EXPERT OPINION

Intrauterine device quo vadis? Why intrauterine device use should be revisited particularly in nulliparous women?

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Objective: This article was written with the objective to respond to the urgent need to improve intrauterine contraception as it is likely that the objectives of LARC will not be met without significant improvement of IUD design. Anatomical variations in size and shape of the uterus are not sufficiently considered, producing harm and suffering, which often lead to early removal of the IUD.

Proposed problem solving: The article describes why IUDs should be revisited to meet the challenge of LARC and proposes how to solve these problems. The opinion statement presented here may be considered provocative but is based on hundreds of women with IUD problems who consult or are referred to the practices of the authors of this article due to the disproportion between the IUD and their small uterine cavity. The solution is simple but requires a revision of the current design of IUDs. One-dimensional (longitudinal) IUDs are likely to be the first option. Framed devices with shortened transverse arm and IUDs which adapt to the width of the given uterus are viewed as second best.

Conclusion: One of the reasons of the high unintended pregnancy rate in the USA may be the paucity of suitable IUDs. Also, the legal climate in the USA seems to be a problem for developers as many lawsuits have recently been reported. Clinical studies conducted in young nulliparous and adolescent women suggest that IUDs that fit well in the uterine cavity, like a shoe, result in better tolerance, less side effects, and last but not least, higher use continuation rates.

Keywords: IUD screening, counseling, frameless IUD/IUS, adapted IUDs, efficacy, tolerance, continuation rate

Introduction

The primary objective of any contraceptive is to avoid unintended pregnancy. The latest figures published by Trussell and his team show that the pill, the contraceptive patch, and the vaginal ring have a typical 1-year pregnancy rate of 9%.¹ Side effects and noncompliance are the main causes for these high failure rates. For this reason, long-acting reversible contraceptive (LARC) methods (eg, intrauterine devices [IUDs] and implants) are advocated. LARC is vigorously promoted by societies such as the American College of Obstetricians and Gynecologists (ACOG), the US-based

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Association of Reproductive Health Professionals, the World Health Organization (WHO), the European Society of Contraception and Reproductive Health Care, the UK Faculty of Sexual and Reproductive Healthcare, and other organizations, as these methods are thought to be the solution for the global problem of unintended pregnancy.² Among LARCs, the IUD, (the denomination is used to indicate both copper and hormone-releasing intrauterine systems (IUSs), or only to indicate copper IUDs) is by far preferred by young US women.³ The most frequently reported reasons for liking the IUD (only one copper IUD is available in the USA) are ease of use and reliability, and for the levonorgestrel intrauterine system (LNG-IUS), lighter menstrual cycles. In Europe, IUDs and the LNG-IUS are more popular than implants because of the burden of insertion and surgical removal.⁴ However, if the IUD/ IUS causes pain and erratic or heavy menstrual bleeding, which are unfortunately common side effects, it will most likely be removed and replaced, often by a less effective method or no method at all. It should be realized that, prior to deciding to remove the IUD/IUS, many women have gone through a period of months of cramping pain, trying to endure the method as they have no alternative. This is not the aim of LARC. Positioning LARC for use in nulliparous and adolescent women can only achieve its goal if the method is continued to be used.⁵ Hence, tolerance is the major issue. Side effects and complications may incite women to file complaints as, for instance, lawsuits in the USA against contraceptive manufacturers are commonplace.⁶ The ability to tolerate an IUD/IUS is the result of several factors related to the provider, the receiver, and the IUD/IUS in its own right. It appears that IUDs and IUSs have the highest probability of being accepted by women if attention is given to these factors starting with the provision of correct information to dispel myths and misconceptions, and providing proper selection of the intrauterine method, comfort at insertion, and correct fitting.

The results of IUD/IUS trials in young and adolescent women are conflicting. Some report high tolerance rates, while others the opposite. Most of these trials have been conducted for a short period of time, 6 months to 1 year, rarely with the licensed "LARC effective period" of 5 years because too many women drop off.^{7–14}

This article will focus on three main determinants of IUD use: screening and counseling prior to IUD/IUS insertion, IUD/IUS selection, and comfort during insertion. Recommendations are provided to maximize continuation of use, and other ways to reduce unintended pregnancy in young women are discussed.

