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Safety and comfort of levonorgestrel-releasing intrauterine device (Jaydess): Results of a Spanish population survey.

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ABSTRACT Objective. To assess the safety, comfort and satisfaction with the use and continuation of LNG-IUS in our population. Material and method. A prospective observational study conducted at a private clinic of gynecology, obstetric and reproductive medicine services. All healthy women aged 18-40 years old with regular menses requesting contraception were recruited. Participants who decided to use the LNG-IUS were included. A survey was given and complimented at 1 week, 1 month, 6 months and a year after placement of the LNG-IUS. A different survey was filled in case of retirement of the LNG-IUS. Results. A total of 114 women participated in the study. After a whole year of use, 95% of women were satisfied of choosing the LNG-IUS as their contraceptive method and more than 90% of all women stated that they wouldn't choose other contraceptive method with a 95% of women willing to recommend its use. Conclusion. The LNG-IUS is a good and safety option for contraceptive method in women despite their parity and age.

KEYWORDS : IUD safety; intrauterine device system; levonorgestrel-releasing intrauterine device; LNG-IUS comfort.

1. Introduction

Intrauterine contraception is convenient, safe and highly efficacious, and is recommended as a first-line option for all women, including adolescent and nulliparous women. It is available as either copper-containing intrauterine devices (CU-IUDs) or a levonorgestrel intrauterine system (LNG-IUS) .

The Mirena LNG-IUS has been the only intrauterine system licensed available in Spain until recently. Since 2013, Jaydess has been in the market and it has shown good results.

Jaydess differentiates from Mirena in levonorgestrel content (13.5 mg vs 52 mg, respectively), years of contraceptive use (3 years vs 5 years, respectively), a smaller frame, a narrower inserter tube, and other characteristics and effects .

The effectiveness of Jaydess has been demonstrated in Phase II and Phase III studies that showed good Pearl indexes (which measures the effectiveness of a birth control method) and low Insler scores (cervical mucus score) .

Despite lower serum levels of LNG with Jaydess (average, ~8 g/24 hours during the first year), there is no evidence that suggests any clinical significant advantage in terms of side effects. What studies have shown in favor of Jaydess, is a high overall user satisfaction rate in adolescents (83.9% at 12 months) and adult women (95% at the end of 3 years) .

Because of being a relatively newly contraceptive method, we conducted this survey to acknowledge the safety, comfort and satisfaction with the use and continuation of Jaydess in our population.

2. Materials and methods.

This was a prospective observational study conducted at a private clinic of gynecology, obstetric and reproductive medicine services. Local ethics committee approved the survey. All participants were provided written informed consent and guarantied an anonymous participation.

All healthy women aged 18-40 years old with regular menses requesting contraception were recruited. Participants who decided to use the LNG-IUS were included and they must previously have a complete clinic history and physical examination with an ultrasound scan to rule out any condition/pathology that would contraindicate the use of an intrauterine system. Women were excluded if they were known or suspected to be pregnant, were lactating, or had a vaginal delivery, Cesarean section, or abortion within 6 weeks before screening. Other exclusion criteria were: a history of ectopic pregnancy; distortion of the uterine cavity (due to fibroids), abnormal uterine bleeding of unknown origin; acute or history of recurrent pelvic inflammatory disease; or any lower genital tract infection not treated.

Only two physicians were responsible to the insertion of the LNG-IUS in all of the participants and all women were instructed to take either 600 mg of ibuprofen and/or 1000 mg of paracetamol 1 hour prior to the procedure. Up to three placement attempts were permitted; if the third attempt was unsuccessful, the participant was withdrawn from the study. The study lasted 1 year since LNG-IUS placement.

Participants had a total of seven scheduled visits to the clinic: a screening visit, placement visit, and five visits at months 1, 3, 6, 9 and 12, after placement. A survey was given and complimented at 1 week, 1 month, 6 months and a year after placement of the LNG-IUS. A different survey was filled in case of retirement of the LNG-IUS.

