INTRODUCTION

The Intrauterine Contraceptive Device (IUCD) is the most widely used reversible form of contraception in the world ***(Habib et al., 2019)***.

Copper IUDs primarily work by disrupting sperm motility and damaging sperm so that they are prevented from joining with an egg. Copper acts as a spermicide within the uterus, increasing levels of copper ions, prostaglandins, and white blood cells within the uterine and tubal fluids. The increased copper ions in the cervical mucus inhibit the sperm's motility and viability, preventing sperm from traveling through the cervical mucus, or destroying it as it passes through ***(Habib et al., 2019)***.

Multiple studies have demonstrated high levels of acceptability of IUDs and continuation rates at 2-3 years are in the range of 67-77%.In fact, continuation rates for IUDs are higher than those for shorter-acting reversible contraceptive methods, such as the pill, ring, contraceptive patch, or depomedroxyprogesterone acetate. The rate of use of IUDs in the United States has increased steadily in the last 2 decades. The most recently published data demonstrates 10.3% of contracepting women aged 15-44 years are using an IUD ***(Dina et al., 2018)***. Although in Egypt the IUD has been the most common contraceptive method since 1988, its use has recently decreased from 36% to 30% ***(Rasheedy et al., 2019).***

Although the IUD is highly effective and acceptable, qualitative and anecdotal evidence has suggested that perceived pain with placement may be a barrier to the use of intrauterine contraception ***(Dina et al., 2018).***

According to the latest practice recommendations for contraceptive use by the Centers for Disease Control and Prevention, the potential barriers to IUD use include anticipated insertion pain and health care providers' concerns about difficult insertion. It is therefore important to identify effective approaches to ease IUD insertion in order to overcome obstacles hindering IUD use ***(Rasheedy et al., 2019).***

Pain may occur at different steps of IUD insertion (applying the tenaculum to the cervix to straighten the cervical canal, passing the sound through the uterine cavity and advancing the inserter tube through the cervix. However, the mild to moderate discomfort or pain that occurs with insertion lessens within minutes for almost all women ***(Abbas et al., 2017).***

Pain reduction strategies during IUD insertion involved use of different medications before or at time of insertion like cervical ripening agents as misoprostol, local anesthetics, non-steroidal anti-inflammatory drugs (NSAIDs), and combinations of two different medications. However, no consensus regarding the optimal analgesic, timing or route of administration prior to

IUD insertion according to most of the published systematic reviews ***(Abdellah et al., 2017).***

Previous researches were focused on the replacement of the multiple toothed vulsellum, used for stabilization of the cervix during insertion, by single tooth tenaculum, suction cervical retractor, Allis forceps, and Littlewoods forceps. Others suggested omission of the step of uterine sounding or the step of vulsellum application during IUD insertion ***(Curtis et al., 2016).***

AIM OF THE WORK

The aim of study is to compare the effect of use of a vulsellum to grasp the cervix during IUD insertion versus not grasping cervix by any tool on the perceived pain during copper intrauterine device (IUD) insertion.

Chapter 1

INTRAUTERINE CONTRACEPTIVE DEVICE

The intrauterine contraceptive device (IUCD) is a form of contraception methods in which a small T'-shaped device, containing either copper or progesterone, is inserted into the uterus. IUCDs are a form of long-acting reversible contraception, which is the most effective type of reversible birth control ***(Winner et al., 2012).***

History of IUCD:

A frequently but not well documented story assigns the first use of intrauterine contraceptive devices (IUCD) to caravan drivers who allegedly used intrauterine stones to prevent pregnancies in their camels during long journeys.