Screening Screening for infection

The risk of pelvic infection, which may lead to infertility, ectopic pregnancy, and chronic pelvic pain, remains one of the major concerns of IUD providers as well as of women. It is known that this is a misinterpretation of the data and has unfortunately resulted in many unintended pregnancies by limiting women's access to a long-term contraceptive method. There is good scientific evidence that the risk of pelvic inflammatory disease (PID) is not increased after the first month following insertion of the IUD. Investigations by WHO showed that the risk of PID is limited to the first 20 days after insertion.¹⁵ The incidence of PID in IUD users remains very low and seems to be associated with young women with the high prevalence of bacterial vaginosis and cervicitis rather than with the insertion of an IUD. The presence of vaginosis increases the infection risk significantly.¹⁶ Antibiotic treatment has not been shown to be beneficial except in women with an increased risk of bacterial endocarditis (eg, women with a valvular prosthesis).¹⁷ Bacteremia can occur during insertion and removal of an IUD but is rare.¹⁸ In general, screening for bacterial vaginosis and the prescription of antibiotics are not required, except if there are signs of cervicitis. Screening could however be recommended in the presence of risky behavior (eg, multiple sexual partners or recent Chlamydia trachomatis or Neisseria gonorrhea infection). Reassessment of PID, possibly attributable to an IUD, however, confirmed that the risk is similar to women who do not have an IUD inserted.¹⁹ The rate of PID in IUD users is low even in regions where the prevalence of sexually transmitted infections is high.²⁰ Clinical evidence has shown that previous use of a copper IUD is not associated with an increased risk of tubal occlusion among nulligravid women.21

In conclusion, WHO suggests that the benefits of IUDs generally outweigh the risks in women of any age, whether parous or not, and that IUDs can be inserted in women younger than 20, provided that these women are at low risk of sexually transmitted infections. However, WHO advises against the use of IUDs in women who have had PID in the previous 3 months.²² ACOG recommends to screen all adolescents at the time of or before IUD insertion.⁵ The IUD can be placed on the same day and treatment administered if the test results are positive (a single oral dose of 1 g of azithromycine or 2×100 mg of oral doxycycline for 7 days).

Screening for uterine anomalies and dimensions of the uterine cavity Screening for congenital uterine anomalies

Congenital uterine anomalies are deviations resulting from maldevelopment as a consequence of abnormalities

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occurring during embryonic life of the Müllerian ducts.²³ As no universally agreed standardized classification systems exist, the true population prevalence of congenital uterine anomalies is difficult to assess. Three-dimensional ultrasound is the easiest method to diagnose uterine anomalies. It has the advantage of being noninvasive and also provides quantitative information on parameters such as fundal indentation or septum length, which is not possible to assess with the endoscopic methods or hysterosalpingography.

Chan et al found, overall, 5.5% uterine anomalies diagnosed in an unselected population. Arcuate uteri are the most common abnormalities in the unselected population affecting 3.9% of all women. Subseptate or septate uteri have a prevalence of 2.3%. Bicornuate uteri are uncommon (0.4%) and 0.1% of cases present a unicornuate uterus. The prevalence of uterus didelphys is approximately 0.3% in an unselected population.²⁴ Interestingly, a similar prevalence of uterine anomalies was reported in a study by Jurkovic et al on 1,046 women attending a gynecological ultrasound clinic for a variety of indications.²⁵ Table 1 summarizes these estimates.

Recently, the European Society of Human Reproduction and Embryology and the European Society of Gynecological Endoscopy proposed a new updated classification system to provide a comprehensive clinical orientation of congenital anomalies of the uterus. Anomalies are classified into the following main classes based on anatomical deviations derived from the same embryological origin (Figure 1): U0 or normal uterus; U1 or dysmorphic uterus; U2 or septate uterus; U3 or bicorporeal uterus; U4 or hemi-uterus (Figure 1).²⁶

In conclusion, screening for congenital anomalies is not practical to carry out routinely. It should be realized, however, that malformation of the uterus may be a reason for IUD problems and side effects such as malposition of the IUD, displacement, partial and total expulsion of the IUD, and uterine perforation, and should be considered if any of these occur.

 Table I Estimates of the prevalence of congenital uterine anomalies

Prevalence of uterine anomalies in unselected population		
Arcuate uterus	3.9%	
Subseptate and septate uterus	2.3%	
Bicornuate uterus	0.4%	
Unicornuate uterus	0.1%	
Uterus didelphys	0.3%	
Overall	5%7%	
Note: Data from Chan et al ²⁴ and lurkovic et al ²⁵		

Note: Data from Chan et al²⁴ and Jurkovic et al.²⁵

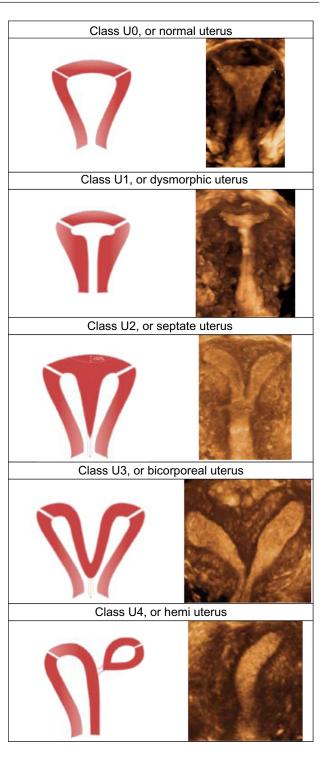


Figure I Classification of main uterine anomalies.

