Acceptability and Satisfaction towards Copper T 380A versus Single Dose Levonorgestrel as Emergency Contraception among Egyptian women

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Abstract

Objective: To assess acceptability & satisfaction towards Cu-T 380A (IUD) versus levonorgestrel (contra plan II) as EC among Egyptian women as primary outcome, and the efficacy, side effects as secondary outcomes.
Method: 336 women fulfill the inclusion & exclusion criteria completed the study distributed as 162 women chose to use levonorgestrel and 174 women chose to use IUD. Patients were followed up for index cycle. Patients were assessed for acceptance of LNG and IUD, side effects, failure rate and resumption of menses.
Results: Acceptability and satisfaction of IUD as EC method were 51.8 % and 98.3%vs. 48.2% and 96.3% of LNG group. 59.3% and 62.1% of LNG and IUD group respectively have resumed their menses within expected time. LNG showed tolerated side effects. The most common side effect among LNG group was heavy bleeding (9.3%) and nausea (7.4%). IUD was left in place as long-term contraception in most of cases (67.2%). Only one woman of IUD group and 2 women of LNG group had pregnancy. Most of participants have been satisfied with their method.
Conclusion: both methods are highly effective methods of contraception after unprotected intercourse and IUDs are cost-effective when left in place as ongoing contraception.

Key Words: emergency contraception, levonorgestrel.

Introduction

Emergency contraception (EC) is a term that refers to all methods of contraception that are administered for usage after intercourse and before implantation It is well established that many unintended pregnancies occur as a result of unprotected intercourse, inadequate contraceptive measures, or failure of a method [1]. In developing countries, about 75 million pregnancies annually are unintended, a number close to the 80 million growth of world population each year [2]. In conservative societies, as in Egypt, many of women with unintended pregnancies will seek unsafe abortion [3]. EC can help reducing mortality and morbidity associated with unsafe abortions [1].

The most commonly used methods of EC can reduce the risk of pregnancy by 75% to 89% [4]. One of the most fictions about EC that they is abortifacient –the idea that can be important obstacle for its usage in Islamic societies as in Egypt. The World Health Organization's "Medical Eligibility Criteria for Contraceptive Use" include no conditions in which the risks of emergency contraception outweigh the benefits [5].

There are two known methods of emergency contraception: hormonal methods (Estrogen only pills, Combined pills [6], antiprogestin pills and progestin only pills), also known as emergency contraceptive pills, and insertion of a copper intrauterine device (IUD) post-coitally [7].

Only the progestin levonorgetrel has been studied for use as an emergency contraceptive method. The original treatment schedule was one 0.75 mg dose within 72 hours after unprotected intercourse and a second 0.75 mg dose 12 hours after the first dose. However, recent studies have shown that

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a single dose of 1.5 mg is as effective as two 0.75 doses 12 hours apart [8].

The insertion of a copper IUD within 5 days of unprotected intercourse has been shown to prevent pregnancy and is an important option for women presented after the 72-hour time frame of when hormonal EC is most effective. Since it is well accepted that implantation occurs 6 to 7 days after ovulation, extending insertion of an IUD up to 7 days after unprotected intercourse may be acceptable if it falls within 5 days of the ovulation day. The post-coital IUD may remain in place to provide ongoing contraception [9].

The aim of the present study was to assess acceptability & satisfaction towards Cu-T 380A (IUD) versus levonorgestrel (contra plan II) as EC among Egyptian women as primary outcome, and the efficacy, side effects as secondary outcomes.

Patients and Methods

After approval of research and ethics committee of faculty of medicine, Suez Canal University, this prospective comparative study was conducted among women presented to outpatient clinic of Obstetrics and Gynecology department, Suez Canal University Hospital. During the period of the study from 0ctober 2013 to April 2014, women of reproductive age (18 – 45 years old) who visited the hospital within 72 hours of single unprotected intercourse wishing to avoid unwanted pregnancy were selected. For women presented within 72 hours, the advantages and disadvantages of both methods (Levonorgestrel and Copper T 380A) were explained and they were asked to choose one of these methods.. The least required sample size for each group were estimated depending on the previously reported efficacy of EC with each method [10] using α error of 0.05 and power of study 80% [11] with (n) not less than 50 participants for each group.

