The Egyptian Journal of Hospital Medicine (January 2021) Vol. 82 (1), Page 1-5

Intrauterine Device Versus Levonorgestrel As Emergency Contraception. Observational Study

Ibrahim Saif Elnasr, Mohamed Fahmy, Haitham Hamza, Heba Mahmoud El-Fiqy, Hesham Ammar

Obstetrics and Gynecology Departments, Faculty of Medicine, Menoufia University, Menoufia Governrate, Egypt

*** Corresponding author:** Ibrahim Saif Elnasr, Tel: +201003086747, Email: Ibrahimalisaifelnasr @gmail.com, ORCID ID; https://orcid.org/0000-0002-5055-228

ABSTRACT

Background: Emergency contraception (EC) is a method to be used in the case of unprotected sexual intercourse, failure of a regular contraceptive method and after rape to try to prevent an unintended pregnancy. They include copper intrauterine devices (IUD) and different types of pills like estrogen-progestin combination pill, levonorgestrel containing pills (LNG). **Objective:** This study was conducted to compare the efficacy; satisfaction, pregnancy rate and side effect of emergency contraception in women who selected either oral levonorgestrel (LNG) or copper intrauterine device (IUD). **Patient and methods:** This observational prospective cohort study was conducted on 200 women enrolled and separated into two groups, IUD group: 100 women used cupper T380A IUD. LNG group: 100 women using levonorgestrel 1.5 mg divided into two doses each 0.75 mg 12 hours a part. Satisfaction was assessed using a 5-point Likert scale.

Results: There was significantly higher rate of contraption efficacy in IUD group compared with LNG group ($p<0.05$). Significantly higher rates of nausea, vomiting and headache in LNG group ($p<0.05$) when compared with IUD group. IUD patients had significantly higher rate of bleeding ($p<0.05$) and higher rate of satisfaction among LNG users ($p<0.05$). Significant association between women satisfaction and efficacy in LNG group ($p<0.05$) and significant association between women satisfaction and efficacy in IUD group ($p<0.05$).

Conclusion: Emergency IUD has higher efficacy than emergency contraceptive pills (LNG) and has fewer side effects. However, there is more satisfaction regarding emergency contraceptive pills (ECP) as compared to IUD.

Keywords: Emergency contraception, Emergency IUD, Levonorgestrel, Emergency contraceptive pills, Intrauterine devices.

INTRODUCTION

Emergency contraception refers to contraceptive methods that are used to protect against pregnancy occurrence after unprotected intercourse **(1).**

In fact, a large percentage of pregnancies occur unintended despite the presence of many methods of contraception. Unintended pregnancies usually occur due to either absence of contraceptives or failure of contraceptive method or after rape **(2).**

Many methods of emergency contraception have been known but, only six methods have been clinically used. These are the high dose estrogens, combined estrogen–progestogens pills (Yuzpe regime), progestogen only (levonorgestrel) pills, IUCD, danazol and mifepristone. EC pills that are used nowadays are marketed in Egypt under brand name contra plan II (two tablets of 0.75 mg levonorgestrel taken together)**(3).**

This study was conducted to compare the efficacy; satisfaction, pregnancy rate and side effect of EC in women who selected either oral levonorgestrel (LNG) or the copper IUD as emergency contraception**.**

PATIENTS AND METHODS

This observational prospective cohort study was conducted in the Obstetrics and Gynecology Department at Menoufia University Hospital, Shibin El-Kom City, Menoufia Governorate, Egypt during the period from May 2017 to May 2018.

Ethical approval:

The respective approvals of the Review Board and the Ethics Committee of Faculty of Medicine , Menoufia University was obtained before proceeding with the study.

The study protocol and its benefits and complications were explained to all participants and all recruited patients completed and signed the "informed consent" form.

Inclusion criteria: Multiparous women. Aged 18– 30 years. Unprotected intercourse within 120 h of presenting (5 days).

In our study we excluded Nulliparous women, women with pelvic infection; women over 30 years of age were excluded to maximize participant fertility, and other contraindications of IUD insertion (abnormal uterine bleeding, genital cancer, pelvic tuberculosis, AIDS or high risk for gynecological infections).

Received: 1/8 /2020
Accepted: 27/9/2020

This study was carried on 200 women separated into two groups:

1. IUD group: 100 women used cupper T380A intrauterine device (manufactured by PREGNA international, India) as emergency contraception.

2. LNG group: 100 women using levonorgestrel 1.5 mg divided into two doses each 0.75 mg 12 hours apart as emergency contraception (Contraplan II 0.75 mg, DKT, Egypt).

All included women in the study were subjected to:

Full history taking including medical, obstetric and gynecological history, General examination and local pelvic examination in case of IUD insertion. Women received their choice of insertion of a copper T 380A IUD or oral LNG 1.5 mg. Participants were provided scripted counseling on both methods. Either method was provided to the patient without charge.