Notes: Schematic representation (left); three-dimensional sonographic images (right). Adapted from Grimbizis GF, Gordts S, Di Spiezio A, et al. The ESHRE/ESGE consensus on the classification of female genital tract congenital anomalies. *Human Reproduction*. 2013;28:2032–2044.²⁶

Abbreviations: ESHRE, European Society of Human Reproduction and Embryology; ESGE, European Society of Gynecological Endoscopy.

Screening for uterine dimensions and IUD selection

As uterine cavities differ considerably in size in all women, and the uterus changes in size and volume during the menstrual cycle, it is unreasonable to expect one standard-sized IUD to fit uterine cavities with different sizes and volumes. Disproportion between the IUD and the uterine cavity often leads to cramping pain, embedment, displacement, partial or total expulsion of the IUD, unintended pregnancy (due to downward displacement, partial or total expulsion), and abnormal or heavy uterine bleeding, resulting in removal of the IUD.27

A major contribution to the understanding of IUD-related side effects has been made by Kurz and Hasson, as well as other researchers, some 30 years ago.^{28,29} These researchers were able to confirm, using measuring instruments (cavimeter, wing sound), that uterine cavities in nulliparous and parous women are usually narrow and concluded that IUDs should be adapted to the width of the uterine cavity to avoid pain and embedment and possible secondary perforation. The latter may be due to the imbalance between the size of the IUD and that of the uterine cavity, causing production of asymmetrical forces. The uterine muscle seems capable of generating enough force to cause an IUD to perforate the myometrium provided it is applied asymmetrically.³⁰

Attention to the size and shape of the uterus prior to inserting an IUD is of paramount importance. The uterine width, a parameter directly related to IUD tolerance and continuation of use, was assessed recently by ultrasound by two independent research groups in Finland and in the USA. It was found in 165 nulliparous women that the median width of the uterine cavity measured at its upper level was 24.4 mm (range 13.8–35.0 mm). In 101 women (62.7%), the transverse width was below this distance.³¹ In line with these findings, Benacerraf et al found a similar cavity width in 91 nulliparous women. They compared women with abnormally and normally located IUDs, with respect to their indication for three-dimensional ultrasound examination, and found that the proportion of patients whose principal indication for scanning was bleeding, pain, or both was significantly greater in those with an abnormally located IUD, including embedded IUD, compared with those whose device showed normal location. The mean width of the uterine cavity of nulliparous women in their study was 27 mm (range 20.2-34.1 mm) which is narrower than the width of a standard IUD (32 mm). They suggest that physicians should consider ultrasonography to measure the uterine cavity before inserting an IUD.³²

Most conventional IUDs have a transverse diameter of between 28 mm and 32 mm. The transverse dimensions of many uteri are far less than the length of the transverse arm of the Paragard IUD (Duramed Pharmaceuticals Inc., Pomona, NY, USA) and Mirena LNG-IUS (Baver, Berlin, Germany), which is 32 mm, resulting in side effects due to distortion, displacement, and expulsion.

When studying Paragard and Mirena in young nulliparous and adolescent women, Berenson et al and Rasheed and Abdelmonem (as well as other authors) found high rates of discontinuation and commented that the most plausible cause of early discontinuation (up to 40% after 6 months to 1 year) in this subset of women is the disproportion between the IUD and the uterine cavity.^{12,13} It seems logical, therefore, that the provider should realize that the only way to obtain a high continuation rate is by using an IUD that is not wider than the width of the uterine cavity. The new smaller version of Mirena, named Jaydess (Skyla in the USA), has a transverse arm length of 28 mm. The results of initial clinical trials³³ are encouraging, but this 28 mm transverse arm may still be too long for many women. An illustration is given in Figure 2. Frameless copper and frameless LNG-IUSs could be optimal from this point of view. Figure 3 (upper row) shows the uterine cavities of young women, assessed by three-dimensional ultrasound before a decision was made to insert an IUD. Which IUD would suit them best? Figure 3 (lower row) also shows small uteri which were, however, fitted with the frameless IUD. As the frameless IUD/IUS, having virtually only a longitudinal dimension of clinical relevance, it will fit all normal uterine cavities, and is therefore probably the best option for most women. Currently most IUD providers make a one-dimensional assessment (length) by sounding the threedimensional uterine cavity before placing a two-dimensional IUD or IUS. This one-dimensional assessment of the uterus is most likely to provide good results if followed by the use of a one-dimensional (frameless) IUD/IUS. This is simple reasoning based on the geometry of the uterine cavity.

