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Original Article

The value of ultrasound guidance during IUD insertion in women with RVF uterus: A randomized controlled trial

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ABSTRACT

Objective: The study objective is to evaluate the benefits of using ultrasound guidance during insertion of Intrauterine device IUD in women with retroverted flexed RVF uteri.
Study design: A randomized controlled trial conducted on 400 women with RVF uteri eligible for IUD insertion. They were randomly divided into 2 groups. Group 1 underwent IUD insertion under ultrasound guidance while in group 2 no ultrasound guidance was used. The primary outcome measure was the (Visual Analogue Scale) VAS pain score reported by the women during insertion. Other outcome included easiness of insertion, the procedure time and occurrence of complications as nausea, vomiting, abdominal cramps, failure of insertion, uterine perforation and bleeding.
Results: The VAS pain score was significantly lower (2.36 ± 1.77 vs. 4.74 ± 2.35, $p < 0.001$), the insertion was much easier (score 4.0 ± 0.9 vs. 2.5 ± 1.27, $p < 0.001$) and the time needed for the procedure was significantly shorter (5.82 ± 2.56 vs. 9.4 ± 4.99 min, $p < 0.001$) in women within the ultrasound guided group when compared to control group.
The total rate of complications was significantly lower (6 vs. 16 %, p 0.001) especially bleeding (2 vs. 9%, p = 0.002), abdominal cramps (10.5 vs. 28 %, p 0.012) and failure of the procedure (0 vs. 3%, p = 005) in ultrasound guided group women when compared to control.
Conclusion: Insertion of Intrauterine device IUD under ultrasound guidance in women with Retroverted flexed RVF uterus easier and less painful than the blind standard technique.

Introduction

Between puberty and menopause, women have to face concerns about childbearing or its prevention with 3 options only. These are sexual abstinence, contraception, or pregnancy [1]. Inspite of the high use of contraception, there is still a significant proportion of sexually active couples reaching 7.4 % does not use contraception, and yearly, 2 out of 100 women between 15 and 44 years of age have an induced termination of pregnancy [2].

In the United States almost half of pregnancies were unintended [3] and 40 % of these ended in induced termination of pregnancy [4]. This high rate of Unintended pregnancies can be minimized through the use of effective cheap contraceptive methods [5].

The use of long-acting reversible contraceptives (LARC) are encouraged by The American College of Obstetricians and Gynecologists to all women particularly adolescents [6].

Several LARC are highly effective as sterilization, but having the disavantage of being irreversible. The main advantages of these methods are “being forgettable,” meaning that minimal attention is required by the user after starting its use. That’s very different from methods that must be used with each act as mechanical methods and methods that should be taken daily as pills. These forgettable methods have a failure rate of less than 2 per hundred women year and considered as the safest methods of contraception [7]. The proportion of women using LARC was increased from 2% in 2002, 6% in 2007, 9% in 2009 to 14 % in 2014 (12 % use IUD and 3% use implants) [8,9]

IUD acts through formation of intrauterine biologic foam which consists of fibrin, phagocytes and proteolytic enzymes [1]. IUDs induces chronic endometrial and tubal inflammatory changes

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hostile to sperms and inhibits both fertilization and implantation [10]

Despite the safety and very low failure rate of IUD [11], its use is restricted to only 7.6 % in developed and 14.5 % in developing countries [12].

These low rates of IUD use is related to fear of pain associated with the procedure (86 % of women reported anxiety and 41 % reported discomfort) and other factors [13]. Another limiting factor is the difficulties encountered during insertion and failure rate that may reach up to 14 % in parous and 20 % in nulliprrous women [14].

Several studies were tried to decrease pain and failure during IUD insertion [15–18]. One study evaluated the value of ultrasound guidance [19] However, none assessed the benefits of trans-abdominal ultrasound guidance during IUD insertion in women with retroverted flexed uterus (RVF).

The aim of our study is to evaluate the benefits of using ultrasound guidance during insertion of IUD in women with RVF uteri.

