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A Comparative Study between the Side Effects of Copper Intrauterine Device in Women with Non-scarred and Scarred Uterus

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Abstract

Background So many women think that the use of intrauterine devices in a scarred uterus carries high complications like increased uterine bleeding and pain and these side-effects may result in early removal of the device.

Objective The study was conducted to show the difference in the side effects of Copper intrauterine device (CuT380A) in women after vaginal deliveries and those with previous scar of cesarean section.

Methods The study group consisted of 411women who were using CuT380A device for contraception which has been fitted for more than 3months (240 of them had vaginal deliveries and 171 had one or more cesarean section scar). Complications of the CuT380A device were compared in both groups in regard to heavy vaginal bleeding (menorrhagia), painful menstrual cycles (dysmenorrhea), cycle irregularity, other types of pain (pelvic pain and backache) and infection. Both groups were further studied and complications were compared according to the duration of intrauterine device insertion.

Results The most common side-effects related to CuT380A were bleeding and pain. Menorrhagia was recorded in 35.42% and 29.24% while dysmenorrhea in 27.08% and 34.50% women of the non-scarred and scarred uterus groups respectively. These side effects were not statistically different between the two groups and they decreased significantly with time; menorrhagia decreased from 40.54% to 27.17% (P-value=0.035) and from 36.27% to 18.84% (P-value=0.014) while dysmenorrhea decreased from 31.76% to 19.57% (P-value=0.039) and from 41.18% to 24.64% (P-value=0.026) in non-scarred and scarred uterus groups.

Conclusion The study revealed that the side-effects of CuT380A device did not differ between non-scarred and scarred uterus and that menorrhagia and dysmenorrhea significantly decreased with time.

Key words CuT380A, non-scarred uterus, scarred uterus.

Introduction

The intrauterine device (IUD) is one of the most convenient methods of birth control because, once inserted, it requires no daily attention from the woman and does not interfere with sexual activity[1].There are a variety of modern IUD in many shapes and sizes available to women in developing countries. To date, the most effective and longest lasting IUD is the Copper T380A (CuT380A), which is being used in 70 countries around the world[2,3], with about 127 million current users [4]. The method is safe, rapidly reversible, inexpensive, highly effective, long-acting and non-hormonal; these attributes make it unique and desirable for many users [2,5].

The copper intrauterine device (IUD) can cause side effectsin some women[5], women are more likely to have increased menstrual loss and

dysmenorrhea but the usually have regular menstrual cycle[6]. It is also possible for women to bleed small amounts daily in the first three to five months of use[6].

The effect of IUD–particularly the effect on local prostaglandins-on the endometrium tends to cause increased menstrual bleeding and dysmenorrhea[7]. Bleeding can be both heavier and more prolonged particularly during the first three to 6 months of use[7].

Anecdotal information accumulated from clinicians and some published information suggests thatside effects from the copper IUD decrease over time [8,9].

IUDs side effects like increased bleeding and pain cause removal of the device within the first year in up to 15% of users[10]; still higher percentages tolerate some level of theseside effects, yet retain use of the method[5].

The study is conducted to highlight the difference in the side effects of CuT380A in women with previous vaginal deliveries and those with previous cesarean section scar.

Methods

This prospective cross-sectional study was conducted during the period from the 1st of Jan.2008 to the 1st of Jan.2010 in a private clinic. Informed consent was taken from each eligible woman.

A total of four hundred & eleven women having CuT380A (Copper T, Leiras OY, Finland) for more than 3months were included in the study, some of these women had the intrauterine device fitted before the study period and others during it.

Two hundred and forty of them had vaginal deliveries (non-scarred uterus group), while the remaining 171 women had one or more cesarean section scar (up to three scars) in their reproductive history (scarred uterus group). All IUDs were inserted by the authorwithin the first 5 days of the menstrual cycle.

Each woman had at least three visits where thorough history and clinical examination including pelvic examination was done. Women with history of operations in the uterus (i.e., myomectomy, hysterotomy and metroplasty) were excluded from the study. All were healthy with regular menstrual cycles before insertion of the intrauterine device and no history of significant gynecological or medical disorders.