An alternative approach is to shorten the arms of existing IUDs or design IUDs with different lengths of transverse

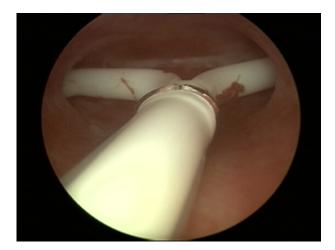


Figure 2 Hysteroscopic picture of Jaydess/Skyla causing pain complaints due to the too long transverse arm in a nulliparous woman.

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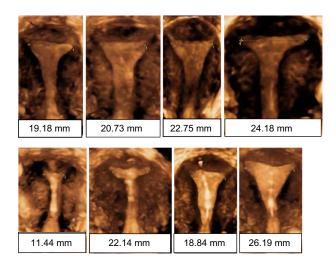


Figure 3 3D ultrasound in nulliparous women.

Notes: Screening three-dimensional (3D) ultrasonography performed in women desiring intrauterine contraception with measurement of the fundal transverse width (upper row); uterine cavities of nulliparous women fitted with a frameless copper IUD. The transverse width of the uterine cavity is indicated below each figure (lower row). **Abbreviation:** IUD, intrauterine device.

arms. Figure 4 shows a T-shaped IUD of which the transverse arm was trimmed to a length of 18 mm. The flexible transverse arms of an experimental Ω -shaped LNG-IUS allow adaptation to the width of the uterine cavity (Figure 5).

In conclusion, studies suggest that high user continuation can be achieved by optimizing the relationship between the IUD and the uterine cavity.^{34,35} An IUD that does not fit well will often lead to side effects (ie, pain, bleeding, embedment, expulsion) and subsequent removal of the IUD. Measuring the width of the uterine cavity may not be practical in most settings. Therefore, frameless IUDs and IUDs with shorter transverse arms should be considered especially for the young.

Counseling – upfront cost, myths, and misconceptions Upfront cost is a major barrier

Most patients want to know the cost of contraception especially for LARC methods as the upfront costs are an important barrier and a deterrent to the use of IUDs in countries which do not reimburse IUDs. It may therefore be useful to work out payment schemes for lower income women. Unlike traditional methods of contraception such as condom and pill, the IUD/IUS, which has a life span of 5 years, is very reasonably priced in the European Union at between 100 Euros and 350 Euros, including IUD/IUS insertion. However, this is still a barrier for many women, especially for the higher priced IUDs. The average wholesale price in the USA of the LNG-IUS is \$844, and the copper IUD is

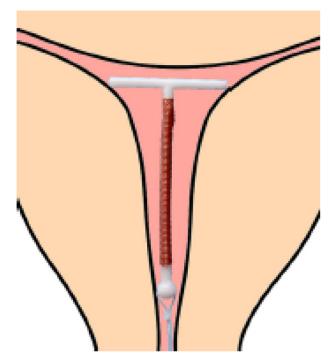


Figure 4 A narrow uterine cavity fitted by a trimmed T-shaped IUD with transverse arm length of 18 mm. Abbreviation: IUD, intrauterine device.

\$718, the costs of the office visit and insertion procedure not included.³⁶ In some European countries, this one-off purchase cost can be settled by an inexpensive and easy financing option. Usually, the woman receives the individual credit agreement within a few weeks. In the USA, contraceptives may be reimbursed under the so-called Obamacare provision (Affordable Care Act). Provision of no-cost contraception has been shown to decrease unintended birth rate, abortions, and repeat abortions.³⁷ An example of a payment scheme is given

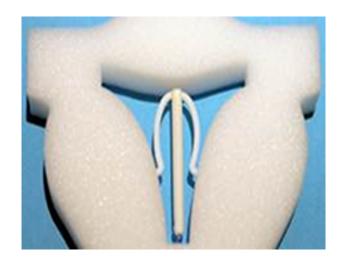


Figure 5 An experimental LNG-IUS capable of adaptation to the individual width of uterine cavity. Abbreviation: LNG-IUS, levonorgestrel intrauterine system.

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in Table 2. Due to the introduction of financing provision, women no longer have to miss the advantages of an IUD providing secure protection for years on especially favorable terms. If the payoff period is 18 months, about 42 months are for free. Compared to other contraceptive methods, the IUD/IUS is the most economical (Table 3).