Women were included in the study after fulfilling previously determined inclusion and exclusion criteria. Women 18 – 45 years old with regular menstrual cycle for last 3 months, in need of emergency contraception (had unprotected intercourse within 72 hours), willing to comply with study requirements, and available for follow up (accessible by telephone) and willing not to have further acts of intercourse during the same cycle. Women with pelvic inflammatory disease or septic abortion within the past 3 months or had gonorrhea, abnormalities of the uterus that distort the uterine cavity, mucopurulent cervicitis, vaginal bleeding of an unknown etiology, ovarian, cervical, or endometrial cancer, previous ectopic pregnancy, thromboembolism, and migraine were also excluded from the study. Patients have reported allergy to copper or Wilson's disease (for participants selecting the copper IUD) or allergy to Levonorgestrel (for participants selecting oral Levonorgestrel) were excluded from the study.

Women who fulfilled the criteria for inclusion and were willing to participate were enrolled for the study. Participants were divided into two groups A and B. Group A included women opted for LNG treatment. Single dose (two tablets of 0.75 mg tablets) was given orally within 72 hours of single unprotected intercourse (known as contra plan II manufactured and marketed by DKT Egypt Co. Group B included women who opted for Cu T 380 came within 72 hours and chose this method Cu T380 was inserted under aseptic conditions. At the beginning of the study, 420 women were presented requesting EC. 336/420 (80%) fulfill the inclusion criteria. 162 chose LNG (48.2%) and 174/336 (51.8%) chose IUD.

At first visit, history was taken about age, parity, coitus-EC interval in hours. The reason for seeking EC was recorded. As women presented within 72 hours were asked to choose one of the studied methods, and acceptance of LNG and Cu T 380 was estimated based on the percentages of women chose each method after explanation of each method for all participants. Participants were followed up within 7 days of vaginal bleeding or spotting. Participants were assessed for resumption of menses, whether early (< 7 days), delayed > 7 days beyond expected date of next menses or within expected time (± 7 days of expected date of next menses). Any side effects were reported as nausea, vomiting, abdominal pain, heavy bleeding, or irregular bleeding. Displacement or expulsion of IUD was reported. Efficacy of EC method was evaluated based on failure rate estimated by occurrence of pregnancy within index cycle as documented by positive urine pregnancy test or ultrasonography examination. Participants were asked if they were satisfied or not by used method. Number of participants willing to continue use IUD after the index cycle as long term contraception method was recorded.

Statistical analysis

Data were processed using SPSS version 15 (SPSS Inc., Chicago, IL, USA). Quantities data were expressed as means ±SD and qualitative data were expressed as numbers and percentages. Student's T-test was used to test significance of difference for quantitative variables while Chi-square and fisher's exact tests were used to test significance for qualitative variables. A probability value (p-value) < 0.05 was considered statistically significant.

Results

Table 1 presents the baseline characteristics of participants in both groups. There was no statistically significant difference between women in IUD and LNG groups regarding all characteristics. As regard to acceptability of each method, 174/336 women have chosen IUD (51.8%) and 162/336 (48.2%) have chosen LNG with no statistically significant difference. Mean age was 28.6 and 29.5 years old in LNG and IUD group respectively. Most of women were para 1 – 2 (70.4% and 82.8% in LNG and IUD group respectively. Most of participants in both groups have previously used contraceptive method (77.8% of LNG group women and 86.2% of IUD group women). Thirty women of LNG group and thirty-six of IUD group have previously used EC. Most of women in IUD group who have previously used EC have used IUD while most of women in LNG group who have previously used EC have used pills either POP or combined pills. 27.8% and 15.5% of women in LNG and IUD groups respectively have presented for EC within 24 hours post-coital while 53.7% of LNG group and 48.3% of IUD group have been presented from 24 – 48 hours post-coital and 18.5% and 36.2% of LNG and IUD groups respectively have been presented 48 -72 hours. Most common indication for EC among studied women was none use of contraceptive method (59.3% and 48.3% in LNG and IUD groups respectively). One patient has presented after rape and was presented after 65 hours and has chosen to be allocated to levonorgestrel group. More than half of the participants in both groups have resumed their menses with ± 7 days of expected time (59.3% and 62.1% of LNG and IUD group respectively). 24.1% of IUD group women had resumed their menses as early as more than 7 days before expected time of next menstruation while 13.8% of the same group and 22.2% of LNG groups had delayed menstruation more than 7 days of expected time of next menstruation. Most of patients have no side effects. The most common side effect among LNG group was heavy bleeding (9.3%) and nausea (7.4%) while 27.6% of IUD group participants have heavy bleeding and 12.1% have irregular menses. Most of women of IUD group have continued to use IUD as long term contraceptive method (67.2%). Failure rate was very low among both groups; only one woman of IUD group and 2 women of LNG group had pregnancy diagnosed by positive pregnancy test and ultrasonography after the index cycle (Table 2).