The forerunners of the modern intra uterine contaceptive device (IUCD) were small stem pessaries used in the 1800s, small button-like structures that covered the opening of the cervix and that were attached to stems extending into the cervical canal ***(Mosher and Pratt, 1991).***

The first IUD was developed by the German physician, Richter of Waldenburg. His device was made of silkworm gut and was not widely used ***(Thiery, 1997).***

Ernst Gräfenberg, another German physician after whom the G-spot is named, created the first Ring IUD, Gräfenberg's ring, made of silver filaments. His work was suppressed during the Nazi regime, when contraception was considered a threat to Aryan women ***(Thiery, 1997).***

He moved to the United States, where his colleagues H. Hall and M. Stone took up his work after his death and created the stainless steel Hall-Stone Ring. A Japanese doctor named Tenrei Ota also developed a silver or gold IUD called the Precea or Pressure Ring ***(Thiery, 1997).***

In 1902, a pessary that extends into the uterus was developed by *Hollweg* in Germany and used for contraception. This pessary was sold for self- insertion, but the hazard of infection was great, earning the condemnation of the medical community. In 1909, Richter succeeded to introduce a silkworm catgut ring with a nickel and bronze wire protruding through cervical os ***(Rasheedy et al., 2019).***

Jack Lippes helped begin the increase of IUD use in the United States in the late 1950s. In this time, thermoplastics, which can bend for insertion and retain their original shape, became the material used for first-generation IUDs. Lippes also devised the addition of the monofilament nylon string, which facilitates IUD removal. His trapezoid shape Lippes Loop IUD became one of the most popular first generation IUDs. In the

following years, many different shaped plastic IUDs were invented and marketed ***(Thiery, 1997).***

These included the infamous Dalkon Shield, whose poor design caused bacterial infection and led to thousands of lawsuits. Although the Dalkon shield was removed from the market, it had a lasting, negative impact on IUD use in the United States ***(Thiery, 2000).***

The modern intra uterine contraceptive device:

The invention of the copper IUD in the 1960s brought with it the capital 'T' shaped design used by most mode IUDs. US physician, Howard Tatum determined that the 'T' shape would work better with the shape of the uterus, which forms a 'T' when contracted. He predicted this would reduce rates of IUD expulsion ***(Thiery, 2000).***

The addition of copper to the IUCD was suggested by Jaime Zipper of Chile, whose experiments with metals indicated that copper acted locally on the endometrium ***(Zipper et al., 1969).*** Howard Tatum combined Zipper's suggestion with the development of the T-shape to diminish the uterine reaction to the structural frame and produced the copper –T. The first copper IUCD had copper wire wound around the straight shaft of the T, the TCu-200 (200 mm of exposed copper wire), also known as the Tatum-T ***(Tatum, 1983).*** More copper was added by the Population Council investigators,

leading to the TCu-380A (380 mm of exposed copper surface area) with copper wound around the stem plus a copper sleeve on each horizontal arm ***(Sivin & Tatum, 1981).***

The contraceptive action of all IUCDs is mainly in the uterine cavity. Ovulation is not affected and the IUCD is not an abortifacient ***(Speroff, 2005; Sivin, 1989).*** Sperm can be obtained by laparoscopy in washings from the fallopian tubes of control women at mid cycle, whereas no sperms are present in the tubal washings from women wearing IUCDs ***(Habashi et al., 1980).***

Prevalence:

Globally, the IUCD is the most widely used method of reversible birth control. The most recent data indicates that there are 169 million IUCD users around the world. This includes both the nonhormonal and hormonal IUCDs. IUCDs are most popular in Asia, where the prevalence is almost30%. In Africa and Europe the prevalence is around 20%. As of 2009, levels of IUCD use in the United States are estimated to be 5.5% ***(The Guttmacher institute, 2012).***

Data in the United States does not distinguish between hormonal and nonhormonal IUCDs. In Europe, copper IUCD prevalence ranges from under 5% in the United Kingdom to over 10% in Denmark in 2006 ***(Kaneshiro and Aeby, 2010).***