Myths and realities about IUD use

Outdated perceptions among women about IUDs continue to negatively impact their use. IUDs are often not selected as the first option because they are misunderstood. It may still surprise many people that the IUD is safer than other forms of contraception.³⁸ Therefore, due attention should be given to keeping women correctly informed about new developments in this field, in comparison to other methods. An emerging body of research has disproved a number of contraindications to intrauterine contraception. Specifically, women of any age or parity and those who are postpartum or post-first-trimester abortion are all eligible for intrauterine contraception. The IUD is also highly suitable for emergency contraception as it will provide continuous protection. The benefits of intrauterine contraception outweigh the risks of a wide variety of medical conditions that might contraindicate the use of combined hormonal oral contraceptives. Providers should be aware of the WHO or the US medical eligibility criteria for contraceptive use.^{22,39} Table 4 discusses the most common myths and misconceptions about IUD use.⁴⁰⁻⁴³

Attention to comfort during IUD insertion

As IUDs are becoming more popular, the issue of pain control is often discussed as related to IUD insertion in young women. Practical advice during counseling is important and should include information about discomfort during pelvic examination, the pain associated with IUD insertion, and information about the benefits and risks of IUD use. Insertion pain cannot be predicted. Ultrasonography does not give additional information to predict pain. According to Kaislasuo et al, dysmenorrhea is the only predictor of severe or intolerable insertion pain due to increased uterine/cervical contractility.³¹ Identifying means of sufficient analgesia, especially in

Table 2 Monthly	cost for financing	IUD/IUS
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Cost of IUD/IUS	Financing period (months)		
in Euro (€350)	6	12	18
Monthly cost	€58.33	€29.60	€20.51

Note: Data from Medipay (<u>https://www.medipay.de</u>).⁷⁹

Abbreviations: IUD, intrauterine device; IUS, intrauterine system.

Method	Total cost	Cost per month
Condom	0.30–1€ per unit	
Combined oral contraception pill	-	€5–12
3-monthly injectable	_	€10
Subcutaneous progestin implant	€350-450	€9–13
Vaginal ring	_	€13-20
IUD/IUS	€150-350	€3–8

Abbreviations: IUD, intrauterine device; IUS, intrauterine system.

nulliparous women, is important. Equally important is an appropriate patient-friendly setting accommodated with indirect light. Not to be forgotten is the use of a narrow and short speculum in young women to facilitate access to the cervix. A 1.0–1.5 cm wide speculum is sometimes necessary in young women. A too large speculum often causes more pain than the IUD insertion procedure. Listening to music during the procedure decreases procedural pain.⁴⁴

The injection of a drop of lidocaine or mepivacaine in the anterior lip of the cervix before placement of a (preferably) atraumatic forceps is a good habit, especially if the patient is anxious or if slow closing of the Allis forceps causes pain or prior to placement of a toothed forceps (eg, Pozzi forceps). The use of a dental syringe with extra-fine needle is highly practical and can also be used for local or loco-regional anesthesia.

After disinfection and gentle straightening of the uterus, a "cotton swab test" (soaked in antiseptic solution) can be done to test the tightness of the internal cervical os and to obtain information on pain sensation. If the test provokes severe pain, additional local anesthesia can be provided prior to sounding the uterus. Additional instrumentation (eg, os finder, cervical dilator), except for a sound to measure the length and flexion of the uterus, is rarely necessary if the test shows that that cavity can be entered easily.

Many believe that the use of misoprostol greatly facilitates IUD insertion.⁴⁵ We recommend the use of 200–400 μ g of misoprostol, orally or vaginally, 3 hours before IUD insertion. Others prefer to place the tablets vaginally in the posterior fornix the night before the procedure (9–12 hours before). Despite conflicting published data about the benefits of misoprostol, significant differences were found in nulliparous women between groups using misoprostol, 400 μ g vaginally, 4 hours before insertion, compared to placebo with less difficulty and less moderate-to-severe pain at IUD insertion.⁴⁶ It may be that the vaginal route could be preferable as plasma concentrations of misoprostol remain substantially higher than when administered by the oral or sublingual routes. However,

Table 4 Myths and misconceptions that still exist related to intrauterine contraception