Material and Methods

A randomized controlled trial conducted on 400 women who attended the contraception clinic at Kasr-Alainy teaching hospital during the duration from January 2017 to January 2018. All participants have signed an informed written consent after explanation of the possible risks and benefits of the study. KasrAlainy ethical committee – The ethical committee of Obstetrics and Gynecology Department in 14 November 2016 has approved the trial that follow the ethical standards of declaration of Helsinki. Approval number 170,143

'Patient and public involvement

The development of the research question and outcome measures were informed by the patient by a professional health care providers with more than 10 years' experience in the field of contraception. All approving women attending the contraception clinic at Kasr Alainy hospital with RVF uterus were involved. The participants were not involved in the design of this study. The results will be disseminated to study participants through direct personal contact. In our randomized controlled trial burden of the intervention was assessed by both the patients and the investigators.

All participants were candidate for IUD insertion and had RVF uterus confirmed by clinical and transvaginal ultrasound examinations (done with the empty bladder to avoid false diagnosis of RVF). Their age ranged from 20 to 40 years old with one or more vaginal and /or cesarean delivery. Exclusion criteria included women with contraindications for IUD insertion as undiagnosed genital bleeding, untreated vaginal or cervical infections, pelvic inflammatory disease, suspected genital malignancy, those with distorted uterine cavity by congenital anomalies, submucous lesions as polyp or fibroids. Women with diseases that affect the perception of pain as those with psychological, neurological disorders or marked dysmemorrhea were excluded from the study.

All women were counseled about different types of IUD and their advantages and drawbacks. That was followed by complete history taking, general and local examinations to ensure adherence to the inclusion and exclusion criteria. All IUDs were inserted at day 5 or 6 of the menstrual cycle [20].

The 400 participants were randomized using open label technique into 2 equal groups. A blocked randomisation with 1:1 ratio was done by a statistician that is not involved in the procedure. In Group I, the woman was asked to keep a full bladder to allow for Real time trans-abdominal ultrasound guidance of the procedure. The woman lied in the dorsal lithotomy position; insertion of lubricated warm Cusco speculum was done to expose the cervix. The cervix was cleaned with povidone- iodine solution. A Tenaculum was used at 12 o clock position to straighten gently the angle of the uterus before IUD insertion. Sounding of the uterus was done then the IUD was folded into the insertion tube then inserted till reaching the fundus. The strings were cut about 2 cm outside the outer cervical os. In group II, the woman was asked to evacuate the bladder and the same steps were done as in group I without ultrasound guidance [20].All procedures were done by the same investigator. The commonly used IUD was Copper followed by Silver then Progesterone impregnated IUD (Table 1). All 400 women did post insertion trans-vaginal scan to check proper insertion. Any woman needed cervical dilatation was excluded from the study.

The primary outcome parameter was the pain score that was experienced by the woman during insertion or within 5 min after it. Visual analogue scale (VAS) was used to assess the pain with 10 points scale in which 0 point means no pain and 10 point means non tolerable pain and the woman was asked to report the degree of pain on the scale. Women with score of $\geq$ 5 (received a single

Table 1
General characteristics of study population.

Characteristic		Ultrasound guided group n = 200	Control group n = 200	Difference between groups (95 % CI)	P value=
Age (years)		25.04 ± 6.22	25.28 ± 6.28	−0989 – 1.463	0.701
Education@	Intermediate	179(89.5 %)	181(90.5 %)	————————————	0.739
	High	21(10.5 %)	19 (9.5 %)		
Parity		1.67 ± 0.90	1.68 ± 0.97	−0.265 – 0.105	0.395
Number of previous CS		1.36 ± 0.48	1.34 ± 0.47	−0.114 – 0.074	0.676
Body mass index (kg/m2)		25.58 ± 2.68	25.64 ± 2.12	−0.989 – 0.535	0.804
Duration (months) from last delivery		6.85 ± 2.809	7 ± 2.816	−0.413 – 0.693	0.619
Previous IUD insertion	none	92 (46 %)	101 (50.5 %)	————————————	0.398
	Successful	100 (50 %)	94 (47 %)		
	failed	8 (4%)	5 (2.5 %)		
Number of previous cesarean sections	No	60 (30 %)	67 (33.5 %)	————————————	0.421
	One previous CS	68 (34 %)	65 (32.5 %)		
	Two or more previous CS	72 (36 %)	68(34 %)		
Type of IUD	Copper	156 (78 %)	151 (75.5 %)	————————————	0.417
	Silver	38 (19 %)	42 (21 %)		
	Progesterone	6 (3%)	7 (3.5 %)		

Values are in the form of mean ± SD, median (range) or count (percent). CS: cesarean section, IUD: intra-uterine device; CI: confidence interval.
@ intermediate education means only school education with a maximum of high school; while high educations means college education or more (postgraduate education).
p value < o.o5 is significant.

