

## Dimensions of the Endometrial Cavity and the Outcome of Inserted Copper T380A Intrauterine Devices

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### ABSTRACT

**Background:** The intrauterine device (IUD) is an important long acting reversible contraceptive (LARC). Reduced contraceptive effectiveness and unintended pregnancy result from IUD displacement or expulsion. One theory about IUD displacement or expulsion is because the size of the uterus cavity and the IUD are incompatible.

**Objective:** This study aimed to evaluate the association between endometrial cavity diameters and IUD displacement or expulsion.

**Methods:** This cohort study was conducted at the Department of Obstetric & Gynecology of Menoufia University Hospital and Qwesna Central Hospital. The study included all women who were seeking contraception by intrauterine device (copper T380A IUD) during the period from March 2022 till December 2023. Ultrasound evaluation of endometrial cavity dimensions (axial length, transverse and antero-posterior diameters) and IUD position was performed for all participants immediately after insertion and during the follow-up visits (1 week, 1 month and 3 months post-insertion). All studied women were divided into 2 groups: Cases and control groups. The control group involved women who had maintained intrauterine IUD without expulsion or displacement. Cases are participants who had IUD expulsion or displacement during insertion or during the follow-up visits. The primary outcome of the study was the association between the endometrial cavity diameters and IUDs displacement or expulsion.

**Results:** There was no significant difference between the studied groups regarding demographic or clinical patient characteristics. Longest transverse diameter (LTD), length of uterine cavity (LUC) and ant-post diameter (APD) were significantly increased among cases ( $53.14 \pm 6.33$ ,  $44.86 \pm 8.89$  and  $44.50 \pm 5.90$  respectively) than controls ( $36.82 \pm 1.92$ ,  $37.78 \pm 5.06$  and  $38.61 \pm 7.75$  respectively,  $P < 0.05$ ). Rates of displacement of IUD among cases at admission, during 1st week and 1st month were 30.8%, 35.9% and 10.3% respectively. Regarding expulsion rate of IUD, no cases with IUD expulsion was reported at admission, 1 week and 1 month post-insertion, while only 4 cases suffered from IUD expulsion at 3 months post-insertion.

**Conclusion:** Increased endometrial cavity dimensions was associated with displacement of the IUD.

**Keywords:** IUD, Displacement, Ultrasound, Endometrial cavity.

### INTRODUCTION

The IUD is a significant LARC. The copper TCU-380A is constructed of a T-shaped high-density polyethylene (HDPE) frame that contains barium sulfate for radioopacity. Exposed copper on the arms and stem produces copper ions, which exacerbate the local foreign body's inflammatory response while also interfering with sperm motility and viability, limiting fertilization. Two polyethylene monofilaments attached to the stem, known as retrieval strings, enable identification and removal. TCU-380A is rated for up to ten years of operation <sup>(1)</sup>.

IUDs need to remain in the uterus environment to avoid unintended pregnancies. Any copper IUD that is more than 2 centimeters partly discharged (displaced downward) needs to be taken out <sup>(2)</sup>. Expulsion or removal for displacement was observed to be related to low maternal age, heavy menstruation, dysmenorrhea, uterine position and the experience of the service provider with reference to insertion <sup>(3)</sup>.

US (ultrasound) which is widely accessible, reasonably priced, and radiation-free, is suitable for evaluating IUDs. Additionally, the US can quickly ascertain whether an IUD is positioned appropriately and may frequently assist in identifying issues

associated to IUDs. By using US alone, IUD displacement and myometrial perforation may be thoroughly assessed <sup>(4)</sup>.

One possibility for IUD ejection or displacement is because the uterine cavity dimensions are incompatible with the IUD. Nevertheless, no correlation was found between the length of the endometrial cavity and the rate of IUD ejection in two prospective trials. Uncertainty surrounds the connection between IUD ejection and uterine cavity size <sup>(3)</sup>. There is still ongoing research concerning the association between uterine cavity dimension and the outcome of inserted copper IUD therefore this study was conducted.

### PATIENTS AND METHODS

This cohort study was conducted at the Department of Obstetrics & Gynecology, Menoufia University Hospital and Qwesna Central Hospital. The study included all women who are seeking contraception by IUD (copper T380A IUD) during the period from March 2022 to December 2023.

**Inclusion criteria:** Women aged 20 to 40 years, with normal menstrual cycles lasting 20-40 days, no heavy

menstrual bleeding, and no contraindication for IUD use.

**Exclusion criteria:** Active uterine infection, malignancy, uterine anatomical anomalies, difficulties to implant or hold the device and unexplained abnormal bleeding.