Myths and misconceptions	Reality
IUDs cause abortion	IUDs do not terminate a pregnancy. The primary contraceptive effect of intrauterine contraception is the
	prevention of fertilization and implantation by interfering with sperm motility and survival. The reaction of
	the intrauterine foreign body with the endometrium activates the release of leukocytes and prostaglandins
	which act not only in the uterus but also in the oviduct and cervix to impede sperm and egg development
IUDs cause pelvic	The issue of increased risk or greater severity of sexually transmitted infection (STI) among IUD users has
inflammatory disease	been a prominent concern. However, the rate of PID is low, with cases concentrated in the first 20 days
	after insertion. The reason for the increased risk during the first weeks after insertion is that bacteria in the
	vagina and cervix can be transported through the cervical canal into the uterine cavity. It is important to tell
	the IUD user that for the majority of the users, fertility is restored immediately after removal of the device;
	irrespective of whether the IUD was used for a few months or for many years
IUDs cause ectopic pregnancy	The risk of ectopic pregnancy in IUD users has been thoroughly investigated. The risk is ten times lower in
110,	IUD/IUS users than in the general population of women using no contraception (0.0–0.5/1,000 women vs
	3.25–5.25/1,000 women). This finding has been confirmed by a meta-analysis of 16 case–control studies. ⁸⁰
	A previous ectopic pregnancy is not a contraindication for the use of an IUD/IUS
IUDs cannot be used	Another myth is that women over 25 years or older are the best candidates for IUD use, and that women
by nulliparous women	over 35 are the ideal candidates. This belief, based on the fear of pelvic infection (PID) and the potential for
	resulting infertility, is no longer justified. There is no biological reason to conclude that a young woman is at
	higher risk than an older woman provided they have similar sexual behaviors
IUD insertion is painful	One of the reasons of the underuse of the IUD is the fear of insertion pain. The insertion of an IUD is not
· · · · · · · · · · · · · · · · · · ·	usually a painful procedure. However, many women, nulliparous women in particular, fear insertion and
	this may be an important reason not to select an IUD. Several measures can be used to reduce patient
	discomfort during the insertion and removal of the IUD: premedication, local anesthesia, and cervix relaxing
	agents, and anxious patients should ask for it. Should physicians pay attention to pain relief, it is likely
	that many more women will request IUDs as their method of contraception. Taking care of pain relief is
	important. When counseling, the provider should inform the woman about the insertion procedure and
	about the measures he/she will take to make insertion less uncomfortable ⁸¹
IUDs cause pain and embedment	IUDs do not necessarily have to cause pain during use if properly fitted in the uterine cavity. Providers should
To b's cause pair and embedmene	select a particular IUD/IUS based on an estimation of the size of the uterine cavity. A standard IUD size will not
	fit cavities of every size and shape. Frameless IUDs are particularly useful for use in nulliparous and adolescent
	women as they are flexible and do not cause any distention of the uterus. IUDs that are too big will often embed
	in the uterine wall. Each woman should request her doctor to select an IUD/IUS that fits into her uterus
IUDs are not effective	IUDs protect 20 times better than the pill, the contraceptive patch, and the vaginal ring against intrauterine
	and ectopic pregnancy, in contrast with the general belief. The commonly held opinion is that oral
	contraceptives are more effective than IUDs. Similarly, physicians and the general public are often poorly
	informed about the effectiveness of IUDs and the effectiveness of contraceptives in general
IUDs are expelled	Total expulsion of a conventional IUD occurs in 5%–10% of women during the first year of use, with
and cause perforation	an increased risk in nulliparous women. The majority of expulsions occur during the first months after
	insertion, with 1% -2% per year thereafter. Frameless, anchored IUDs reduce the risk of expulsion
	approximately five-tenfold, on condition that the IUD is properly inserted. The overall risk of perforation
	with IUD insertion is around $1-2/1,000$ women. Perforation is often caused by unskilful insertion, poor
	technique due to the absence of training, and lack of attention to contraindications. Women should discuss
	these issues with their providers. IUDs that do not fit can progressively migrate through the uterine wall
	due to forceful contractions of the uterus
IUDs cause abnormal and heavy	Erratic and heavy menstrual bleeding is the most common cause for IUD discontinuation. The impact on
menstrual bleeding	menstrual blood loss with copper IUDs can be minimized by reducing the surface area of the foreign body.
mensurual bleeding	The small frameless GyneFix 200 IUD, releasing copper ions from the outer as well as inner surface of the
	copper tubes, does not increase menstrual blood loss in contrast to all other copper IUDs simply because it is
	much smaller. On the other hand, all hormone-releasing intrauterine systems strongly reduce menstrual blood
	loss. Many users of hormonal IUDs develop amenorrhea (have bleed-free periods). In many countries, this is
	becoming a trend. Several measures are possible to manage erratic menstrual bleeding and spotting if present
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Notes: This is a list of the most frequent myths and misconceptions. Data from WHO Scientific Group on the Mechanism of Action Safety and Efficacy of Intrauterine Devices, ³⁸ Center for Disease Control and Prevention, ³⁹ Wildemeersch et al⁴⁰ and Ortiz et al.⁴¹ **Abbreviations:** IUD, intrauterine device; PID, pelvic inflammatory disease; IUS, intrauterine system.

most women prefer the oral route to vaginal application.⁴⁷ If misoprostol is used for cervical priming, it is recommended that a nonsteroidal analgesic be added to reduce its prostaglandin-mediated side effects and uterine cramping. Of

relevance, misoprostol could help reduce failed insertion. In a recent study among nulliparous women, 27 of 138 (19.6%) TCu380A IUD insertions were unsuccessful for emergency contraception.⁴⁸ Some physicians claim that applying heat to the lower abdomen (using electric heating pad, or a microwave-heated cherry seed pillow) may significantly reduce painful sensations.⁴⁹ If the patient is having severe discomfort with the insertion of the sound or requires cervical dilation, then the administration of a paracervical block or even conscious sedation (such as propofol or midazolam) can be used. However, this is rarely necessary and perhaps only in extremely anxious women.

