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Revisión de Conjunto

Barriers to the use of intrauterine devices among healthcare professionals: **Evidence against misconceptions**

Barreras al uso de los dispositivos intrauterinos entre los profesionales sanitarios: evidencia frente a creencias erróneas

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Abstract

Key words:

Contraception. Contraceptive methods. Intrauterine devices. Levonorgestrel. Unplanned pregnancy. Family planning.

Long-acting reversible contraception (LARC) refers to highly effective methods that are suitable for most women. Despite being the best known long-acting reversible contraception methods, the copper intrauterine device (Cu-IUD) and the hormonal (levonorgestrel) device (LNG-IUD) are used by only 6.9% of women of childbearing age in Spain who use any method of contraception. This may be a consequence of barriers to the use of IUDs among health professionals that affect young and/or nulliparous women in particular. The present review addresses available scientific evidence regarding the main factors creating barriers to the use of intrauterine devices. These factors include possible difficulties during insertion and associated pain, the risk of perforation during the insertion or of expulsion once inserted, the effects on dysmenorrhoea and on menstrual bleeding pattern, the risk of ectopic pregnancy or of pelvic inflammatory disease, the speed of recovery of fertility after removal, the impact of price, and the cost-benefit ratio of intrauterine devices. It also addresses the barrier that results from possible rejection of intrauterine devices by women owing to misconceptions.

Resumen

Los anticonceptivos reversibles de larga duración o LARC (por sus siglas en inglés Long-Acting Reversible Contraception) son métodos altamente efectivos aptos para la mayoría de las mujeres. El dispositivo intrauterino de cobre (DIU-Cu) y el hormonal, con levonorgestrel (DIU-LNG), pese a ser los anticonceptivos reversibles de larga duración más conocidos, son usados en España por el 6,9% de las mujeres en edad fértil que usa algún método. Se cree que esto responde a barreras al uso de dispositivos intrauterinos existentes entre los profesionales sanitarios que afectarían especialmente a mujeres jóvenes y/o nulíparas. En la presente revisión se aborda la evidencia disponible sobre los principales aspectos que generan una barrera al uso de los dispositivos intrauterinos. Estos aspectos incluyen las posibles dificultades durante su inserción y el dolor que esta puede causar, el riesgo de perforación durante la inserción o de expulsión una vez insertado, el efecto sobre la dismenorrea y el patrón de sangrado menstrual, el riesgo de embarazo ectópico o de enfermedad inflamatoria pélvica, la rapidez de recuperación de la fertilidad tras la retirada, el impacto del precio y la relación coste-beneficio de estos métodos. Igualmente, se aborda la barrera que puede suponer el posible rechazo al uso del dispositivo intrauterino por parte de la mujer a consecuencia de creencias erróneas.

Palabras clave:

Anticoncepción. Métodos anticonceptivos. Dispositivos intrauterinos. Levonorgestrel. Embarazo no deseado Planificación familar.

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INTRODUCTION

Unplanned pregnancy remains a serious problem in Spain, especially among young women (1). The main contraceptives used by this population include the condom and the pill (2), both of which depend to a large extent on adherence, thus reducing their effectiveness (3). Long-acting reversible contraception (LARC) refers to methods that are recommended by international medical societies for women who require effective contraception, including young women, provided that there are no specific contraindications (4,5). Since these methods do not depend on the active participation of the users, they are highly effective (low Pearl index or number of unplanned pregnancies per 100 women and year) (5) and provide long-lasting contraceptive protection for as long as the user wishes (6,7). Furthermore, most women can use this approach, even adolescents (8).

The copper IUD (Cu-IUD) and the hormonal device with levonorgestrel (LNG-IUD) are the most widely used methods in Spain and neighboring countries (9,10). However, the IUD is not very widely used in Spain, given that it is the preferred method in only 6.9% of fertile women who use a contraceptive method (2). This is in part due to barriers between health professionals that mainly affect young and/or nulliparous women. Young women make up a group with a high rate of unplanned pregnancies in Spain (11,12) and in which LARC could be particularly beneficial (5,13,14). Currently marketed approaches include various types of Cu-IUD device with different copper levels and sizes and 2 LNG-IUD devices with different hormonal levels and sizes (52 mg of LNG and 32 x 32 mm vs 13.5 mg and 28 x 30 mm). This variety enables better adaptation to the needs and preferences of the individual user while offering an opportunity to overcome barriers to use.