IUD insertion:

After disinfection and gentle straightening of the uterus, the IUD was loaded into the insertion tube. The loaded insertion tube was passed through the cervical canal until resistance was met at the uterine fundus and the blue flange was at the external cervical os. With the solid white rod steady, the insertion tube was withdrawn approximately 1 cm, releasing the IUD. The insertion tube was gently moved up to the fundus of the uterus, ensuring placement of the IUD at the level of the fundus. The insertion tube was held steady, the white rod was withdrawn. Then gently the insertion tube was withdrawn. Following removal of insertion device, the IUD strings were readily visualized in the vagina. Using long-handled scissor, the strings were trimmed so that approximately 3 cm are visible extending, from the external cervical os.

Oral LNG was dispensed as per the clinic protocol for EC, which is in accordance with state laws and regulations. All follow-up was done by phone, or clinic visit.

Satisfaction with the method used was evaluated after 1-month and assessed at all other follow-ups using a 5-point Likert scale (very unsatisfied, unsatisfied, neutral, satisfied, and very satisfied). When necessary, follow up was confirmed by review of clinic visit records or phone calls for three months.

All participants had pregnancy test (Genzyme Diagnostics using quantitative Beta-subunit human chorionic gonadotropin (B-HCG) (manufactured by PREGNA international, India)considered negative if ≤20 IU/L).

- **Primary outcome measures:** was the rate of unwanted pregnancy in the 3 months after start of EC.
- **Secondary outcome measures:** were use of an effective method of contraception with a typical use pregnancy rate of less than or equal to 9% per year, IUD removals and expulsions and side effects of both methods.
- **Emergency contraception (EC) failure** was diagnosed when pregnancy occurs during the 1st month after start of EC.

Statistical analysis

Data obtained from our study were computed using SPSS versions 17 under the platform of Microsoft Windows XP, Professional Edition. Continuous data were expressed in the form of mean ± SD while categorical data were expressed in the form of count and percent. Comparison of continuous data were performed utilizing student t-test, while categorical data were done using Chi-square test. P value less than 0.05 was considered statistically significant.

RESULTS

There was no significant difference between both groups regarding age, parity, residence and educational level (Table 1).

Table (1): Patient's characteristics**.**

patient's characteristics		**LNG n=100**	**IUD n=100**	**Student t test**	
				T	**p-value**
Age (years)		27.0 ± 3.2	26.7 ± 3.7	0.57	0.57
Parity		2.3 ± 0.8	2.3 ± 0.9	0.08	0.94
Residence	**Urban**	34	41	1.04	0.306
	Rural	66	59		
Education	**Illiterate**	23	20	1.02	0.6
	Secondary	54	61		
	University	23	19		

There was significantly higher rate of contraption efficacy in women using IUD when compared with women using ECP (Table 2).

Table (2): The efficacy of emergency contraceptives in the studied women.

Efficacy	**LNG n=100**	**IUD n=100**	**Chi-square test**	
			X2	**P-value**
Effective	86	95	4.7	0.03
	14	5		

There was significantly higher rates of nausea, vomiting and headache in ECP group when compared with IUD group. On the other hand, IUD patients had significantly higher rate of bleeding (Table 3).

Table (3): Comparison between the studied groups regarding the reported side effects.

Side effects	LNG n=100	IUD n=100	Chi-square test	
			X2	P-value
None	6	17	5.9	0.015
Nausea	83	1	124.0	0.0001
Vomiting	47	1	58.0	0.0001
Bleeding	9	44	31.4	0.0001
Colic	26	35	1.9	0.17
Headache	6	-	6.2	0.013
Menorrhagia	-	1	1.0	0.32
Infection	-	2	2.0	0.16
PID	-	1	1.0	0.32

Table 4 shows higher rate of satisfaction among ECP users.

Table (4): Comparison between the studied groups regarding satisfaction.

Satisfaction	LNG n=100	IUD n=100	Chi-square test	
			X2	P-value
Very unsatisfied	1	1	10.7	0.031*
Unsatisfied	5	13		
Neutral	11	23		
Satisfied	77	56		
Very Satisfied	5	7		

Table 5 shows significant association between women satisfaction and efficacy in both of ECP group IUD group.

Table (5): The relation between satisfaction and efficacy in both groups.

Efficacy	LNG				IUD			
	Satisfied (n=82)	Unsatisfied (n=18)	Chi-square test		Satisfied (n=63)	Unsatisfied (n=37)	Chi-square test	
			X2	P-value			X2	p-value
Effective	74	12	6.8	**0.009**	62	33	4.2	**0.041**
Failed	8	6			1	4		

Table 6 shows no significant relation between women satisfaction and the reported side effects in ECP group and significant relation between women satisfaction and the reported side effects in IUD group.

