Comparing the complications of 2 copper intrauterine devices: T380A and Cu-Safe 300

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مقارنة المضاعفات الناجمة عن غرز نوعَيْن من اللوالب الرحمية النحاسية: T380A والـ Cu-Safe 300

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الخلاصة: قارنت هذه الدراسة ذات الحالات والشواهد المفردة التعمية، بين المضاعفات الناجمة عن غرز نوعَيْن من اللوالب الرحمية، في إحالات متتابعة أجريت في عيادات جامعة الشهيد بهشتي للعلوم الصحية في جمهورية إيران الإسلامية. وتم عشوائياً توزيع النسوة اللاتي انطبقت عليهن معايير الدراسة (وعددهن= 110) لتلقي أحد اللولبَيْن: النحاسي T380A (الشواهد) أو الـ Cu-Safe 300 (الحالات). واشتكت النسوة من ألم يتراوح بين المعتدل و الوخيم أثناء غرز اللولب في 69.1٪ من الشواهد، و47.3٪ من الحالات. و لم تُلاحَظْ فروق يُعْتَدُّ بها إحصائياً بين المجموعتَيْن من حيث وجود نزف، أو دُوَار، أو ألم مغصي. وبعد المتابعة لمدة ثلاثة أشهر، تبيَّن حدوث تَبَقُّع spotting في 16.3٪ من الشواهد، و32.7٪ من الحالات. وكان الألم والنزف الحيضي أقل في مجموعة اللولب Cu-Safe-300، ولو أن التبقُّع كان أقل بعد مضي ثلاثة أشهر في مجموعة اللولب النحاسي T380A. وتوصي الباحثتان بقوَّة بإجراء دراسات حول المضاعفات الطويلة الأمد.

ABSTRACT This single-blind case–control study compared the complications of 2 intrauterine devices in consecutive referrals for device insertion in clinics of Shaheed Beheshti University of Medical Sciences, Islamic Republic of Iran. Women who met the inclusion criteria (***n*** = 110) were randomly allocated to receive copper T380A (controls) or Cu-Safe 300 (cases). Moderate or severe pain during the device insertion was reported in 69.1% of controls and 47.3% of cases. Bleeding, vertigo and crampy pain at insertion were not significantly different between the groups. After 3 months follow-up, blood spotting was reported in 16.3% and 32.7% of controls and cases respectively. The Cu-Safe-300 group had less pain and menstrual bleeding but copper T380A had less spotting after 3 months. Studies on longer term complications are strongly recommended.

Les complications de deux dispositifs intra-utérins au cuivre : étude comparative des DIU T380 A et Cu-Safe 300

RÉSUMÉ Cette étude cas-témoins en simple aveugle a comparé les complications de deux dispositifs intra-utérins (DIU) dans une série de cas consécutifs consultant pour insertion de DIU les services de l'Université des Sciences médicales Shaheed Beheshti en République islamique d'Iran. Les femmes répondant aux critères d'inclusion (n = 110) ont été randomisées pour recevoir soit le T380 A (témoins), soit le Cu-Safe 300 (cas). Une douleur modérée ou sévère a été ressentie pendant l'insertion par 69,1 % des témoins et 47,3 % des cas. Il n'est apparu aucune différence significative entre les groupes en ce qui concerne les saignements, vertiges et crampes à l'insertion. À l'issue d'un suivi de 3 mois, 16,3 % des témoins et 32,7 % des cas ont signalé l'existence de saignotements (***spotting***). Sur 3 mois, le Cu-Safe 300 a été associé à une douleur moins importante et à un flux menstruel moins abondant tandis que le T380 A s'est accompagné de saignotements moins fréquents. L'étude des complications des DIU sur un plus long terme est fortement recommandée.

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Introduction

The complications of intrauterine contraceptive devices (IUDs) are a key concern in midwifery [*1*]. The World Health Organization (WHO) has reported that the incidence of complications is up to 40% for some IUDs [*2*]. Pain and bleeding are the most common side-effects leading to preterm removal of IUDs [*1,3*]. Applying better IUDs and inserting them correctly are important factors in reducing the risk of complications that can lead to abandonment of the method and the risk of unwanted pregnancy.

Among IUDs, the copper T380A is the most commonly used, whereas the newer Cu-Safe 300 is reported to lead to fewer complications [*4–6*]. It has a thread with no knit; hence, it is expected to cause less infection. Its tube is also smaller at 3 mm diameter, which is appropriate for women with a narrow cervix. Its insertion is easy with no need for sterile gloves [*6*], which makes it cost-effective. It has less weight, more flexibility, and less spontaneous ejection. Since no anchoring mechanism is applied, it causes less damage to the endometrium and hence less crampy pains and spotting for users.