The present review addresses available evidence on the main barriers to the use of IUDs, many of which affect young and/or nulliparous women in particular. These barriers include possible difficulties during insertion and potential associated pain, the risk of perforation during insertion or expulsion after insertion, the effect on dysmenorrhea and menstrual bleeding pattern, the risk of ectopic pregnancy or pelvic inflammatory disease (PID), the speed of recovery of fertility after withdrawal, the impact of price, and the cost-benefit ratio. Similarly, we analyze the barrier to recommendation of these methods constituted by the possible rejection of the IUD by the user based on misconceptions.

BARRIER 1: INSERTION OF THE INTRAUTERINE DEVICE CAN BE DIFFICULT AND PAINFUL

One of the main barriers to more widespread use of IUDs is the belief that the insertion process is difficult and

painful, both during insertion and afterwards. This barrier is particularly important in the case of adolescent women, since they have a smaller endometrial cavity, and in the case of nulliparous women, since they have a narrower cervix (15).

Evidence on the difficulty of inserting an IUD in nulliparous women shows that the rate of failed insertion is very low. One study in Sweden and Finland found that insertion failed in 2.1% of cases (16); this finding was similar to that reported from a subsequent study in Sweden (2.7%), where insertion was performed mainly by midwives (17). Insertion was considered easy in 85% of cases in the first study and in 72% of cases in the second (16,17).

Few data are available to compare pain during insertion in nulliparous women and in women who have undergone vaginal delivery. In a study of 2,019 women who received their first Cu-IUD, pain was generally mild, although somewhat more severe in nulliparous than in multiparous women (mean, 2.7 cm vs 1.9 cm, respectively, on a 10-cm visual analog scale) 18).

At present, smaller IUDs, in which the insertion tube is smaller in diameter, could go some way to overcoming the fear of a difficult or painful insertion. This aspect is reflected in the results of a phase II trial comparing the efficacy and safety profile of a larger LNG-IUD with a higher hormonal load (32 x 32 mm, 52 mg; Mirena®, Bayer) with the smaller size and lower hormonal level of a currently marketed device (28 x 30 mm, 13.5 mg; Jaydess®, Bayer) and another LNG-IUD of the same size but with an intermediate hormonal level (19.5 mg, not marketed). Overall, 98.5% of insertions were successful at the first attempt. The researchers classed the insertion as easy in 94.0% of those women who used the 13.5-mg/19.5-mg device, compared with 86.2% of those who used the 52-mg device (p < 0.001). In the case of the 13.5-mg/19.5-mg device, 72.3% of the women felt that the insertion was not painful or that it caused mild pain compared with 57.9% of those who used the 52-mg device (19). The 52-mg device is currently marketed in Europe as Evoinserter™, which has an insertion tube with a smaller diameter. A phase III study that evaluated the efficacy and safety profile of the 13.5-mg and 19.5-mg devices found that 99.5% of insertions were successful and that 89.6% were considered easy (20) (94.5% in women who had had a vaginal delivery vs 84.2% in nulliparous women) (21). A study of the 13.5-mg device in adolescents (12-17 years) showed that insertion was successful in 99.7% of cases. The insertion was considered easy in 94.4% and painless or moderately painful in 89% (22).

In addition to the size of the IUD, the experience of the health professional with insertion is essential, since it has been shown that the initial degree of difficulty perceived diminishes with experience (20,23-25). As for the effect of pharmacological measures on insertion-related pain, a review showed that evidence supporting this approach

was lacking (26). Nevertheless, while misoprostol has not proven able to reduce the pain associated with insertion, it has been shown to make the procedure easier (27).

BARRIER 2: THERE IS A RISK OF PERFORATION DURING INSERTION OF THE INTRAUTERINE DEVICE

The risk of perforation during insertion of an IUD is very low (~1 of every 1,000 insertions) (28,29), with no differences between the 2 types of IUD (29). The fear of perforation is greater in nulliparous women owing to the smaller size of their uterine cavity and greater resistance of the cervix to dilation. However, while scarce, evidence on the risk of perforation in nulliparous women shows that there is no greater risk with respect to women who have already given birth (17,21,30,31). In contrast, breastfeeding during insertion has been associated with a risk of perforation that is almost 6 times greater (29).