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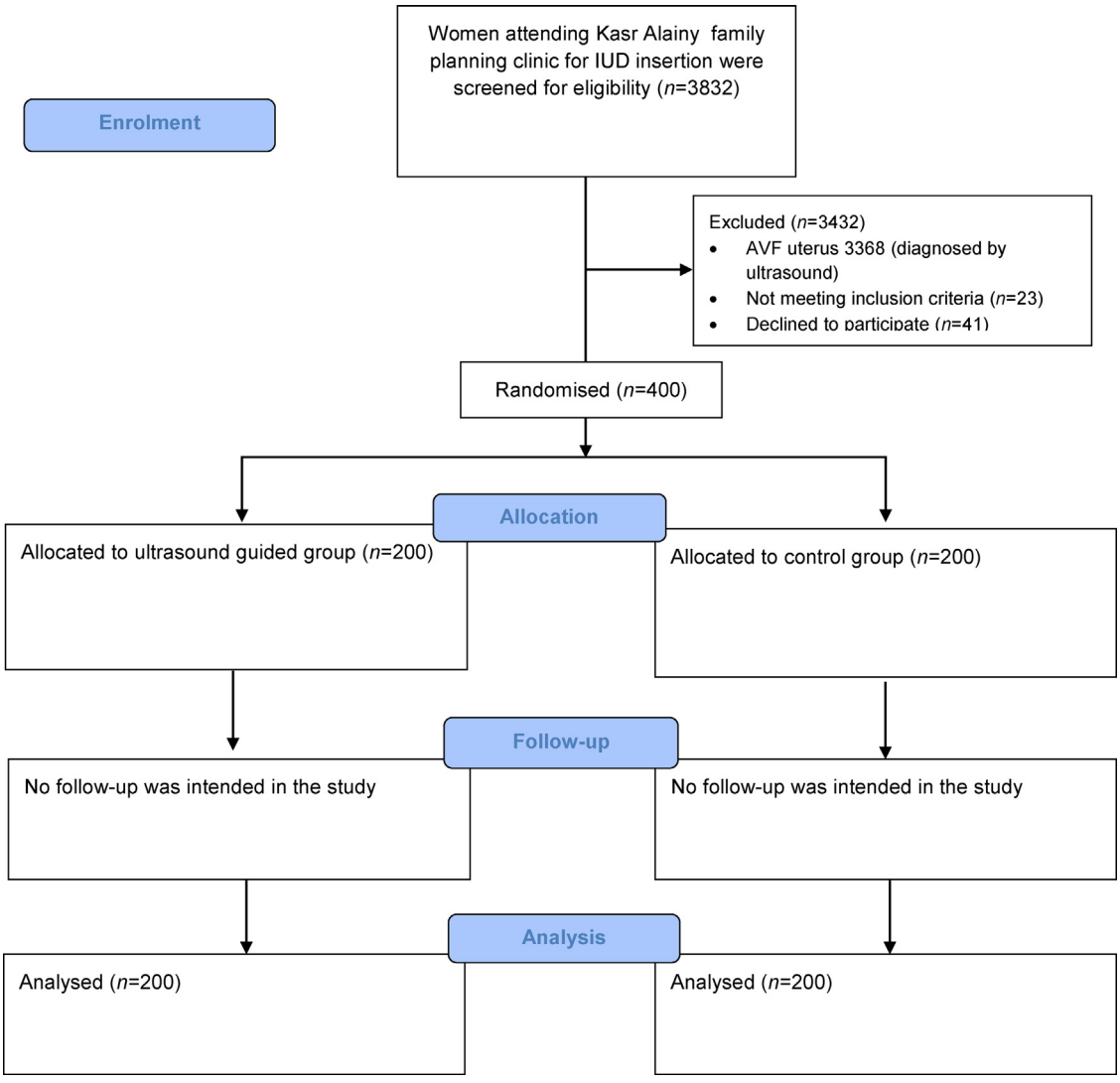