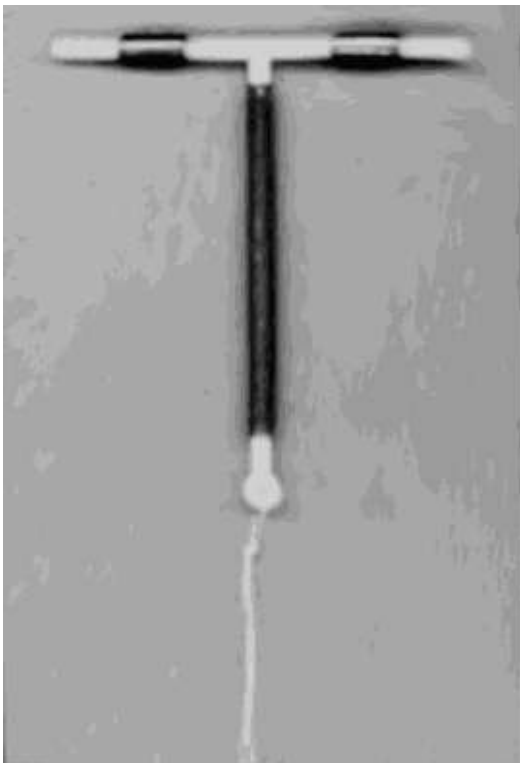

Figure (1): Photo of a common IUCD (Paragard T 380A) ***(Winner et al., 2012).***

Device description:

There are a number of models of the copper IUCD available around the world. Most copper devices consist of a plastic core that is wrapped in a copper wire ***(Kulier and O'Brien, 2008).*** Copper IUCD containing noble metals are becoming increasingly popular because they are more resistant to corrosion. In the "Gold T IUCD", which is made in Spain and Malaysia, there is a gold core, which further prevents the copper from fragmenting or corroding. Gold ring Medusa is a

differently shaped German version of the Gold T ***(Winner et al., 2012).***

Another form of AuCu IUCD is called Goldlily. Goldlily consists of a layer of copper wires wrapped around an original layer of gold wires, and it provides electrochemical protection in addition to ionic protection ***(World Health Organization, 2010).***

Silver IUCD is similar to Goldlily, and Goldring Medusa is available in an AgCu version as well. Nova-T 380 contains a strengthening silver core, but does not incorporate silver ions themselves to provide electrochemical protection ***(NetDoctor,2006).***

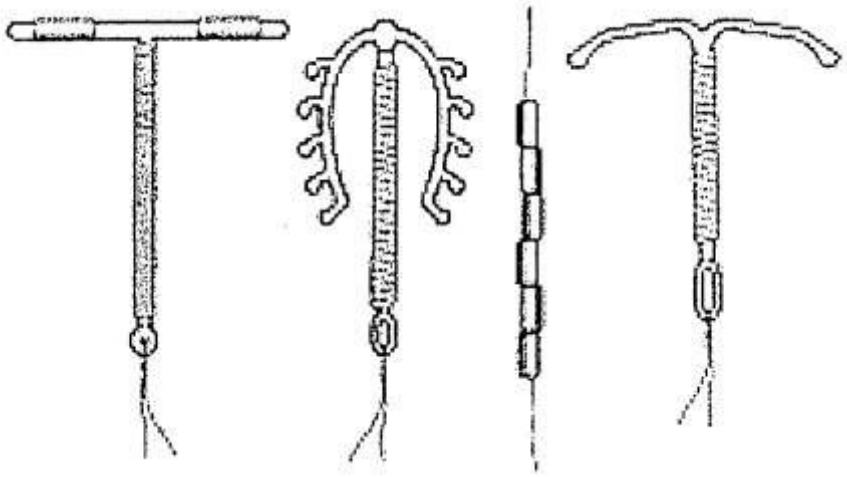

Figure (2): Different shapes of IUCDs**.**

Types of intra uterine contraceptive device

The types of intrauterine devices available, and the names they go by, differ by location ***(Elsedeek, 2015).***

There are two types available:

- Nonhormonal copper lUCD-ParaGard
- Hormonal IUCD-Mirena & Skyla

Non hormonal copper IUD:

Figure (3): A copper T shaped IUD with removal strings.

Copper IUDs primarily work by disrupting sperm mobility and damaging sperm so that they are prevented from joining with an egg. Copper acts as a spermicidal within the uterus, increasing

levels of copper ions, prostaglandins, and white blood cells within the uterine and tubal fluids ***(Grimes, 2007).***

The increased copper ions in the cervical mucus inhibit the sperm's motility and viability, preventing sperm from traveling through the cervical mucus, or destroying it as it passes through ***(Oritz and Croxatto, 2007).*** Copper can also alter the endometrial lining.