BARRIER 3: THE INTRAUTERINE DEVICE CAN BE EXPELLED AFTER INSERTION

The risk of an IUD being expelled after insertion is low: 1 in every 20 women in 5 years (28). Available annual rates do not exceed 6%(23, 30-33). While the risk of expulsion is thought to be greater in nulliparous women, current evidence does not support this belief (23, 32-37). The Cu-IUD is associated with a greater risk of expulsion than the LNG-IUD (33), especially in nulliparous women (38). A phase II study that compared LNG-IUD of different sizes and hormonal levels found the expulsion rate at 36 months to be 1.6% for the 52-mg device and 0.4% for the 13.5-mg device (19). In a phase III study, the cumulative rate of expulsion for the 13.5-mg device at 3 years was 4.6% (20).

BARRIER 4: INTRAUTERINE DEVICES CAUSE DYSMENORRHEA

A limited number of women (< 10%) may experience episodes of dysmenorrhea when using contraceptives, including IUDs, although these are usually transient and moderate (39-43). The possibility of dysmenorrhea advises against using the IUD in women who already have the condition, although dysmenorrhea is not normally a contraindication for use (39,41,44).

Available evidence indicates that because of their hormonal level, LNG-IUDs may help to relieve dysmenorrhea. At the end of the phase II study (3 years) comparing the LNG-IUDs mentioned above, the percentage of women without dysmenorrhea increased from 49.9% to 82.0% with the 13.5-mg device and from 43.7% to 83.7% with the 52-mg device (19). A study of adolescent women using

the 13.5-mg device showed that the percentage without dysmenorrhea increased from 38% to 62% at the end of the first year (22). This effect seems to be based on anti-proliferative action, induction of glandular atrophy, and decidualization of endometrial tissue by LNG, all of which considerably reduce bleeding (45). This beneficial effect cannot be extrapolated to the Cu-IUD.

BARRIER 5: INTRAUTERINE DEVICES LEAD TO CHANGES IN MENSTRUAL BLEEDING PATTERN

The change in bleeding pattern after insertion of an IUD is very important, since it is one of the main reasons a user discontinues the method (5,6). The effect on the bleeding pattern is different for both types of IUD. The adverse effects of the Cu-IUD include intermenstrual bleeding during the first month and a moderate increase in the intensity and duration of bleeding (46). In contrast, use of the 52-mg device is associated with a gradual reduction in menstrual bleeding to the extent that at 6 months, 25% of women presented some degree of spotting and 44% amenorrhea (47).

The bleeding pattern should be evaluated before inserting an IUD. It is also important to determine whether the woman experiences heavy menstrual bleeding (blood loss >80 mL per cycle), since this affects the choice of device. The 52-mg device has been the treatment of choice for heavy bleeding for more than a decade (48,49). The number of days of bleeding and spotting decreases and the frequency of amenorrhea increases with the duration of use (maximum 3 years) of the 13.5-mg device (Fig. 1) (19). However, the frequency of amenorrhea after 1 year with the 13.5-mg device is lower than that observed with the 52-mg device, ranging from 2.7% to 12.7% and from 5.9% to 23.6%, respectively, measured at the second and last 90-day reference period (p=0.012) (19).

Changes in bleeding pattern have an important effect on the degree of satisfaction with the method used. Amenorrhea can be seen positively (no menstruation-associated discomfort) (50) or negatively (loss of femininity or fertility or the possibility of pregnancy) (51). In the phase III study with the 13.5-mg device, most of the women who used it (76.4%) were satisfied or very satisfied with their bleeding pattern, and only 4.7% discontinued the method because of changes in bleeding pattern at the end of the third year (20).

BARRIER 6: INTRAUTERINE DEVICES INCREASE THE RISK OF ECTOPIC PREGNANCY

The risk of ectopic pregnancy is yet another major concern on the part of health professionals when

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recommending IUDs (15). Of the infrequent pregnancies that do occur in IUD users, a high proportion are ectopic (6% vs 1.4% in women who do not use contraceptives) (5). The risk increases in inverse proportion to the copper or hormone level (52-55). Therefore, although the relative risk of an ectopic pregnancy is greater, the absolute risk is very low (1/1,000 users in 5 years) owing to the high efficacy of the method (5). Table I shows the different rates for ectopic pregnancy compared with oral contraception or not using contraception (45). A history of ectopic pregnancy does not contraindicate use of an IUD (8).

BARRIER 7: INTRAUTERINE DEVICES CAN CAUSE PELVIC INFLAMMATORY DISEASE

Infection by *Chlamydia trachomatis* is the most common sexually transmitted infection in Europe and the main cause of PID, which can lead to loss of fertility. There is a belief that inserting an IUD, regardless of the type, carries a permanent risk of PID. This belief particularly affects nulliparous women (15,56), especially if they are single or have multiple sexual partners (56), thus indicating that this fear is founded more on possible risky sexual behaviors than on greater susceptibility to PID.