In the Islamic Republic of Iran, IUDs are the second most commonly used form of contraception after oral contraceptives. Investigating the advantages and disadvantages of different IUDs is important to identify which are less likely to cause pain and bleeding (especially as bleeding or spotting may interfere with religious ceremonies or sexual intercourse due to cultural or religious beliefs). Therefore, this study was conducted to compare the complications of T380A with Cu-Safe 300 in women referring to health clinics of Shaheed Beheshti University of Medical Sciences in 2001.

Methods

This single-blind clinical trial was conducted with 110 women between 20 and 40 years who were sequentially referred to clinics for IUD insertion and randomly assigned to receive the Cu-Safe 300 or T380A IUD. Women were excluded if they were nulliparous, had any symptoms or signs of sexual transmitted disease or were taking drugs acting on the menstrual cycle. They were also excluded if they had current or recurrent active pelvic infection or a history of: uterus or cervix malignancy, ectopic pregnancy, fallopian tube surgery, clotting disorders, Wilson disease, heart valve disease or previous IUD spontaneous ejection.

Letters of introduction and permission were taken from the research and health authorities of the university to be presented to officials of the health centres. Written informed consent was obtained from all participants in the study.

One month before IUD placement, the women were assessed for a normal urogenital system: position of uterus, characteristics of menstrual cycle, amount of monthly bleeding, lack of dysmenorrhoea and 1 or 2 regular postpartum menses. Laboratory examinations, including haemoglobin level, haematocrit level and cervical smear were performed. Women with values within the normal range were included in the study.

After collection of sociodemographic and clinical data (age, woman's and husband's education and occupation, pregnancy history, uterus position, cervix type, previous IUD use) on a standard form, the women were instructed by co-workers of the study about how to record menstrual symptoms. The amount of menstruation was recorded using Higham et al.'s chart system [*7*] and the presence of any blood

spotting or crampy pains were recorded by a calendar system. Severity of dysmenorrhoea and pain were measured using a visual comparative scale [*8,9*] and a verbal multidimensional scoring system [*9–11*]. Different identification and notification cards were given to the subjects to identify and inform them about warning signs and symptoms and about the contact information of researchers, as required.

At the clinics the IUDs were inserted by the co-worker using the manufacturer's instructions. Any problems occurring during IUD placement, including uterus perforation, abortion, vasovaginal and anaphylactic shock, uterine cramps and bleeding, were documented. Early complications such as infection, conception, pain, dysmenorrhoea, ectopic pregnancy, spontaneous ejection, spotting, and increased amount and duration of bleeding were also noted. The subjects were followed up and examined over 3 months to assess IUD complications at different intervals in a predetermined schedule: 15 days after IUD insertion, after 1st menstruation, and after the 2nd and 3rd months of menstruation.

Data obtained from demographic forms and other charts were classified and analysed by *t*-test, and chi-squared tests with *SPSS* for Windows.

Results

The data showed no significant difference between the personal and medical characteristics of the 2 groups of women; they were similar in terms of socioeconomic status, age, number of pregnancies, deliveries, abortions, lactation, and location and size of uterus (Table 1).

Table 2 shows that 52.7% of women suffered moderate and severe pain during insertion of the T380A compared with only 47.3% for Cu-Safe 300 ($P < 0.02$). IUD complications in each group during and immediately after insertion are also presented in Table 2. There were no significant differences between the 2 groups in the proportion of women experiencing vertigo, crampy pains and severe bleeding during and after insertion.

The amount of bleeding (mean pictorial blood loss assessment scores) over the 3 months follow-up showed no significant difference between the 2 groups (Table 3). The number of women experiencing blood spotting was similar in the 1st and 2nd month, but twice as many women in the Cu-Safe 300 group had spotting in the 3rd month ($P < 0.07$) (Table 4). The mean number of days of spotting decreased in both groups over 3 months and was less in the T380A group than the Cu-Safe 300 group at the 2nd month (3.4 versus 7.1 days, $P < 0.001$) and 3rd month (4.2 versus 5.1 days, $P < 0.002$) (Table 5). The number of women who experienced crampy pains over the 3 months follow-up was not significantly different between the groups (Table 6).