**Sample size estimation:** Considering the analysis of earlier research <sup>(5)</sup> that included women with TCu 380A IUD and reported that participants with LTD  $\geq 37$  mm had a higher risk (OR 4.98, 95%CI 1.01-24.49) of expulsion or removal for displacement after controlling for the amount of monthly flow, dysmenorrhea, parity, and uterine position, as well as LUC. The least sample size calculated using the online openEpi program version 3 is 142 subjects increased by 5% to avoid dropout, so the least sample size should be 149 subjects using the power of the study 80% and confidence level 95%.

All the recruited participants underwent meticulous history taking (including contraceptive history) and physical examination (abdominal examination and vaginal examination) to identify any exclusion criteria.

Only copper T380A IUD was used in this study (the vertical and horizontal arms were 36 & 32 mm long respectively). The IUD was inserted postmenstrual (within seven days of the end of menstruation), post-abortion (after two weeks), and postpartum (after six weeks). Follow-up visits are scheduled, one week, and 1 or 3 months after IUD insertion. Women were questioned at each visit to acquire information about any problems of IUDs (pain/bleeding) and examined by US to check for expulsion, displacement, or any other abnormality had occurred.

Displacement is deemed to occur when the distance between the upper end of the IUD and the external uterine fundus is greater than 2 cm, as determined by ultrasonography during follow-up <sup>(3)</sup>. All the ladies in the study were separated into two groups: Cases and controls. Cases included women who had IUD ejection or displacement during implantation or follow-up. The control group consisted of women who had neither expelled or displaced their intrauterine devices and were matched to the cases.

All participants in the current study underwent US evaluation of endometrial cavity dimensions, which measured the axial length of the uterine cavity, LUC (distance between the uterine fundus's endometrium and the cervical internal os), the length of the widest

transverse width of the coronal part of the uterine cavity, LTD (the maximum distance between the two margins of the coronal of the uterine cavity assessed by abdominal US), and anteroposterior diameter (APD). All participants had an US immediately after insertion and within seven days of IUD insertion. The same service provider performs the US measurements for matched cases and controls.

**Outcomes:** The primary outcome of the trial was the association between endometrial cavity diameters and IUD displacement or expulsion.

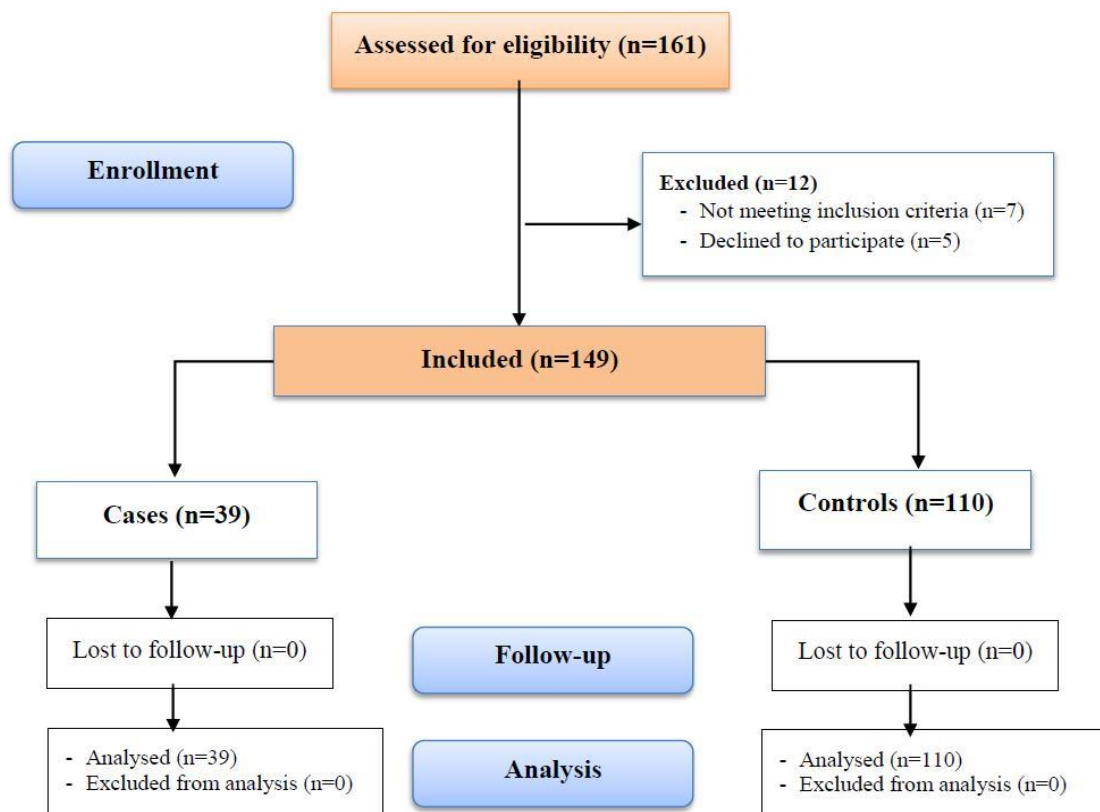
**Ethical approval:** The study was accepted by The Ethics Committee of Menoufia University Hospitals and Cairo University in Egypt (IRB: 11/2021OBSG15). Every patient provided an informed written permission to accept the procedure. The study adhered to the Helsinki Declaration throughout its execution.

