

**Discontinuation Rates among Copper Intrauterine
Device Users in Primary Healthcare Unit and
University Clinic. Is There a Difference?**

Thesis

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Obstetrics and Gynecology

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بِسْمِ اللَّهِ الرَّحْمَنِ الرَّحِيمِ

وَقَدْ اَعْمَلُوا فَسَيَرَى اللَّهُ عَمَلَكُمْ
وَرَسُولُهُ وَالْمُؤْمِنُونَ

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List of Abbreviations

ACOG	: American College of Obstetricians and Gynecologists
ASUMH	: Ain Shams University Maternity Hospital
CDC	: Centers for Disease Control and Prevention
COC	: Combined Oral Contraceptives
CRF	: Case Record Form
CU-IUD	: Copper containing intrauterine device
DHS	: Demographic and Health Surveys
IUCD	: Intrauterine contraceptive device
IUD	: Intrauterine device
LARC	: Long acting reversible contraceptive
LNG	: Levonorgestrel
LNG-IUS	: Levonorgestrel containing intrauterine system
MBL	: Menstrual blood loss
OCPs	: Oral contraceptive pills
PID	: Pelvic inflammatory disease
POP	: Progesterone only Pills
RCTs	: Randomized controlled trails
WHO	: World Health Organization

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ABSTRACT

Background: In Egypt, despite the high percentage of women using IUD according to Demographic and Health Surveys (DHS) 2014 (52.9%) of total women using contraceptive methods, the discontinuation rates among Cu-IUD users (within 12 months of use) reached 14.3% in 2014.

Aim of the Work: The aim of the study was to compare between primary health care unit and university family planning clinic in discontinuation rate among copper IUD users. **Patients and Method:**

Study design: prospective analytical observational study. **Study setting:** This study was conducted at family planning outpatient clinic of Ain Shams University Maternity Hospital and El-Zahraa primary health care unit for a year. This study enrolled 260 women who attended family planning clinic for Cu- IUD insertion. Total 100 subjects were included from each clinic. Rest of subjects were lost on follow up either after 6 months or 12 months. Some others refused to participate or gave wrong personal contacts. **Results:** On follow up at 6months, IUCD

discontinuation was 5% in the university clinic & 7% in the primary health care (PHC) unit. While at 12months follow up, discontinuation was 28% in the university clinic & 40% in the PHC unit. Despite the difference, this was not statistically significant (p-value = 0.073).

Conclusion: In our study, analysis of data revealed that there were no statistically significant difference between discontinuation rate among Copper IUD users in university clinic and primary healthcare unit. The main cause of IUD discontinuation was bleeding; and anemia was present in 66.6% of patients complaining from bleeding.

Keywords: CU-IUD: Copper intrauterine device, discontinuation, contraception, satisfaction

PROTOCOL OF A THESIS SUBMITTED FOR PARTIAL
FULFILMENT OF MASTER DEGREE IN OBSTETRICS
AND GYNECOLOGY

Title of the Protocol: Discontinuation Rates Among
Copper Intrauterine Device Users in
Primary Healthcare Unit and
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Difference?

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**What is already known on this subject? AND
What does this study add?**

The intrauterine device (IUD) is one of the most widely used reversible, long-term contraceptive methods in the world. But despite all its advantages; discontinuation rate of IUD ranged from 9.6% to 37.3 % (according to Demographic and Health Surveys data). In Egypt, in 2014, the discontinuation rate of IUD (within 12 months of use) was 14.3%. This study explores the differences around this rate in Egyptian university clinic and primary healthcare clinic with detailed percentages of possible causes.

1.INTRODUCTION/REVIEW

The intrauterine device (IUD) is one of the most widely used, reversible contraceptive methods in the world (**Ali et al., 2011**). IUD is convenient, safe and highly efficacious. It is recommended as a first-line long-term contraceptive option for women of all reproductive ages, including adolescent and nulliparous women (**ACOG, 2012**).

IUD is globally used by 15% of women aged 15–49 years (**Ekiz et al., 2016**). In Egypt, the percentage of women using IUD according to Demographic and Health Surveys (DHS) 2014 is 52.9 % (**Family planning 2020, 2016**).

These high rates of IUD usage are due to its advantages such as reversible fertility immediately after removal, no need to daily reminder, no effect on breastfeeding, lack of hormonal effects, no interference with sexual activities and medications. But despite all of these advantages; it doesn't always succeed (**Aoun et al., 2014**).

Analyses of DHS data indicate that 38% of women with an unmet need for modern contraception have used a modern method of contraception in the past but have chosen to discontinue use. This phenomenon, *called contraceptive discontinuation*, is defined as starting contraceptive use and then stopping for any reason while still at risk of an unintended pregnancy (**Castle et al., 2016**).

Unintended pregnancy is common worldwide: Eighty-five million pregnancies, representing 40 % of all pregnancies, were unintended in 2012 (**Sedgh et al., 2014**). In 2016, according to DHS there were 952, 000 unintended pregnancies in Egypt (**Family planning 2020, 2016**). A sizable share (30%) of unintended pregnancies in developing countries is due to contraceptive failure (**Polis et al., 2016**).