At the 1st month, 3 women in both groups suffered spontaneous ejection of the IUD and only 1 woman (Cu-Safe 300 group) at the 2nd month.

Discussion

Our study showed that pain on insertion of the Cu-Safe 300 IUD was less than for the T380A device. This has not been investigated in similar studies, and it may be due to the greater flexibility and smaller size of the Cu-Safe 300. The frequency of crampy pains, severe bleeding and vertigo immediately after IUD placement were similar in both groups. Since IUDs are foreign objects, crampy pains immediately following insertion may be the result of attempted

Table 1 **Medical characteristics of the women according to type of intrauterine device (IUD)**

Variable	Type of IUD	
	T380 A (*n* = 55)	**Cu-Safe 300 (*n* = 55)**
Age [Mean (SD) years]	27.4 (5.2)	27.8 (5.4)
Pregnancy history [Mean no. (SD)]		
Pregnancies	2.11 (1.10)	2.04 (2.05)
Deliveries	2.00 (1.01)	1.87 (0.99)
Abortions	0.11 (0.36)	0.15 (0.04)
Current breastfeeding (%)		
Yes	50.9	49.1
No	49.1	50.9
Position of uterus (%)		
Anteverted	45.5	49.1
Middle	23.6	18.2
Retroverted	30.9	32.7
Size of uterus [Mean (SD) cm]	8.00 (0.62)	7.98 (0.69)
Cervix type (%)		
Nulliparous[a]	34.5	32.7
Parous	65.5	67.3
Previous IUD use		
Yes (%)	9.1	7.3
No (%)	90.9	92.7
Mean (SD) no. of times	1.30 (0.50)	1.43 (0.71)
Reasons for previous IUD removal (%)		
Rejection	75.0	58.8
Infection	0.0	17.6
Menstrual disturbances	6.2	11.8
Desire for pregnancy	18.8	11.8
Woman's education (%)		
Primary school	41.8	32.7
Secondary school	20.1	43.6
High school	34.5	18.2
University	3.6	5.5
Husband's education (%)		
Illiterate	14.5	3.6
Primary school	30.9	23.6
Secondary school	29.2	45.5
High school	21.8	20.0
University	3.6	7.3

Table 1 **Medical characteristics of the women according to type of intrauterine device (IUD)** ***(concluded)***

Variable	Type of IUD	
	T380 A (*n* = 55)	Cu-Safe 300 (*n* = 55)
Woman's occupation (%)		
Housewife	94.5	92.7
Employed	5.5	7.3
Husband's occupation (%)		
Unemployed	7.3	5.4
Manual worker	30.9	20.0
Government clerk	18.2	29.1
Self-employed business	43.6	45.5
Housing type (%)		
Private	21.8	14.6
Rented	63.7	74.5
No rent	14.5	10.9
House area/person [Mean (SD) m^2]	14.8 (6.6)	16.1 (6.3)

[a]All women were parous, but some had nulliparous cervix after caesarean section birth.
SD = deviation, n = total number of respondents.

rejection. In addition, it seems that endometrial irritation during menstruation leads to bleeding, and fear causes vertigo immediately after insertion.

Changes in the menstrual cycle were similar in both groups, and while the amount of bleeding was not significantly different between groups, there was clinically less bleeding in the Cu-Safe 300 group. The number of days of spotting was greater in the T380A group. Kari found that the amount and duration of monthly bleeding increased in T380A group [*4*]. Another study showed bleeding disorders were more intense with the T380A than Cu-Safe 300 [*12*]. Vanker et al. found similar findings in their 3-year study [*13*]. Kurz and Meier considered increased bleeding as a reason for preterm removal of Cu-Safe 300 [*6*]. Tolley and co-workers, in their 6-month study, reported increased bleeding amount in IUD users. They found an opposite relation between bleeding days and possible continuation in IUD application [*14*]. The reasons for less bleeding and more spotting in Cu-Safe 300 may still be its smaller size and greater movement from fundus to deeper parts of the uterus respectively.

Crampy pains were similar in both groups. Preterm removal due to pain was reported more in T380A than Cu-Safe 300 [*12*] while Kurz and Meier found pain as the reason for preterm removal of Cu-Safe 300 [*6*]. Zhou and Xiao [*15*] and Cox et al. [*16*] reported increased pain as the reason for discontinuation in IUD application. According to WHO, pain is the main reason for IUD removal in 40% of cases [*2*]. Crampy pains reduce over time, suggesting that the pain is unrelated to the IUD type but to an initial attempt to reject the IUD as a foreign body.

