overall mean milk-to-plasma ratio of 0.28 ± 0.09 . Progestin

concentrations increased after dosing to reach a peak between 1 and 4h in plasma and between 2. The maximal LNG concentrations ranged from 9.8 to 22.3ng ml⁻¹ in plasma. The mean terminal half-life of LNG was 29h in plasma.

This study reported that there was no statistically significant difference between the studied groups as regards general examinations as blood pressure. Also we showed that there was statistically significant difference between the studied groups as regard Systolic BP at follow-up.

Ronnerdag and Odlind [17] reported a slight increase in blood pressure over 12 years of continuous use of LNG-IUS. Conversely, Nilsson et al., [18] found a slight decrease in both systolic and diastolic blood pressures after 1 year of use.

Nilsson et al., [18] who found a significant decrease in diastolic blood pressure and a slight decrease in systolic blood pressure after 1 year of use and reported that it is a promising alternative for middle-aged hypertensive women. The mechanism of decrease is not known but requires further investigation. Research on middle-aged hypertensive women will shed light on this controversial issue.

Raudaskoski et al., [19] observed a decrease in systolic blood pressure at 3 and 6 months, whereas no change was observed in diastolic blood pressure.

Rezk et al., [11] showed that Mean systolic blood pressure among the studied patients was 115 ± 5.33 (mmHg) pretreatment decreased to 110 ± 4.81 (mmHg) after 6 months follow-up. Also, systolic and diastolic blood pressure showed no statistically significant difference before and after 6 months follow-up (p=0.17, 0.985 respectively)

This study showed that there was high statistically significant difference between the studied groups as regard platelets, BT, CT and PT.

Lieberman et al., [20] showed that Examination showed marked jaundice and multiple excoriations. The liver was enlarged and somewhat tender to palpation. Laboratory results showed bilirubin of 7.0mg/dL, ALT 80U/L and Alk P 170U/L. Because of persistent jaundice, she underwent endoscopic retrograde cholangiopancreatography which was normal. A liver biopsy showed intrahepatic cholestasis with minimal inflammation and bile duct proliferation. She eventually began to improve and all laboratory values were normal or near normal 6 months later.

Conclusion:

Among the Egyptian, the LNG-IUS does not have any adverse effects on metabolic parameters, TGs, LDL and blood sugar levels. Most of the studied patients were very or somewhat satisfied with methods and 30.43% were neutral or somewhat not satisfied, the same result for recommend the method.

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دراسة مقارنة بين تناول عقار الليفونورجيستريل عن طريق المهبل مقابل الفم كوسيلة منع حمل طارئة

خلفية البحث: إن الوصول إلى وسائل منع الحمل الطارئة وحاجتها إلى زيادة الوعى والراحة أمران مهمان للغاية فى الوقت الحاضر. تعتبر وسائل منع الحمل بعد الجماع أو الطارئ إستراتيجية بسيطة وموثوقة وفعالة. ومع ذلك، هناك حاجة إلى معالجة المضاعفات المرتبطة بمنع الحمل الطارئ قبل أن تتحقق إمكاناتها الكاملة.

الهدف من البحث: المقارنة بين تناول الليفونورجيستريل عن طريق المهبل تناوله عن طريق الفم كوسيلة لمنع الحمل الطارئ.

المريضات وطرق البحث: هذه دراسة مقارنة مستقبلية، أجريت فى مستشفى الحسين الجامعى خلال الفترة من فبراير ٢٠٢١ حتى أغسطس ٢٠٢١، على ٢٠ امرأة بدورة منتظمة مقسمة إلى مجموعتين متساويتن: المجموعة الأولى تناوان الليفونورجيستريل ١٠٥ مجم كجرعة وحيدة عن طريق المهبل (قرصان وحيدة عن طريق المهبل (قرصان من كونترابلان)، والمجموعة الثانية: من الليفونورجستريل ١٠٥ مجم كجرعة وحيدة عن طريق المهبل (قرصان من عقار كونترابلان ٢).

نتائج البحث: لم يكن هناك فرق نو دلالة إحصائية بين المجموعات المدروسة فيما يتعلق بالقياسات البشرية. لم يكن هناك فروق ذات دلالة إحصائية بين المجموعات المدروسة فيما يعلق إحصائية بين المجموعات المدروسة فيما يعلق بمستوى البلازما من الليفونوجيستريل. كان هناك فرق ذو دلالة إحصائية عالية بين المجموعات المدروسة فيما يتعلق بالصفائح الدموية، زمن النزيف، التصوير المقطعى المحوسب وزمن البروثرو مبين. كان معدل الحمل أقل في المجموعة المهبلية مع عدم وجود فرق معتد به إحصائيا بين المجموعتين. توجد فروق ذات دلالة إحصائية بين المجموعات المدروسة فيما يتعلق بالغثيان وآلام البطن والصداع والقيًا.

الاستنتاج: لدى المصريين، لا يوجد أى آثار سلبية النظام داخل الرحم الذى يفرز الليفونورجيستريل على معايير التمثيل الغذائى، والدهون الثلاثية، والبروتين الدهنى منخفض الكثافة ومستويات السكر فى الدم. كان معظم المرضى الخاضعين للدراسة راضين جداً أو إلى حد ما عن الطرق وكان ٣٠٠٤٪ محايدين أو غير راضين إلى حد ما عن نفس النتيجة التوصية بهذه الطريقة.