A review of clinical trials on IUDs by the World Health Organization (WHO) has shown that the global incidence of PID among the 22,908 insertions and 51,399 women-years of follow-up included in the trials was 1.6 cases per 1,000 women-years of use (57). After adjusting for confounders, the risk of PID was found to be 6 times greater during the first 20 days after insertion, whereas it was low and constant during the 8 years of follow-up (57). This suggests that the pathogenesis of PID in the first 20 days after insertion is associated with the transmission of pathogenic bacteria (*C. trachomatis, Neisseria gonorrhoeae*) that cause asymptomatic infections when the device is fitted. Therefore, it is important to identify signs of vaginitis or cervicitis and to analyze the presence of pathogens before fitting

Table I.Rate of ectopic pregnancies with different contraceptive methods

	Ectopic pregnancies/100 women- years
LNG-IUD	0.02-0.045
Oral contraceptives	0.05
DCu-IUD	0.25
No methods	1.2-1.6
No methods (25-34 y)	7.5-10.6

Adapted from Gutiérrez et al. 2014 (45).

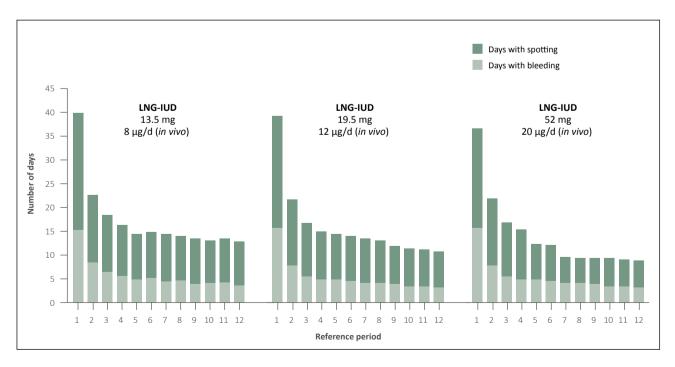


Figure 1. Mean number of days with menstrual bleeding or spotting by 90-day reference period for 3 years using the LNG-IUD 13.5 mg (reference periods 1-12). Adapted from Gemzell-Danielsson et al. 2012 (19). Reproduced with the authors' permission. Cu-IUD, copper intrauterine device; LNG-IUD, intrauterine device with levonorgestrel.

the device in women at a high risk of sexually transmitted infections, even if they do not present symptoms (58,59). The IUD can be inserted on the same day, without waiting for test results. If the test result is positive, treatment can be initiated with the IUD already fitted (59). In any case, a recent systematic review (2016) of 2 studies in which an IUD was fitted in women with positive results for both pathogens on insertion showed that the rate of PID was not greater than that of women who opted for other methods (60).

A study performed over 3 years in more than 2,500 users of the Cu-IUD or LNG-IUD revealed that the cumulative rate of PID with the Cu-IUD was similar to that of women who did not use the PID, whereas with the LNG-DIU (52 mg) it was even lower (2.0 vs 0.5; p < 0.013) (61). This result indicates that the LNG-IUD would have a protective effect on the development of PID. This effect could be due to its mechanism of action, so that thickening of the cervical mucus, which hampers the passage of sperm cells to the uterus, would also hamper the passage of bacteria (61).

BARRIER 8: WE DO NOT KNOW HOW LONG IT TAKES TO REGAIN FERTILITY AFTER WITHDRAWAL OF THE INTRAUTERINE DEVICE

Despite including a limited number of women, studies that have analyzed the impact of withdrawal of the IUD on fertility consistently show that fertility is recovered quickly and effectively (62). The studies also show that the rate of pregnancy after withdrawal is generally high and similar to that of the general population and that the causes of infertility are the same. Recovery of fertility is quick, even in women whose IUD was withdrawn owing to complications. The birth rate was shown to be high. In addition, normal results were recorded for preterm births, birth weight, and sex ratios in newborns (62).