#### *Statistical analysis*

An IBM compatible personal computer running SPSS version 25.0 and MEDCALC V.19.6.1 software was used to gather, tabulate, and statistically analyze the data. The statistics were separated into two sections: Descriptive statistics: numbers (N) and percentages (%) were used to represent qualitative data, while Mean  $\pm$  SD, median, and range were used to represent quantitative data. The  $X^2$ -test, which examine the relationship between two qualitative variables, was one of the tests of significance employed in analytical statistics. Whenever there were less than five predicted cells, Fischer's exact test was employed. Two groups of normally distributed data were compared using quantitative variables using the student t-test (t). Multiple regression analysis was carried out using categorization (cases and controls), and independent variables were identified using binary logistic regression. The Pearson's correlation test was used to look for correlations. P-value  $\leq 0.05$  was qualified as statistically significant.

#### **RESULTS**

A flowchart of the study population was shown in figure (1). Of the recruited 161 women, 12 women were excluded from the study (5 women declined consent, and seven women did not meet the inclusion criteria) and so 149 women were available to participate in the study and were divided into 2 groups, cases (n=39) and controls (n= 110) (**Figure 1**).



**Figure (1):** Showed the study population

There was no significant difference between the studied groups regarding demographic or clinical patient characteristics (**Table 1**).

**Table (1):** Demographic & clinical patient characteristics among the studied groups (n=149)

	Cases (n=39)	Control (n=110)	Test of significance	P value
<b>Age/year</b>				
Mean $\pm$ SD	24.87 $\pm$ 3.53	27.48 $\pm$ 5.98	<i>t</i> 2.252	0.062
Range	20.00-33.00	19.00-40.00		
<b>Parity</b>				
CS	27(69.2%)	71(64.5%)	0.573 $\chi^2$	
NVD	12(30.8%)	39(35.5%)		0.751

t: independent test,  $\chi^2$ : chi-square, CS: cesarean section, NVD: normal vaginal delivery.

All endometrial cavity dimensions including LTD, LUC and APD were significantly increased among cases (53.14  $\pm$  6.33, 44.86  $\pm$  8.89 and 44.50  $\pm$  5.90 respectively) than controls (36.82  $\pm$  1.92, 37.78  $\pm$  5.06 and 38.61  $\pm$  7.75 respectively P < 0.05) (**Table 2**).

**Table (2):** Ultrasound endometrial cavity dimensions among the studied groups (n=149)

Variable	Cases (n=39)	Control (n=110)	<i>t</i>	P value
<b>LTD (mm)</b>				
Mean $\pm$ SD	53.14 $\pm$ 6.33	36.82 $\pm$ 1.92	15.848	<0.001*
Range	43.00-64.10	30.20-40.00		
<b>LUC (mm)</b>				
Mean $\pm$ SD	44.86 $\pm$ 8.89	37.78 $\pm$ 5.06	4.704	<0.001*
Range	33.20-65.20	27.20-50.00		
<b>APD (mm)</b>				
Mean $\pm$ SD	44.50 $\pm$ 5.90	38.61 $\pm$ 7.75	4.914	<0.001*
Range	35.10-54.30	24.00-92.00		

LTD: Longest transverse diameter, LUC: length of the uterine cavity, APD: ant-post diameter, t: independent test, \*: significant.

Rates of displacement of IUD at admission and after 1 week, 1 month and 3 months post-insertion were 30.8%, 35.9%, 10.3% and 12.8% respectively. Regarding expulsion rate of IUD, no cases with IUD expulsion was reported at admission, 1 week and 1-month post-insertion, while only 4 cases suffered from IUD expulsion at 3 months post-insertion (Table 3).