Neglected indications for IUD use

Intrauterine contraception could play a significant role to reduce unintended pregnancies by inserting IUDs for emergency, postabortal, and postpartum contraception. IUDs are still underused in these situations; a lost opportunity to substantially reduce the occurrence of repeat unintended pregnancies and induced abortions.

Emergency contraception

In 1976, copper IUDs were shown to be highly effective for emergency contraception.⁵⁰ They have three main advantages over oral hormonal emergency contraception: 1) Efficacy is higher for a copper IUD, with pregnancy rates not exceeding 0.1%, compared with much higher pregnancy rates of progestin-only and ulipristal emergency contraception.51,52 2) A copper IUD can be inserted at least 5-7 days after unprotected intercourse, or up to 5 days after the earliest estimated day of ovulation. In this situation, the copper IUD may act by preventing implantation; when used long-term, it usually prevents fertilization.⁵³ 3) Once inserted, an IUD can provide ongoing contraception for 5 years or more. A recent study suggested that women appear to have interest in "same-day" IUD insertion following unprotected intercourse, particularly better educated young women and those who had a prior unwanted pregnancy.54

Immediate postabortion contraception

Women who have an IUD inserted immediately after an abortion have fewer pregnancies and repeat abortions than women who schedule insertion of an IUD during a follow-up visit.⁵⁵ The IUD/IUS is also probably the most appropriate birth control method to reduce the number of repeat abortions.⁵⁶ Gynecologists and obstetricians have an ethical obligation to do everything that is possible to ensure that postabortion contraception, with a focus on LARC methods, becomes an integral part of abortion and postabortion care, in line with the recommendations of the International Federation of Gynecology and Obstetrics and of several other organizations.¹ Frameless IUDs have been successfully used

for the prevention of repeat abortions. Continuation rates after 1 year were over 90% in these postabortion studies and no expulsions were reported.^{57,58} This finding contrasts with higher expulsion rates reported for using conventional IUDs.^{59–61} If a disproportion between the IUD and uterine cavity occurs, early discontinuation will be the outcome, as observed in postabortion studies (Wildemeersch, unpublished data, 2014).

Immediate postpartum contraception

IUD insertion after delivery is convenient for many women because the motivation for contraception is high and it does not interfere with breastfeeding in the early postpartum period. However, the expulsion rate with TCu380A was high (up to 25%–30%) and acceptability rates low (25–30% continuation rate at 6 months).^{62,63} To circumvent these high expulsion rates, a method to anchor an IUD has been attempted. The expulsion rate was reduced but still too high (approximately 10%–12%).⁶⁴ It is hoped that a new anchoring technique for immediate postplacental insertion after vaginal delivery will eventually become available.

Immediate postplacental IUD insertion at the time of cesarean section, ie, through the hysterotomy, provides a good opportunity to achieve long-term contraception with minimal discomfort to the patient.⁶⁵ No studies have shown any increase in the risk of infection or other complications related to this method of IUD insertion. Moreover, some reports indicate that women who deliver by cesarean section may have lower expulsion rates than those who deliver vaginally, with immediate IUD insertion. A recent Cochrane analysis found that the risk of expulsion associated with IUD placed at the time of cesarean section was significantly lower than the expulsion rates seen with transvaginal placement of IUDs immediately following vaginal delivery of the fetus and placenta.⁶⁶

Çelen et al conducted a study in 245 Turkish women with term pregnancies delivered by cesarean section. The participants were examined before hospital discharge and at 6 weeks, 6 months, and 12 months postpartum. There was one case of an unplanned pregnancy (0.4%). There were no serious complications associated with immediate IUD insertion during cesarean section. The cumulative rates of expulsion, removal for bleeding/pain, and other medical reasons were 17.6, 8.2, and 2.4 per 100 women per year, respectively. The continuation rates were 81.6% and 62% at 6 months and 12 months, respectively. It was concluded that immediate postplacental IUD insertion during cesarean section provides adequate protection against pregnancy. However, more than one fourth of the participants discontinued IUD use due to spontaneous expulsion or other medical reasons.⁶⁷

Despite the fact that other studies observe a lower expulsion rate with cesarean deliveries,68 the challenge to solve the displacement and expulsion problems continues. A simple anchoring technique for the suspension of a frameless copper IUD is currently in development. This method, which is derived from the experience obtained over the years and the multitude of clinical investigations performed with the frameless copper IUD, may solve the expulsion problem and also provide either short-term or ultra-long-term contraception. Such an approach could be highly cost-effective as well, especially when the IUD cost would be incorporated in the cost of the operative procedure. Another advantage is the reversibility of the method. Long-acting copper IUDs have been compared with tubal sterilization and found to be equally effective.^{69,70} These devices could replace irreversible sterilization. Many women stop planning further pregnancies after their first or second cesarean section. As the anchored method is reversible, this device could be used as a sterilization or temporary method.