A study of 2,841 women using contraceptives showed that the long-term use of combined oral contraceptives, injectable contraceptives, or Cu-IUD has a negative effect on fertility (time taken to become pregnant), which depends on the duration of use. In contrast, the progestin pill alone or the LNG-IUD 52-mg device had no significant effect: all of the users of the LNG-IUD whose device was withdrawn owing to the desire to become pregnant became pregnant within 1 month (63). The effect with the Cu-IUD on fertility was also demonstrated in a retrospective study performed in 2013. The authors analyzed 1,770 Chinese women—some of whom were older (mean age, 37.3 (5) years; range, 21-53 years) who had lost children in the 2008 earthquake and who had opted for withdrawal of the Cu-IUD in order to become pregnant. The results showed that, even though the rate of pregnancy after withdrawal was high (80.1%), it fell in inverse proportion to time with the Cu-IUD to

stand at 89.8% in those who had used the device for under 5 years and from 81.1% and 75.2% in those who used it, respectively, for 6-10 years and >10 years. Of those who conceived, 88% did so before the end of the first year (64).

Studies carried out in users of the 52-mg device showed that after withdrawal, the endometrium recovers rapidly, ovulation is re-established, and fertility remains unchanged (65,66). The rate of pregnancy at 2 years was similar to that of the general population (86.6%), and 96% of women became pregnant during the first year (65). The time using the LNG-IUD did not affect the subsequent rate of pregnancy (66).

A review of 17 prospective studies that provided data on the rate of pregnancy after discontinuation of the contraceptive method showed that after use of oral contraceptives or the 52-mg device, the pregnancy rate at 1 year was 79-96%, whereas with the Cu-IUD it was 71-91%. These rates are similar to those reported after discontinuation of barrier methods and to those reported in women who did not use contraception. No increase in complications associated with pregnancy or adverse fetal outcomes was reported (67).

BARRIER 9: INTRAUTERINE DEVICES ARE EXPENSIVE

Although the initial cost of the IUD and its insertion is higher than that of a short-term method, the cost of the IUD diminishes with each year of use, since, once inserted, it requires no additional expenditure. According to the National Institute for Health and Care Excellence (NICE), the 4 LARC methods are more cost-effective, even after 1 year of use, than short-term methods such as combined oral contraceptives. Of the LARC methods used, IUDs and implants are more cost-effective than injectable methods (5).

A study of 1,000 women aged 20-29 years carried out in 2015 in the USA compared the cost-effectiveness of not using any contraceptive method, using LARC (Cu-IUD, LNG-IUD 52 mg, or implant), or using a shortterm method (oral contraception, vaginal ring, patch, injectable contraceptive) over 5 years. The authors found that the Cu-IUD and LNG-IUD had to be used for at least 2.1 years for them to generate savings with respect to the use of short-term methods and 3 years with respect to condoms (68). Figure 2 shows the costs of each option studied. A similar study comparing the cost-effectiveness of LNG-IUD 13.5 mg with that of the same short-term methods in 1,000 women aged 20.29 years over 3 years showed that the former resulted in fewer unplanned pregnancies (64 vs 276) and a lower total cost (US\$1,283.5 vs US\$1,862.6), with a saving of 31% over the 3 years(69).

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Table II.

Recommendations for improving the information provided to women for each of the barriers to using an IUD

1. Insertion of the IUD can be difficult and painful

- Provide the patient with detailed information on the insertion procedure: time, preparation, potential discomfort/pain during and after insertion, time to recovery of activities of daily living.
- Quantify perceived pain in comparison with the patient's experience (period pain, placement of piercings, etc).
- Provide positive information: tell the patient about the high percentage of successful insertions, as well as about women who do not feel pain or in whom pain is mild or moderate.
- Avoid negative expressions such as "Only a small percentage of women feel pain" or "The first insertion fails in only a small percentage of women".
- Make every effort to relieve potential anxiety. Provide measures for managing pain if it arises.

2. There is a risk of perforation during insertion of the IUD

- Be positive when informing the patient about the low frequency of perforation.
- Dispel the idea that perforation is more frequent in nulliparous women.
- Indicate warning signs that are suggestive of perforation and provide guidelines.

3. The IUD can be expelled after insertion

- Be positive when informing the patient about the low frequency of expulsion.
- Dispel the idea that perforation is more frequent in nulliparous women.
- Indicate warning signs that are suggestive of expulsion and provide guidelines.

4. IUDs cause dysmenorrhea

- When taking the history and providing advice on contraception, ask the patient about period pain and her perception of how this affects her activities of daily living and quality of life.
- Inform the patient that in addition to the effectiveness of this method, the LNG-IUD can lead to a marked improvement in pain associated with menstruation.
- Explain in a comprehensible way how this effect is achieved.