Most of participants have been satisfied with their method (96.3% of LNG group and 98.3% of IUD group). Only 2 patients of LNG group and 1 patient of IUD group are not satisfied (Table 3).

Table (1)
Characteristics of participants in both groups of the study:

Characteristics		LNG group (n=162)	IUD group (n=174)	P-value
Age	Mean ± SD	28.6 ± 7.3	29.5 ± 6.7	0.5 (NS)
	Range	20 – 38	19 – 39	
Parity	NP	15 (9.2%)	3 (1.7%)	0.1 (NS)
	P1-2	114 (70.4%)	144 (82.8%)	
	≥P3	33 (20.4%)	27 (15.5%)	
History of abortion		6 (3.7%)	9 (5.2%)	0.9 (NS)
History of previous contraception		126 (77.8%)	150 (86.2%)	0.4 (NS)
Previous used method of contraception#	IUD	39 (30.9%)	93 (62%)	0.01*
	OCP	75 (59.6%)	42 (28%)	
	Condoms	12 (9.5%)	15 (10%)	
	Others	18 (14.3%)	15 (10%)	
History of previous EC		30 (18.5%)	36 (20.7%)	0.9 (NS)
Previous method for EC	IUD	6 (20%)	21 (58.3%)	0.2 (NS)
	POP	15 (50%)	9 (25%)	
	Combined pills	9 (30%)	6 (16.7%)	
Coitus-EC interval (hours	< 24 hours	45 (27.8%)	27 (15.5%)	0.07 (NS)
	24 – 48 hours	87 (53.7%)	84 (48.3%)	
	48 – 72 hours	30 (18.5%)	63 (36.2%)	
Indications for EC	Non use of contraception	96 (59.3%)	84 (48.3%)	0.3 (NS)
	Slippage of condom	9 (5.6%)	21 (12.1%)	0.4 (NS)
	Breakage of condom	21 (12.9%)	18 (10.4%)	0.9 (NS)
	Incorrect use of contraception	21 (12.9%)	27 (15.5%)	0.9 (NS)
	Displaced/expelled IUD	14 (8.6%)	24 (13.7%)	0.4 (NS)
	Rape	1 (0.6%)	0 (0%)	0.9 (NS)

*Statistically significant difference, NS: no statistically significant difference,
LNG: Levonorgestrel, POP: progestin only pills, EC: emergency contraception,
IUD: Intrauterine device, OCP: oral contraceptive pills, NP: nulliparous
#More than method could have been previously used.

Table (2)
Resumption of menses and side effects:

Characteristics		LNG group (n=162)	IUD group (n=174)	P-value
Resumption of menses	Early	30 (18.5%)	42 (24.1%)	0.5 (NS)
	On time	96 (59.3%)	108 (62.1%)	
	Delayed	36 (22.2%)	24 (13.8%)	
Side effects	Nausea	12 (7.4%)	0 (0%)	0.1 (NS)
	Vomiting	9 (5.6%)	0 (0%)	0.2 (NS)
	Abdominal pain	6 (3.7%)	18 (10.3%)	0.3 (NS)
	Heavy bleeding	15 (9.3%)	48 (27.6%)	0.02*
	Irregular menses	12 (7.4%)	21 (12.1%)	0.6 (NS)
	Displaced/expelled IUD	-	3 (1.7%)	-
Continue to use method for long term contraception		-	117 (67.2%)	-
Pregnancy within index cycle (failure rate)		2 (1.2%)	1 (0.6%)	0.5 (NS)

*Statistically significant difference, NS: no statistically significant difference,
LNG: Levonorgestrel, IUD: Intrauterine device
#Percentages are of women who didn't continue to use long term contraceptive method after current cycle.