The participants were subjected to a questionnaire using special form that include the age, parity, number of cesarean sections, duration of IUDs insertion, days of bleeding, cycle regularity, cyclic pain and amount of bleeding before and after IUDs insertion and other complaints (backache, chronic pelvic pain and infection) and IUDs removal.

Dysmenorrhea was considered when the patient complained from cyclic pain which was not experienced by the patient before IUDs insertion which necessitated medical treatment (i.e. NSAID). Menorrhagia was considered when more number of pads where changed with passage of clots. Recurrent genital infection was considered when the patient gave history of repeated attacks of infection with clinical and bacteriological evidence of genital infection after IUDs insertion. Other gynecological complaints (backache, chronic pelvic pain and inter-menstrual spotting) were also recorded.

The data collected and arranged in tables and classified according to the groups of patients and duration of insertion. We compared first the side effects of intrauterine device between the two groups of women, then they were further divided into subgroups according to the duration of intrauterine device insertion; since most side-effects decrease over time especially within the first12-24months, we chose to compare these effects before and after 12months.

The two groups were also compared for rate of intrauterine device removal rate according to the cause of removal.

All these groups were subjected to comparison and statistical analysis using descriptive statistics (table, frequency and percentage) and inferential statistics (chi-square test) to find

any association between variable data. P-value less than 0.05 was considered significant.

Results

The age of the participants range from 18 to 47 years (mean of 31.2, SD ±7.26) for the non-scarred uterus group and (31.6, SD ±6.57) for the scarred uterus group. No statistical difference is seen between the two groups (P = 0.597).

Regarding the parity: women with 0-2 children; 88(36.67%), 62(36.26%) non-scarred and scarred uterus groups, women with 3-4 children; 93(38.75%), 80(46.78%) respectively and women with more than 5 children: 59(24.58%), 29(16.96%) respectively. No statistical difference present between these groupsrespectively (P = 0.120).

Duration of the menstrual flow after IUDs insertion is not different between the two groups, with a mean of 5.28(SD ±1.54) days for the non-scarred uterus group and 5.45(SD ±1.36) days for the scarred uterus group and the P is 0.246.

Table 1 compares the side-effects of CuT380A device between the two groups; menorrhagia is more prevalent in the non-scarred uterus group: 85women (35.42%) compared to 50(29.24%) in the scarred-uterus group with a P-value of 0.189, while dysmenorrhea is more in those with history of previous scar: [59(34.50%) vs. 65(27.08%) women in the non-scarred uterus group, P=0.106].

Regular cycles are observed more in the non-scarred uterus group; only 19.58%of women have irregular cycles compared to 18.71%suffer from inter-menstrual spotting and irregular cycles in the scarred uterus group. No statistical difference is found between them (P = 0.825).

The women who suffered from backache and pelvic pain are more in the scarred uterus group (as seen in the table).

Incidence of genital infection is comparable in both groups; 12(5.00%) and 8(4.68%) women respectively with a P = 0.881.

The duration of IUD insertion is "less than 12 months" in 148(61.67%) women with non-scarred uterus compared to 102(59.65%) with scarred uterus, and the duration is "equals-more than 12months" in 92(38.33%) and 69(40.35%) in both groups respectively. No statistical differences are detected (P = 0.680).

Table 1. Comparison between the side-effects of copper IUD in non-scarred and scarred uterus

Complications	NVD (n=240)		C/S (n=171)		P-value
	No.	(%)	No.	(%)	
Menorrhagia	85	35.42	50	29.24	0.189
Dysmenorrhea	65	27.08	59	34.50	0.106
Irregular cycle	47	19.58	32	18.71	0.825
Backache	21	8.75	18	10.53	0.545
Pelvic pain	19	7.92	17	9.94	0.474
Genital infection	12	5.00	8	4.68	0.881

NVD = Normal vaginal delivery, C/S = caesarian section

The complications according to the duration of IUD insertion are studied in both groups (table 2 and 3). Some parameters like menorrhagia and dysmenorrhea shows statistical significant decline after 12months of insertion in both groups: menorrhagia [40.54%, 27.17%, (P=0.035) vs. 36.27%, 18.84%, (P=0.014) for non-scarred and scarred uterus groups], dysmenorrhea [31.76%, 19.57%, (P = 0.039) vs. 41.18%, 24.64%, (P=0.026) respectively] while other parameters shows non-significant changes, but when we compare these effects according to duration after insertion between non-scarred and scarred uterus (Table 4), no

significant statistical differences are detected between all parameters.The study shows also that 80(33.3%) women and 48(28.07%) women are symptom-free in non-scarred and scarred uterus groups.