Fig. 1. Consort flow chart.

injection of intramuscular 75 mg Diclofenac Sodium (Voltaren, Novartis, Basel, Switzerland).But diclofenac was not given as a routine in all cases. Other outcome included easiness of the procedure recorded by the gynecologist using the same VAS scale where 0 point is the easiest and 10 point is the most difficult procedure, the needed time for insertion (calculated from the time when the gynecologist is holding the IUD and start to insert it till removal of the speculum) and occurrence of complications as nausea, vomiting, failure of insertion, uterine perforation and bleeding (Bleeding that necessitate diaper use is considered as complication while spotting is not considered as a complication). These symptoms were assessed at the time of the procedure or within 30 min of it.

Sample size calculation was based on difference in pain score between the two study groups as the primary outcome. Based on a previous study that assessed pain score during IUD insertion in women with previous cesarean delivery (to provide baseline outcome data for the placebo group), the average pain score during IUD insertion in women of their control group was 6.5 with a standard deviation of 0.9, [18].We set the minimal clinically significant difference in pain score at 0.5 [20]. Therefore, we needed 195 subjects in each study group to detect this difference with 99 % power and alpha of 0.05. Sample size calculation was done using IBM SPSS Sample Power software, release 3.0.1 (IBM Corp., Armonk, NY, USA).

Data were statistically described in terms of mean ± standard deviation (± SD), or frequencies (number of cases) and percentages when appropriate. Comparison of numerical variables between the study groups was done using Student *t* test for independent samples. For comparing categorical data, Chi-square (χ^2) test was performed. Exact test was used instead when the expected frequency is less than 5. Multivariate stepwise linear regression analysis was used to test for the preferential effect of US guide on easiness score after adjusting for important factors.*p* values less than 0.05 was considered statistically significant. All statistical calculations were done using computer programIBM SPSS (Statistical Package for the Social Science; IBM Corp, Armonk, NY, USA) release 22 for Microsoft Windows

Results

The consort flow chart of participants is shown in Fig. 1,We analysed 400 cases of retroverted flexed uterus coming for IUD insertion.

No significant difference was found between the ultrasound guided IUD insertion and the control group as regard to age, parity,

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Table 2
Pain during IUD insertion and other outcome data.

Characteristic		Ultrasound guided group n = 200	Control group n = 200	Difference between groups (95 % CI)	P value
Pain score during IUD insertion (from 0 to 10)		4.36 ± 1.77	6.74 ± 2.35	2.971 – 2.789	<0.001*
Women needed aanalgesia		47 (23.5 %)	96 (48 %)		<0.001*
Easiness of IUD insertion	Women without previous CS	5.67 ± 1.12	4.01 ± 1.09	−1.930 - -1.420	<0.001*
	Women with previous one CS	4.13 ± 0.78	2.48 ± 1.21	−1.890 - -1.390	<0.001*
	Women with 2 or more previous CS	3.78 ± 1.038	2.53 ± 1.387	−1.656–0.840	<0.001*
	Total	4.65 ± 0.9	2.81 ± 1.27	−1.716 - -1.284	<0.001*
Time of insertion		5.82 ± 2.56	9.4 ± 4.99	4.8 – 6.360	<0.001*
Failed insertion		0(0%)	6 (3%)		0.03@
Perforation		0(0%)	2(1%)		0.499
Bleeding		4(2%)	18(9%)		0.002@
Nausea and/or vomiting		0 (0%)	1 (0.5 %)		0.892
Infections		5(2.5 %)	8(4%)		0.398
Any complication		12 (6%)	32 (16 %)		<0.001*

Values are in the form of mean ± SD or count (percent).. CI: confidence interval, CS: cesarean section, IUD: intra-uterine device.
@ p value <0.05 is significant.
* p value <0.001 is highly significant.

Table 3
Multivariate stepwise linear regression model to assess the effect of ultrasound guidance on easiness score during insertion of IUCD adjusting for: BMI, education, number of previous cesarean sections, duration (months) from last delivery and previous IUD insertion.