Table (3)
Satisfaction of participants among both groups:

	LNG group (n=162)	IUD group (n=174)	p-value
Satisfied	156 (96.3%)	171 (98.3%)	0.6 (NS)
Not satisfied	6 (3.7%)	3 (1.7%)	

NS: no statistically significant difference, LNG: Levonorgestrel, IUD: Intrauterine device

Discussion

Basically, there are two accepted methods for emergency contraception: the first one is hormonal methods and the second one is insertion of a postcoital intrauterine contraceptive device (IUCD). Hormonal method should be initiated within 72 hours of intercourse [3].

In the present study only 72/336 (21.4%) women have been present within 24 hours postcoital. In the study of Chen and colleagues [12], 82.7% of participants took the drug during the first 24 h after unprotected intercourse. This difference can be ascribed mainly to cultural difference and knowledge concerning emergency contraception. Time-effect relationship that was shown in few of previous reports [4, 13], was not seen in others studies [14 – 16] as same as the present study.

Results of most of previous results regarding efficacy and failure of levonorgestrel are consistent with the present study and prove the high efficacy of this regimen [4] while others show higher failure rates [17]. Gainer and colleagues have reported failure rate with the use of levonorgestrel about 1.3% [18] that is similar to the present study however rates low as 0.2 have been also reported [12].

Unlike levonorgestrel, we didn't find any differences in findings of previous reports regarding its efficacy. Reported failure rates were as low as reported in our study [19, 20]. Another recent meta-analysis in 2012 by Cleland et al., [21] has reported that IUD is highly effective method of EC with failure rate of 0.09%.

As regarding side effects, present findings were consistent with previous findings as no major side effects were reported with either method with only reported cases of tolerable gastrointestinal side effects with levonorgestrel [3, 4, 12]. The post-coital IUCD is associated with potential complications such as cramps, bleeding, infection, perforation, and expulsion [3]. This supports the findings of the present study. We have reported expulsion of IUD in three cases (1.7%) besides patients experienced heavy bleeding (27.6%) and irregular menses (12.1%).

The majority of the participants in the present study have resumed their menses within the expected time (59.3% and 62.1% in levonorgestrel group and IUD group respectively). Similarly in the 1998 WHO study [4], the onset of next menses for women taking the 2-dose levonorgestrel regimen shows that 15% of women having an early onset of menses, 57% having menses return within 3 days of the expected day, and 28% experiencing a delay of more than 3 days. In other trials, a higher frequency of women tended to have an early onset of menses. The time to resumption of menses may be affected by the timing of EC use related to the expected date of ovulation [15].

Menstrual patterns following use of levonorgestrel has been well studied in 2006 by Gainer and coworkers [18]. They have showed that Levonorgestrel emergency contraception is associated with significant but transient changes in menstrual patterns in a significant proportion of users [18].

As regarding acceptability of IUD as a method for EC, a total of 174/336 (51.8%) preferred to use IUD. An interest in IUD as EC has been previously evaluated by Schwarz et al., [22]. They have surveyed a total of 412 women who requested EC, 12% of them expressed interest in same-day insertion of an IUD. They have reported that interest in IUD as EC method among EC seekers increased with higher educational level.

Conclusion

Both levonorgestrel and IUDs are highly acceptable methods of contraception after unprotected intercourse. Because they are safe, highly effective with tolerable side effects. IUDs can be left in place as ongoing long contraception. Women of reproductive age should be provided with a prescription for hormonal EC in advance of need. We should recommend option of IUDs in the range of emergency contraception offered to patients presenting after unprotected intercourse, increasing both public and professional awareness of emergency contraception and on improving access to this important therapeutic intervention.

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