Table 2. Complications according to the duration of copperIUD insertion after vaginal delivery (non-scarred group)

Complications	Duration after vaginal delivery				P-value
	<12months		≥12months		
	No.	%	No.	%	
Menorrhagia	60	40.54	25	27.17	0.035
Dysmenorrhea	47	31.76	18	19.57	0.039
Irregular cycle	27	18.24	20	21.74	0.507
Backache	14	9.46	7	7.61	0.622
Pelvic pain	12	8.11	7	7.61	0.889
Genital infection	8	5.41	4	4.35	0.715
Total	148	61.67%	92	38.33%	

Table 3.Complications according to the duration of copper IUD insertion after cesarean section (scarred group)

Complications	Duration after scar				P-value
	<12months		≥12months		
	No.	%	No.	%	
Menorrhagia	37	36.27	13	18.84	0.014
Dysmenorrhea	42	41.18	17	24.64	0.026
Irregular cycle	20	19.61	12	17.39	0.715
Backache	10	9.80	8	11.59	0.708
Pelvic pain	9	8.82	8	11.59	0.552
Genital infection	5	4.90	3	4.35	0.866
Total	102	59.65%	69	40.35%	

Table 4.Comparison between the side-effects of copper IUD in non-scarred and scarred uterus according to the duration after insertion

Complication	Normal Vaginal Delivery		Caesarian Section		P-value
	<12months	≥12months	<12months	≥12months	
Menorrhagia	60	25	37	13	0.670
Dysmenorrhea	47	18	42	17	0.890
Irregular cycle	27	20	20	12	0.653
Backache	14	7	10	8	0.477
Pelvic pain	12	7	9	8	0.535
Genital infection	8	4	5	3	0.848

As shown in table 5, a total of 58(24.17%) and 33(19.30%) women in non-scarred and scarred uterus groups removed the intrauterine device for different reasons. Menorrhagia and different types of pain resulted in 15.51%, 12.12% IUD removal in both groups

representing the majority of medical cause for removal, while 44(75.86%), 26(78.79%) women respectively removed the IUD for other reasons (desire for pregnancy, fear from side-effects like possibility of perforation, fear from future infertility, coital problems, religious causes…).

Table 5.IUDs removal according to the cause of removal

Cause of removal	Non-scarred group		Scarred group		P-value
	No.	%	No.	%	
Menorrhagia	6	10.34	2	6.06	0.488
Dysmenorrhea and other types of pain	3	5.17	2	6.06	0.858
All other side-effects (inter-menstrual bleeding, infection)	5	8.62	3	9.09	0.939
Other causes (desire for pregnancy, fear from side-effects…)	44	75.86	26	78.79	0.750
Total	58	100	33	100	

Discussion

Many studies published on IUDs have consistently reported findings in favor of IUD use. Notable among these findings are: IUDs are not abortifacients; newly developed IUDs are highly effective and the efficacy is long-lasting, with lower removal rates attributable to bleeding and/or pain [(11)].These complaints are not uncommon among IUD users in the first months after insertion [(1)]. Complications and complaints reported during the study period were mostly related to menstrual disturbances. The most frequently reported menstrual complaints among both groups were menorrhagia anddysmenorrhea.

Different studies showed menorrhagia as one of the important menstrual disturbance after loop insertion:

Daniel andMishell[(12)] found that Copper IUDs were associated with increased menstrual blood loss by about 50%, particularly during the first few post-insertion cycles.This amount of blood loss does not usually cause anemia [(13)].Other studies gave different values for menorrhagia ranged from 6.2%, 35.4% and 56.3%[(1,5,15)].Comparable ranges of values are obtained in our study (35.42% for non-scarred uterus group and 29.24% for the scarred uterus group).