Table (6): The relation between satisfaction and side effects in both groups.

Parameters	LNG				IUD			
	Satisfied (n=82)	Unsatisfied (n=18)	Chi-square test		Satisfied (n=63)	Unsatisfied (n=37)	Chi-square test	
			X^2	P			X2	P
None	5	1	0.008	0.93	14	3	3.3	0.7
Nausea	66	12	1.6	0.2	-	1	1.7	0.19
Vomiting	39	8	0.06	0.81	-	1	1.7	0.19
Bleeding	6	3	1.6	0.21	28	16	0.01	0.91
Colic	23	3	0.99	0.32	20	15	0.79	0.37
Headache	4	2	1.02	0.31	-	-	-	-
Menorrhagia	-	-	-	-	-	1	1.7	0.19
Infection	-	-	-	-	-	2	3.5	0.62
PID	-	-	-	-	-	1	1.7	0.19

DISCUSSION

Unintended pregnancy is a common public health problem worldwide. Unwanted pregnancies will result in induced abortion (legal or illegal, safe or unsafe) or in childbirth [4].

Emergency contraception is the second chance to prevent pregnancy when sex was forced or when a regular contraceptive method failed, was not used at all, or was used incorrectly [5].

EC is the only method that can be effective after sex has taken place. For this reason, it is especially important for female who have been raped or coerced into sex [6].

EC methods include pills like progestin only pill (LNG), estrogen progestin combination pill, antiprogestin pill (mifepristone), and progesterone modulator uripristal acetate (UPA) and copper intrauterine devices (IUD) [7].

The intrauterine copper device (IUCD) is effective for emergency contraception if inserted within 5 days after intercourse or up to day 12 of the menstrual cycle if sure that there is no pregnancy. Its advantage is that it can be used after the period of 3 days for ECP and continue as a long term non-permanent contraceptive [1].

Levonorgestrel works by inhibiting the luteinizing hormone (LH) surge if taken before the surge has started. In other words, it works to delay or prevent ovulation but is ineffective if ovulation, fertilization, or implantation has already occurred [8].

In the present study, it was shown that oral LNG pills provided contraceptive efficacy of 86.0 %. However, in the study conducted by **Farajkhoda *et al.*** [9] the efficacy of oral LNG was 100.0 %. Moreover, in the study conducted by **Festin *et al.*** [10] the authors estimated the effect of increased body mass index (BMI) on pregnancy rates with levonorgestrel (LNG) 1.5 mg used as emergency contraception (EC). Overall pregnancy rate was low at 1.2%.

It showed be noted that the efficacy of oral LNG pills is related to relation of time of administration to the day of ovulation as shown by the study of **Noé *et al.*** [11] who found that the overall contraceptive efficacy of LNG-EC was 68% if taken around the days of ovulation while it was 100.0 % effective if taken before ovulation.

The present study showed significantly higher rate of contraption efficacy in women using IUD when compared with women using ECP. This is in agreement with the study conducted by **Turok *et al.*** [12] who followed women for 1 year after choosing either the copper T380 IUD or oral LNG for EC. The 1-year cumulative pregnancy rate in women choosing the IUD was 6.5% vs. 12.2% in those choosing oral LNG.

Also our results are consistent with the results of systematic review published by **Mittal** [7] who concluded that copper IUD is the most effective emergency contraceptive with advantage of providing continued contraception.

Also study conducted by **Bellows *et al.*** [13] compared the cost-effectiveness of 4 emergency contraception strategies over 1 year. The study found that the copper IUD has the least cost in most cases.

Comparison between both groups regarding the reported side effects showed significantly higher rates of nausea, vomiting and headache in ECP group when compared with IUD group. But IUD patients had significantly higher rate of bleeding. This is in agreement with the Society of Obstetricians and Gynecologists of Canada Guidelines which concluded that nausea and vomiting are common side effects with ECP while bleeding is common with emergency IUD [14]. Also, in the study conducted by **Kolarov *et al.*** [15], the commonest side effect with oral LNG contraceptive tablets was nausea. Another important side effect in women using oral LNG was headache. This is line with the meta-analysis done by **Glasier *et al.*** [16], who identified headache as a common adverse event after use of oral LNG. In addition, the study conducted by **Festin *et al.*** [17], found that the commonest side effects with oral LNG were nausea, headache, abdominal and pelvic pain.

Comparison between the studied groups regarding women satisfaction revealed better satisfaction with ECP. This is in harmony with the study conducted by **Turok *et al.*** [18], in their study, they assessed the desire of women presenting for emergency contraception (EC) to participate in a study offering the copper intrauterine device (IUD) or oral levonorgestrel (LNG) and follows up of both groups for six months after EC administration. The study showed better satisfaction rate among women using ECP when compared to those who chose IUD.