**Table (3):** Rates of displacement/expulsion of IUD at admission and after 1 week, 1 month, and 3 months post-insertion (n=39)

IUD	Cases (n=39)							
	At admission		1 week		1 month		3 months	
	N	%	N	%	N	%	N	%
Displacement	12	30.8	14	35.9	4	10.3	5	12.8
Expulsion	0	0.0	0	0.0	0	0.0	4	10.3

## DISCUSSION

The present study aimed to evaluate the association between endometrial cavity diameters and IUD displacement, or expulsion. Our study showed that there was no significant difference among the studied groups regarding the age of the participants. In agreement with our study, **Awaga et al.** <sup>(6)</sup> performed a research on 200 women who were randomly assigned to 2 groups: The Cu T380A group and the Multiload-375 group, with 100 women in each. According to **Awaga et al.** <sup>(6)</sup>, Age and other sociodemographic traits of the enrolled patients did not differ statistically significantly across the research groups. Furthermore, **Mahmoud et al.** <sup>(7)</sup> found that study participants' mean age was  $29.17 \pm 4.56$  years and that there was no significant difference regarding age. Also, **Singal et al.** <sup>(8)</sup> showed that the study's female participants had an average age of  $23.12 \pm 2.42$  years.

Our study showed that all endometrial cavity dimensions including LTD, LUC and APD were significantly increased among cases ( $53.14 \pm 6.33$ ,  $44.86 \pm 8.89$  and  $44.50 \pm 5.90$  respectively) than controls ( $36.82 \pm 1.92$ ,  $37.78 \pm 5.06$  and  $38.61 \pm 7.75$  respectively,  $P < 0.05$ ). **Liang et al.** <sup>(3)</sup> observed that, after controlling for LUC and other confounding variables, the relationship with  $LTD \geq 37$  mm and expulsion or displacement (OR 4.98; 95%CI 1.01–22.49) among TCu380A users was statistically significant, which is consistent with our findings.

According to the corresponding quartiles of LUC (39 mm for TCu380A), LTD (27 mm for MLCu 375 and 37 mm for TCu380A), and D1 (15 mm for MLCu375), women were divided into two groups (small or big uterine cavity) in the research by **Liang et al.** <sup>(3)</sup>.

Additionally, after controlling for parity, uterine position, and monthly flow volume, **Liang et al.** <sup>(3)</sup> discovered that women with TCu380A who had  $LTD > 37$  mm were more likely to be expelled or removed for displacement (OR 4.64; 95% CI 0.97–22.24), while the correlation was not statistically significant.

Additionally, among MLCu375 or TCu380A users, women with greater LTD were more likely to be expelled or displaced, indicating that there was no statistically significant correlation between TCu380A displacement or expulsion and LUC.

Our study showed that the rates of displacement of IUD at admission and after 1 week, 1 month, and 3 months post-insertion were 30.8%, 35.9%, 10.3% and 12.8% respectively. Regarding the expulsion rate of IUD in the current study, no cases with IUD expulsion were reported at admission, 1 week, and 1 month post-insertion, while only 4 cases suffered from IUD expulsion at 3 months post-insertion. In another study, in a study of women who got a copper IUD just after vaginal birth, **Gurney et al.** <sup>(9)</sup> found that 8.0% of the women had fully or partially expelled the IUD by six months. 8.0% (95% CI 4.7%–13.4%) of the participants were expelled completely within 6 months, with 69.2% of them being identified prior to clinical assessment. Just 55.6% of participants still had the original IUD in situ after six months after taking into account women who had their IUDs removed, partly ejected, or misplaced. **Escudero et al.** <sup>(10)</sup> reported an expulsion rate of 4.9 per 100 woman-years in the first year that decreased with each subsequent year, which is consistent with our findings. Additionally, the first month after insertion accounted for 31.7% of the expulsions. Furthermore, two hundred and sixty-seven patients were monitored for 12 weeks while the remaining 16 experienced partial or total IUD expulsion, according to **Fadiloglu et al.** <sup>(11)</sup>. After three months, there were no discernible differences between the groups under study in terms of in-place, displacement, and explosion. Moreover, **Singal et al.** <sup>(8)</sup> found that after a year, there were two pregnancies, 21 removals, and 16 expulsions, with a 91% continuation rate. Additionally, **Wu et al.** <sup>(12)</sup> discovered that 111 women (5.7%) stopped using CuT380A prior to the 12-month follow-up period because bleeding (36.0%) and partial expulsion (34.2%) were the most frequent causes of removal.

## STRENGTH POINTS

The current study was carried out at two gynecological centers, Menoufia University Hospital and Qwesna Central Hospital.

## LIMITATIONS

The primary drawback of the current investigation was the relatively small sample size, therefore more RCTs including larger sample size is recommended to reinforce our observations.

## CONCLUSION

Increased endometrial cavity dimensions were associated with the displacement of the IUD.

**No funding.**

**No conflict of interest.**

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