Most copper IUDs have a plastic T shaped frame that is wound around with pure electrolytic copper wire and/or has copper collars (sleeves). The arms of the frame hold the IUD in place near the top of the uterus. The TCu 380A (e.g. Pregna® and ParaGard®) measures 32 mm (1.26") horizontally (top of the T), and 36 mm (1.42") vertically (leg of the T). Copper IUDs have a first year failure rate ranging from 0.1 to 2.2% ***(Kulier et al, 2007).***

In the Eurogine Gold T IUD®, ***(eurogine.com, 2016)*** which is made in Spain, there is a gold core, which further prevents the copper from fragmenting or corroding. Goldring Medusa® is a differently shaped German version of the Gold T. ***(viomed.de, 2016)*** Another form of Golden copper IUD is called Goldlily® which is made by the Hungarian company, Radelkis. Goldlily® consists of a layer of copper wires wrapped around an original layer of gold wires, and it provides electrochemical protection. ***(radelkis.hu, 2016)***, Silver IUDs also exist. Radelkis also makes Silverlily®, which is similar to

Goldlily®, and Goldring Medusa® is available in a silver copper version as well. Nova T 380® contains a strengthening silver core.

Other shapes of IUD include the scaled U shaped IUDs, such as the Load® and Multiload®, and the frameless IUD that holds several hollow cylindrical minuscule copper beads. The frameless IUD is held in place by a suture (knot) to the fundus of the uterus. It is mainly available in China, Europe, and Germany, although some clinics in Canada can provide it. A framed copper IUD called the IUB SCu300A coils during deployment to form a three dimensional spherical shape and is based on a shape memory alloy core ***(Baram et al, 2014)***.

In addition to copper, noble metal and progestogen IUDs, patients in China can get copper IUDs with indomethacin. This non hormonal compound reduces the severity of menstrual bleeding, and these coils are popular ***(Li et al., 2011).***

Advantages of the copper IUD include its ability to provide emergency contraception up to five days after unprotected sex. It is the most effective form of emergency contraception available ***(Cleland et al., 2012).*** It works by preventing fertilization or implantation; however does not affect already implanted embryos ***(CDC Contraceptive Guidance, 2010)*** It contains no hormones, so it can be used while breastfeeding, and fertility returns quickly after removal

(Belhadj et al., 1986). Copper IUDs are also available in a wider range of sizes and shapes than hormonal IUDs.

Disadvantages include the possibility of heavier menstrual periods and more painful cramps ***(Grimes et al., 2007).***

The hormone-releasing IUD:

The concept of intra-uterine administration of progesterone for contraception was introduced in the US in 1970s. Following this work, the levonorgesterel-releasing intra-uterine system was designed in Finland gaining a license there for contraception in 1990 and soon after in the UK. Its excellent contraceptive benefits have led to its wide-spread use. Since that time, the non contraceptive health benefits of these systems secondary to the effect of the local action of the progesterone on the endometrium have been observed and researched. This evidence has supported the granting of the license for the use of the levonorgestrel releasing system for non contraceptive indication of menorrhgia and for the development of different types of intra-uterine system designed for the treatment of other non-contraceptive indications ***(Hockey et al., 2005).***

Progestasert:

The Progestasert was the first progesterone-releasing intra-uterine system on the market. This has a drug reservoir of 38 mg of progesterone within its polymer of polydimethyl siloxan incorporated onto a T-shaped polymeric platform. The

covering membrane allows a release of 65ug of progesterone daily into the uterine cavity for 18-24 months. It was manufactured in the US and received FDA approval in 1976 for use as a contraceptive in parous women for 1 year with a two year bio-availability. It was available briefly in the UK until marketing for this product ceased in the summer of 2001 ***(Luukkainen et al., 2001)***.

The levonorgestrel releasing IUD:(LNG-IUD) (Mirena®,Skyla®, Liletta® and Metraplant-E®)

Mirena®:

Figure (4): MIRENA ***(Centers for Disease Control and Prevention, 2010).***

The Mirena® Intrauterine System (LNG-IUD) has a T-shaped frame (based on the Nova T IUCD) 32 mm by 32 mm