The incidence of excessive bleeding was found to be the highest at the 12th-month follow-up by V. Parikh and Gandhi [(14)] and de Araujo, et al [(16)] showed a decline in menorrhagia from 10.6% in the first 3months compared to 4.3% after one year while Hubacher et al [(5)] showed 56.3% at 9-19weeks and 53.9% at 19-39 weeks. In our study, incidence of menorrhagia was reported to be significantly lower in women with "equals-more than 12 months" fitted loopfor bothnon-scarred and scarred uterus groups [from 40.54% to 27.17% for NVD cases (P=0.035) and from 36.27% to 18.84% (P=0.014) for C/S cases].

Days of menstrual cycle in women after TCu380A reached 5.9days [(5)], we had 5.28(SD ±1.54) days for the non-scarred uterus group and 5.45(SD ±1.36) days for the scarred uterus group and a P-value of 0.246.

In their study of Hubacher et al[(5)], inter-menstrual spotting was present in 20% at 9-19weeks increasing to 24.9% at 19–39 weeks; our values ranged from19.58% for NVD cases and 18.71% for C/S cases. With time, inter-menstrual spotting was increasing in NVD cases (from 18.24% to 21.74%) and decreasing in C/S cases (from 19.61% to 17.39%) although both were non-significant changes. In addition, 30.6 % of the TCu380A IUD users reported dysmenorrhea, while Reinprayoon et al [(1)] reported 59.1%. Our study showed 65 (27.08%) vs.59 (34.50%) in non-scarred, scarred uterus groups respectively.

A large study of 2700 Copper IUD users in India found that complaints of pain and bleeding decreased over a 24-month period [17]. Moreover, Hubacher and coworkers reported menstrual pain of 38.3% at 9weeks, 30.6 at 9-19weeks and 32.6% at19-39weeks. Menstrual pain was decreasing significantly with time in both groups of the study.

The relatively high number of reports of menstrual complaints did not result in a large number of IUD removals because of bleeding and pain. The 12-month gross cumulative life table rates for removal because of bleeding and pain were only 3.79 per 100 women for the TCu380A[1]. The one-year continuation rate among parous women using the Copper T 380A is 92.1%. This rate suggests that this IUD is very well tolerated [12], in our study bleeding and pain resulted in 15.51%, 12.12% IUD removal in non-scarred and scarred uterus groups.

D. Hubacher, P. Chen and S. Park [5] reported different types of inter-menstrual pain as 18.7%, our study shows backache as 8.75% and 10.53%, pelvic pain 7.92% and 9.94% in scarred and non-scarred uterus groups.

de Araujo et al [16] reported 7.7% pain of different types at 3months, decreasing to 6.4% pain at 1year and 4.6% at 2years, a decline that is seen in the non-scarred uterus group only in the current study (although not significant).

Vaginitis and cervicitis were the most commonly reported types of genital infection in a study of D. Reinprayoon[1] with a range of 5%–7%, our study results are also comparable (12(5.00%), 8(4.68%) respectively).

Our study reveals that menstrual complaints significantly decrease with time but no difference between the two groups while inter-menstrual complaints not significantly change with time and also no difference between the two study groups.

Women's overall satisfaction with TCu380A remains high, as evidenced by the average first-year continuation rate of 78% [18]. Although side effects from TCu380A decreased over time, the product still causes problems that often lead to premature removal[19].But sincesexually active women need protection from pregnancy, the copper T380A with its low rates of failure during the initial 5–10 years of use plus the long, highly effective life, the absence of systemic effects such as those associated with steroid contraception and the economic benefits of using a supply-free reversible contraceptive for up to 20 years permits women as young as those in their mid to late 20s to use a single device until they experience menopause. Continuation of contraception with this device poses, after observation, no known additional risks to IUD users, who remain at liberty to change their choice of contraception at any time before menopause [20].

Conclusion

The study revealed that the side-effects and rate of IUD removal did not differ between the non-scarred and scarred uterus groups and that even though some of those side-effects decreased with time (menorrhagia and dysmenorrhea) but they were not different between the two groups.

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