Discussion

It is likely that intrauterine contraception could be far more attractive if IUDs designed to fit well in the uterus were used. At least 50% of nulliparous women have an intrauterine cavity width at the fundal level of <24 mm, thus significantly narrower than currently available IUDs with a 28 mm or 32 mm transverse arm. It is not surprising that an IUD which is too big for the uterine cavity will often lead to early discontinuation. Health care providers should be aware that many IUD users endure pain to keep the method they have finally selected after much hesitation and for which they may have made an important financial effort.

The transverse arm of a T-shaped IUD in nulliparous women should probably be not longer than 24 mm and this short arm might even be too long for some women. It is known that the uterus is theoretically capable of generating forces of around 50 N, which is sufficient to produce IUD embedment, or in some cases uterine perforation, even after the IUD is confirmed to be correctly placed using ultrasound.³⁰

In addition, dislocated IUDs result in higher pregnancy rates.⁷¹ Also, expulsion rates are expected to increase significantly when IUDs are misplaced or have moved away from the fundus.⁷² Particularly with respect to copper IUDs, when the distance between the upper end of the IUD to the serosal surface of the uterus is >2 cm, as measured by ultrasound at the beginning of the menstrual cycle, removal of the IUD should be considered to protect the woman from an unintended pregnancy. Removals for downward displacement of MLCu375 and TCu380A IUDs were 12.7% and 6.0%, respectively, in a Chinese study reported by Wu et al.⁷³

The general principle in medicine is "First, do no harm." It is evident that if an IUD causes harmful effects, including embedment, the result will be removal of the IUD in the majority of cases. A review of recent IUD studies mentioned continuation rates as low as 48% after 1 year of use.⁷⁴ The National Institute for Health and Care Excellence, UK, guidelines on LARC informed that health care professionals should be aware that up to 60% of women discontinue using LNG-IUS within 5 years because of bleeding and pain and/ or systemic progestogenic side effects.⁷⁵

In the CHOICE study, the continuation rates were relatively high during the first year but they dropped rapidly thereafter, especially in adolescent women.⁷⁶ Repeat teenage pregnancies are on the increase.⁷⁷ In 1982, van Os, inventor of the Multiload IUD, expressed his hope to improve IUD selection by measuring the uterine cavity and inserting "tailor-made" devices. "We will then probably be able to get better continuation rates which are now between 70% and 80% for the first year of use for practically all IUCDs (intrauterine contraceptive devices). Maybe this can be enhanced to 80%–90%."⁷⁸ Many current IUDs do not belong in the uterine cavity in which they were inserted. A one-dimensional frameless IUD or IUS probably provokes the least reaction from the uterus and is likely to be universally tolerated, as clinical trials suggest.^{34,35}

Conclusion

Young men and women are a highly vulnerable population. They deserve to be informed correctly and have access to high-quality and effective reproductive health care assistance. Discussions about contraception should address risks and benefits associated with IUDs, and the different designs that may be better tolerated and result in high use continuation. Moreover, same-day postcoital and immediate postabortion IUD insertion (or referrals to facilities that provide this service) should be offered as an option whenever possible. The consequences of unintended sex and unintended pregnancy are far too great. As adolescent pregnancy remains a huge public health problem, more research is urgently needed to study new IUD methods as those described in this article, and compare them with existing birth control methods, in adolescent and young women for interval, postcoital, and postabortion contraception in order to reduce the unplanned pregnancy rates in the world.

This article was written with the objective to respond to the urgent need to improve intrauterine contraception as it is probable that the objectives of LARC may not be met without significant improvement of IUD design. More widespread access to the existing IUDs may not be sufficient. Women should have access to better performing IUDs taking into account the anatomical variations in size and shape of the uterus to avoid harm and side effect which often lead to early removal of the IUD. The solution is simple but requires a revision of the current design of IUDs. One-dimensional (longitudinal) IUDs are likely to be the best option; framed devices, provided with shortened transverse arm and IUDs which adapt to the width of the uterus, are viewed as second best. One of the reasons of the higher unintended pregnancy rate in the USA compared to Western Europe may be the paucity of suitable IUDs. Appropriate IUDs could reduce this gap.

Disclosure

Dirk Wildemeersch has been involved in the optimization of new, innovative drug delivery systems for use in the uterus. He is currently an advisor in devising new concepts in controlled release for contraception, gynecological treatment, and prevention of infectious diseases. All other authors report no conflicts of interest in this work.

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