CONCLUSIONS

Emergency IUD has higher efficacy than emergency contraceptive pills (ECP) and has fewer side effects. However, there is more satisfaction regarding ECP as compared to IUD.

- **Strength of the study:** Recruitment of large sample size.
- **Limitations of the study:** Missed follow up of many cases.
- **Acknowledgements:** The authors would like to acknowledge the contribution of residents and nursing staff at Obstetrics and Gynecology Outpatient Clinic of Menoufia University Hospital.
- **Funding:** This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.
- **Disclosure of interest:** The authors report no conflict of interest.

REFERENCES

1. **Kwa S, Sivalingam N (2012):** Issues in emergency contraception for the adolescent. Malays Fam Physician**,** 7(1):37-40.
2. **Gizzo S, Fanelli T, Di Gangi S *et al.* (2012):** Nowadays which emergency contraception? Comparison between pastand present: latest news in terms of clinical eficacy, side efects and contraindications .Gynecological Endocrinology**,** 2012:1-6.
3. **Li H, Lo S, Ho P (2013):** Emergency contraception. Best Pract Res Clin Obstet Gynaecol., 28(6):835-44.
4. **Glasier A, Gemzell-Danielsson K, Bouchard P *et al.* (2014):** ISGE statement on oral emergency contraception. Gynecol Endocrinol**.,** 30(10):681-2.
5. **Cameron S, Li H, Gemzell-Danielsson K (2017):** Current controversies with oral emergency contraception: a review. BJOG**.,** 124(13):1948-1956.
6. **Westley E, Kapp N, Palermo T *et al.* (2013):** Family Care International, NY, USA b World Health Organization, Geneva, Switzerland c Stony Brook University, NY, USA d University of South Florida, FL, USA International Journal of Gynecology and Obstetrics**,** 123 :4–6.
7. **Mittal S (2016):** Emergency contraception: which is the best? Minerva Gynecol**.,** 68(6):687-99.
8. **International Federation of Gynecology and Obstetrics (2015):** Mechanism of action: how do levonorgestrel-only emergency contraceptive pills (LNG ECPs) prevent pregnancy? https://www.cecinfo.org/icec-publications/mechanism-action-levonorgestrel-emergency-contraceptive-pills-lng-ecps-prevent-pregnancy/
9. **Farajkhoda T, Khoshbin A, Enjezab B *et al.* (2009):** Assessment of two emergency contraceptive regimens in Iran: levonorgestrel versus the Yuzpe. Niger J Clin Pract**.,** 12(4):450-452.
10. **Festin M, Peregoudov A, Seuc A *et al.* (2017):** Effect of BMI and body weight on pregnancy rates with LNG as emergency contraception: analysis of four WHO HRP studies. Contraception**,** 95(1):50-54.
11. **Noé G, Croxatto H, Salvatierra A *et al.* (2011):** Contraceptive efficacy of emergency contraception with levonorgestrel given before or after ovulation. Contraception**,** 84(5):486-92.
12. **Turok D, Godfrey E, Wojdyla D *et al.* (2013):** Copper T380 intrauterine device for emergency contraception: highly effective at any time in the menstrual cycle. Hum Reprod**.,** 28(10):2672-2676.
13. **Bellows B, Tak C, Sanders J *et al.* (2018):** Cost-effectiveness of emergency contraception options over 1 year. Am J Obstet Gynecol**.,** 218(5):508.9.
14. **Dunn S, Guilbert E, Lefebvre G *et al.* (2003):** Clinical Practice Gyneacology and Social Sexual Issues Committees, Society of Obstetricians and Gyneacologists of Canada (SOGC). Emergency contraception. J Obstet Gynaecol**.,** 25(8):673-9.
15. **Kolarov G, Dimitrov A, Chernev T *et al.* (2004):** Emergency contraception with levonorgestrel for teenagers--efficacy, tolerability, and level of information awareness]. Akush Ginekol (Sofiia)**,** 43(1):26-31.
16. **Glasier A, Cameron S, Fine P *et al.* (2010):** Ulipristal acetate versus levonorgestrel for emergency contraception: a randomised non-inferiority trial and meta-analysis. Lancet**,** 375(9714):555-562.
17. **Festin M, Bahamondes L, Nguyen T *et al.* (2016):** A prospective, open-label, single arm, multicentre study to evaluate efficacy, safety and acceptability of pericoital oral contraception using levonorgestrel 1.5 mg. Hum Reprod**.,** 31(3):530-40.
18. **Turok D, Gurtcheff S, Handley E *et al.* (2010).** A pilot study of the Copper T380A IUD and oral levonorgestrel for emergency contraception. Contraception**,** 82(6):520-5.