5. IUDs lead to changes in menstrual bleeding pattern

- Together with the patient, evaluate the bleeding pattern before insertion of an IUD.
- Explain the bleeding pattern that is characteristic of each type of IUD.
- Together with the patient, analyze the reasons for and benefits of reducing bleeding and amenorrhea.

6. IUDs increase the risk of ectopic pregnancy

- Provide advice on the effectiveness of all types of contraception.
- Always inform the patient about the risk of ectopic pregnancy in absolute terms and compare the rate of ectopic pregnancy with the IUD, other contraceptive methods, or no contraceptive methods.
- Indicate warning signs that are suggestive of ectopic pregnancy and provide guidelines.

7. IUDs can cause pelvic inflammatory disease

- Take a clinical history and perform a physical examination to rule out signs and behaviors that point to a high risk of sexually transmitted infection.
- Inform the patient about routes of contagion by sexually transmitted diseases and advise her to combine the IUD with condoms in order to prevent infection.
- Indicate warning signs that are suggestive of pelvic inflammatory disease and provide guidelines.

8. We do not know how long it takes to regain fertility after withdrawal of the IUD

- Inform the patient about the immediate recovery of fertility after withdrawal of the IUD.
- Provide appropriate information on the useful life of each device and of the option to withdraw it before the end of the useful life.
- Provide guidelines on withdrawal of the IUD:
 - If contraception is required, begin immediately.
 - If the patient wishes to become pregnant, take preconception measures.

9. IUDs are expensive

- Provide advice on all contraceptive methods irrespective of the woman's financial situation.
- Inform the patient about the cost of each method over comparable time periods (annual cost, 3 years, 5 years).
- Together with the patient, analyze the costs associated with the use of each method:
 - Costs associated with visits to the doctor.
 - Costs associated with the use of sanitary napkins or other hygiene methods.
 - Time taken and frequency of visiting the doctor/pharmacy.
 - Costs associated with the use of analgesia (where applicable).

BARRIER 10: WOMEN ARE UNWILLING TO USE THE INTRAUTERINE DEVICE

The lack of knowledge about the various contraceptive methods among women, which is the result of inadequate sex education, encourages misconceptions about contraceptives in general or about specific methods in particular. The negative attitudes generated lead some women not to use any method or discontinue/change their current method, thus causing the recommendation to be passed on to other women (70,71).

Advice on contraception by health professionals and the way information is presented have been shown to play a key role in the decision taken by the woman (72-74). Advice on contraception is also relevant, since the user's satisfaction with the method chosen and its eventual success depend on adequate knowledge and perception of the method (5). Women who do not know the effectiveness and safety of LARC, women who do not receive appropriate information, and women with misconceptions about the various methods cannot use this approach as a contraceptive method, thus increasing the possibility of them using less effective methods. Several studies have shown that once a woman has heard about LARC methods, she is interested in learning more about them (75-78).

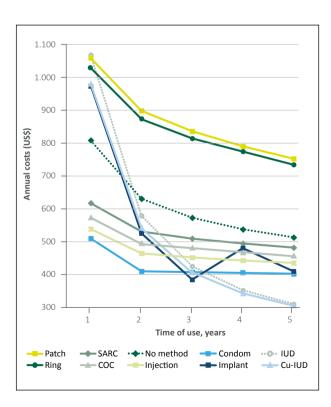


Figure 2. Annual costs of the contraceptive method. Reproduced with the authorization of Trussell et al. 2015(68) COC, combined oral contraceptive; Cu-IUD, copper intrauterine device; LNG-IUD, uterine device with levonorgestrel; SARC, short-acting reversible contraception.

Women, even adolescent and nulliparous women, should be informed that LARC is the best approach to contraception in most cases. Various international societies recommend informing users about LARC when advice on contraception is provided, even if the potential user requests or shows a preference for another method (4,28). Advice should include the advantages of LARC methods, namely, their high effectiveness regardless of motivation and adherence, good continuation rates, and the high degree of satisfaction among users. It should be highlighted that the methods are reversible and that, when they are withdrawn, fertility is regained quickly. Similarly, the methods are cost-effective and have few contraindications (5,79). We must counter misconceptions about IUDs, many of which are influenced by the beliefs of the health professional, probably owing to the negative attitude of the professional toward the use of the IUD, especially in young and nulliparous women. Table II presents a series of recommendations for health professionals to help them provide appropriate advice on each of the barriers to the use of the IUD.

In order to favor use of the IUD, guidelines recommend facilitating insertion on the day the patient seeks advice on contraception where possible and if pregnancy can be reasonably ruled out (5,79).

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