Characteristic	Beta coefficient (adjusted difference for pain score)	95 % CI for B coefficient (95 % CI for adjusted difference for pain score)	P value
Ultrasound guided group vs. control group	1.492	1.284 – 1.700	<0.001

level of education, body mass index, duration from last delivery and the type of IUD inserted (Table 1).

The number of previous successful and failed IUD insertion and the number of previous cesarean deliveries showed no statistical difference between the 2 study groups (Table 1).

The pain score was significantly lower, the insertion was much easier and the time needed for the procedure was significantly shorter in women within the ultrasound guided group when compared to control (Table 2).

The total rate of complications was significantly lower especially bleeding, and failure of the procedure in ultrasound guided group women when compared to control. Other complications as infection and perforation were similar in the 2 groups (Table 2).

Multivariate stepwise linear regression model showed a significant effect of ultrasound guidance on easiness score during insertion of IUD (Table 3).

Discussion

Our study found that insertion of IUD under ultrasound guidance in women with RVF uterus is associated with less pain during insertion.

According to our findings, Ultrasound guidance in women with RVF uterus was associated with easier insertion reported by the gynecologist and shorter insertion time.

Insertion of IUD under ultrasound guidance in women with RVF uterus was associated with lower rate of complications associated with the procedure especially bleeding.

Elsedeek in her cohort study tried to assess the value of trans-abdominal ultrasound guidance in detection of proper IUD insertion. She assessed the position of IUD at the end of procedure and after 1 week in 80 parous women. Proper IUD fitting and ideal placement was achieved in 32 (80 %) and 27 (68 %) vs. 39 (98 %) and 38 (95 %) women in the blind and ultrasound guided group respectively (P = 0.04 and 0.02). She concluded that ultrasound guidance increased success and proper fitting of IUD placement when compared to the traditional blind technique [21].

Dakhly and Bassiouny in their randomized controlled study tried to minimize the pain and duration of IUD insertion through the use of transabdominal ultrasound guidance and decreasing the use of instruments during the procedure. They randomized 102 women to either trans-abdominal guided or traditional blind IUD insertion. They found that guidance with IUD was associated with lower pain scores evaluated by Visual Analogue Scale (2.4 ± 2.1 vs. 5.0 ± 1.7, $p < .001$) and shorter procedure (32.2 ± 14.8 vs. 77.7 ± 30.6secons, $p < .001$) when compared to the traditional technique. They concluded that the guidance with trans-abdominal ultrasound can replace the blind technique in IUD insertion [19].

Abbas and colleagues tried to replace the routine use of uterine sounding with ultrasound use before IUD insertion for assessment of uterine length and direction. Their study included 87 women randomized to either routine sounding or ultrasound guidance. They found that both techniques have similar successful insertions with easier and shorter procedure in the uterine sound-sparing approach. Moreover there was a higher satisfaction score among those in the uterine sound-sparing approach with similar IUD placement inside the uterus assessed after 4 weeks of insertion. They concluded omitting uterine sounding can be done during IUD insertion if proper ultrasound evaluation of uterine length and direction was done before the procedure [22].

Our trial is unique being the first randomized controlled one that evaluates the benefits of ultrasound guidance during IUD insertion in women with RVF uterus. We also included a large sample size to give more than 99 % power to our findings and all procedures were done by one of the investigators only to avoid inter-observer variability. The main limitation of our study is it depends on subjective findings as pain and easiness scores. We tried to limit variability in pain perception through randomization process and exclusion of any conditions that may affect pain perception. Multivariate regression analysis was done to nullify the effects of basal characteristics that may affect pain perception. We overcame the variability in easiness score through restricting the performance of the procedure to one experienced investigator only. Another limitation was no availability of the follow up return

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visits data to ensure proper placement and expulsion rates. However future trials should investigate the value of ultrasound guidance among gynecologists with different experience of IUD insertion with longer follow up duration.

We concluded that insertion of IUD under ultrasound guidance in women with Retroverted flexed RVF uterus easier and less painful than the blind standard technique

Synopsis

Insertion of IUD under ultrasonographic guidance in women with RVF uterus easier and less painful than the blind technique

Compliance with ethical standards

The study was performed in accordance with the Declaration of Helsinki ethical standards. Informed consents were taken from study participants.

Declaration of Competing Interest

The authors report no conflicts of interest in this work.

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