Unintended pregnancies can have many undesirable physical, emotional and social consequences for individuals. In 2012, 38% of all unintended pregnancies worldwide ended in an unplanned birth, 13% in miscarriage, and 50% in unsafe abortion (which is the third major cause of maternal mortality worldwide) (**Polis et al., 2016**).

The majority of cases of contraceptive discontinuation are not due to the desire to get pregnant (**Curtis et al., 2011**). Causes include both method-related failures (i.e., failure of a method to work as expected leading to accidental pregnancy) and user-related failures (i.e., failure stemming from incorrect of use or dissatisfaction with the method including side-effects and health concerns or no further need (i.e. menopause) or method-switching (**Ali et al., 2011**).

In study held within 14 countries, the median probability of discontinuing an IUD (within 12 months of use) ranged from 9.6 % to 37.3 % (**Ali et al., 2011**). In Egypt the discontinuation rate of IUD (within 12 months of use) was 14.3% in 2014 (**Khalifa et al., 2017**).

There is evidence suggesting that the quality of services influences contraception discontinuation rates. IUD use was positively associated with the quality of public family planning services in Egypt, which stresses the need to improve service quality, particularly counseling, so that women are forewarned about side effects and reassured about health concerns (**Ali et al., 2014**).

The present study compares between discontinuation rate among Copper IUD users in university clinic and primary healthcare clinic with detailed rates of each possible cause.

2.AIM/OBJECTIVES

The aim of the study is to compare between primary health care unit and university family planning clinic in discontinuation rate among copper IUD users.

The Research Hypothesis: (Null hypothesis)

- In women using copper IUD, discontinuation rate in primary health care unit and university clinic may be similar.

The Research Question:

- In women using copper IUD, Does discontinuation rate in primary health care unit and university clinic differ?

3.METHODOLOGY:

Patients and Methods

- **Type of the study:**
 - A prospective analytical observational study.
- **Study setting:**
 - Family planning Outpatient clinic of Ain Shams Maternity Hospital, (ASUMH)
 - El-zahraa primary health care unit.
- **Study population:**
 - Study period: 1 year
- **Inclusion criteria:**
 1. Age from 18-49 years.
 2. Women planning for Cu-IUD insertion as a contraceptive method.
- **Exclusion criteria:**
 1. Any woman with condition included in Category 3 or 4 for Cu-IUD in medical eligibility criteria for contraceptive use (MEC) WHO-2015.
 - **Sample size:** was calculated using PASS 11 (Sample size computer program). After review of literature, no

previous similar study was done before, so assume a discontinuation rate of 50% among Cu-IUD users in primary healthcare unit and 25% among Cu-IUD users in university clinic. Based on these values; the study will include 170 Cu-IUD users; equally selected as 85 subjects from each clinic. But due to the expected drop outs, recruitment will start by 200 women from each clinic.

- **Methods:**

- **Enrollment:** Subjects will be enrolled from women attending family planning for Cu- IUD insertion in primary healthcare unit and university clinic. Two hundred women will be enrolled from each clinic.
- **Informed Consent:** All participants will give their informed consent prior to enrollment.
- **Data collection & recording:** Data of each patient will be recorded in a Case Record Form (CRF) [*Appendix I*].
- **Follow up visits /questionnaire:** will be conducted from each subject at 6months and 12months after Cu-IUD insertion. User satisfaction score and haemoglobin serum level will be included in the questionnaire [*appendix II*].

Primary outcome:

- To measure the discontinuation rate among copper IUD users in primary health care unit and university clinic.

Secondary outcomes:

- To identify reasons of discontinuation among Copper IUD users and percentage of each cause in both university clinic and primary health care unit.
- To exclude Anemia from reasons of Cu-IUD discontinuation.

- To measure copper IUD users' satisfaction of the contraceptive method in both university clinic and primary health care unit.
- **Statistics:**
 - Descriptive statistics for measured variables will be expressed as range, mean and standard deviation (for metric data); range, median and interquartile range (for discrete data); and number and proportions (for categorical data). Cu-IUD discontinuation findings in each clinic will be compared using the *t*-test or the Mann-whitney U test depending on whether the measured parameters are Gaussian variables. A *P*-value of 0.05 or less will be considered statistically significant.
- **Ethical considerations:**
 - 1- Informed Consent Forms:**
 - Before being admitted to the study, the patient must consent to participate after the nature, scope, and steps of the study have been explained in a form understandable to her.
 - 2- Confidentiality:**

Only the patient number and patient initials will be recorded in the CRF. The investigator will maintain a personal patient identification list (patient numbers with the corresponding patient names) to enable records to be identified.
 - 3- Protocol approval:**

Before the beginning of the study and in accordance with the local regulation followed, the protocol and all corresponding documents will be declared for ethical and research approval by the council of obstetrics and gynaecology department, Ain Shams University; according to the WMA Declaration of Helsinki.

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