The rate of spontaneous ejection was similar in both groups at the different in-

Table 2 **Pain severity and complications experienced during and immediately after intrauterine device (IUD) insertion according to type of device**

Complication	Type of IUD				
	T380A		Cu-Safe 300		
	No. of women (*n* = 55)	%	No. of women (*n* = 55)	%	*P*-value
Pain severity score during insertion					
None or low	17	30.9	29	52.7	0.02
Moderate to severe	38	69.1	26	47.3	
Vertigo/weakness during and after insertion					
No	44	80.0	45	81.8	NS
Yes	11	20.0	10	18.2	
Pain during and after insertion					
No	7	12.7	18	32.7	0.02
Yes	48	87.3	37	67.3	
Crampy pains during and after insertion					
No	35	63.6	41	74.5	NS
Yes	20	36.4	14	25.5	
Severe bleeding during and after insertion					
No	45	81.8	45	81.8	NS
Yes	10	18.2	10	18.2	

NS = not significant.

Table 3 **Amount of bleeding before insertion of intrauterine device (IUD) and at 3 months follow-up according to type of device**

Interval	Type of IUD	
	T380A Mean PBAC score (SD)	Cu-Safe 300 Mean PBAC score (SD)
Before IUD insertion	54.6 (12.9)	56.5 (13.9)
1st menstruation	93.6 (25.6)	91.6 (23.2)
2nd menstruation	100.6 (20.7)	96.5 (21.2)
3rd menstruation	101.4 (21.3)	95.0 (23.5)

PBAC = pictorial blood loss assessment chart (menorrhagia is ≥ 100) [7].
SD = standard deviation.

tervals. However, Boateng et al. found a higher rate of ejection in Cu-Safe 300 than T380A [*12*] and Wu et al. reported opposite findings [*17*]. Kurz and Meier considered spontaneous ejection as one of the complications of the Cu-Safe 300 [*6*], while Cox et al., and Zhou and Xiao believed that it was generally the complication of IUD application [*16,17*]. There were no cases of conception, pelvic infection or uterus perforation in this study. Wu had similar findings [*17*], although Kurz reported concurrent pregnancy with Cu-Safe 300 [*6*] and Cox

Table 4 **Blood spotting experienced in the subjects over 3 months follow-up according to type of intrauterine device (IUD)**

Spotting experienced after insertion	Type of IUD				*P*-value
	T380A		Cu-Safe 300		
	No. of women (*n* = 55)	%	No. of women (*n* = 55)	%	
1st month					
No	37	67.3	31	56.4	NS
Yes	18	32.7	24	43.6	
2nd month					
No	36	70.6	33	64.7	NS
Yes	15	29.4	18	35.3	
3rd month					
No	41	83.7	33	67.3	< 0.007
Yes	8	16.3	16	32.7	

NS = not significant.

observed some cases of conception with the IUD [*16*].

In general, this study showed some advantages to the Cu-Safe 300, as insertion pain was significantly less common than with the T380A and there was some evidence that the amount of menstrual bleeding was lower. Furthermore the Cu-Safe 300 does not need sterile gloves and plunger for insertion and can be placed and removed more easily than T380A due to the smaller size of the inserter tube (3 mm). More long-term research is needed to better determine the type and extent of IUD complications. To guarantee IUD efficiency and improve women's health, it is suggested that manufacturers continually strive to produce the safest devices with the highest effectiveness.

Table 5 **Number of days of blood spotting after intrauterine device (IUD) insertion over 3 months follow-up according to type of device**

Month after insertion	Type of IUD		*P*-value
	T380A Mean no. of days (SD)	Cu-Safe 300 Mean no. of days (SD)	
1st month	6.6 (1.1)	6.7 (1.3)	NS
2nd month	3.4 (1.7)	7.1 (1.3)	< 0.001
3rd month	4.2 (1.5)	5.1 (1.2)	< 0.002

SD = standard deviation; NS = not significant.

Table 6 **Crampy pains experienced over 3 months follow-up after intrauterine device (IUD) insertion according to type of device**

Crampy pain after insertion	Type of IUD			
	T380A		Cu-Safe 300	
	No. of women (*n* = 55)	%	No. of women (*n* = 55)	%
1st month				
No	35	63.4	41	74.5
Yes	20	36.6	14	25.5
2nd month				
No	34	65.4	32	62.7
Yes	18	34.6	19	37.3
3rd month				
No	32	65.3	37	75.5
Yes	17	34.7	12	24.5

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