Satisfaction was assessed using five-point Likert-type scales and was taken from the most recent survey received from each subject for both continuers and discontinuers. The electronic medical record was used to clarify subjective data when necessary.

Data were analyzed using Microsoft Excel and GraphPad software. We used descriptive statistics and for categorical data, Fisher's exact test was performed using a $p<0.05$ to determine significance.

3. Results.

A total of 114 women participated in the study (see table 1). All women completed at least three study surveys and 112 completed the whole study. Mean age was 32.63 (range 26-40) years. More than 86% of women had completed professional or degree studies and the rest had finished compulsory education. Race/ethnicity was recorded as a hundred percent Caucasian women

Table 1. General characteristics of women enrolled in the study.

Characteristics		n
Number of participants		114
Age in years		32.63 (26-40)
Body mass index		23.03 ±
Parity	Nulliparous	48 (42.10%)
	Multiparous	66 (57.90%
Civil status	Married	90 (78.94%)
	Divorced	12 (10.52%)
	Separated	6 (5.27%)
	Single	6 (5.27%)
Grade of studies	Compulsory studies	15 (15.8%)
	Professional degree	39 (31.56%)
	College or above	60 (52.64%)
Health insurance	Yes	105 (92.10%)
	No	9 (7.9%)

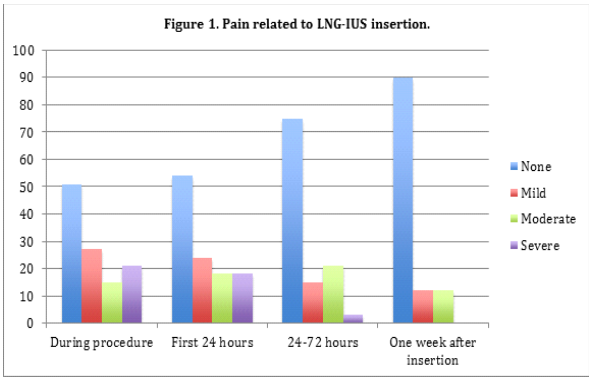
3.1. Insertion visit and a first week visit.

The majority of women felt very well informed (55.26%) and well informed (23.68%) for the advantages and disadvantages of LNG-IUS insertion leaving around 21% that responded neutral (see table 2). Symptoms from pre-medication (ibuprofen and/or paracetamol) were relatively infrequent with a 10.52% reporting mild lightheadedness and nausea, and another 10.54% more severe symptoms (see table 2).

Table 2. Pre-insertion of LNG-IUS.

Data		n (%)
Informed	Very well informed	63 (55.26)
	Well informed	27 (23.68)
	Neutral	24 (21.06)
	Little informed	0
	None information	0
Symptoms from pre-medication (lightheadedness and/or nausea)	Severe	12 (10.54)
	Moderate	0
	Mild	12 (10.54)
	None	90 (78.94)

For pain symptoms related to insertion see Figure 1. The majority of women reported none or mild pain during insertion (68.41%) and none or mild lightheadedness and nausea (76.3%). Sixty-eight percent of women reported none or mild pain in the first 24 hours and almost seventy-nine percent within the next 72 hours. Around 90% of women (89.47%) felt none or mild pain within the first week of insertion.



3.2. First month after insertion.

After one month of LNG-IUS insertion, more than a half of women reported irregular periods (63.15%) with around 70% indicating less flow, spotting or even no menstrual flow. Only 9% of those women used another contraceptive method but half of these patients used condoms because of risk for sexually transmitted diseases. Almost 40% of women reported mild cramps during their period and only 21% indicated pain with intercourse.

3.3. Sixth month after insertion.

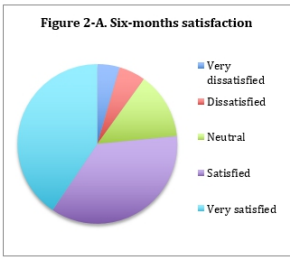
More than a half women reported regular periods after six months of use with only 10% indicating heavy bleeding. Seven women needed combined oral contraceptives because of spotting and cramps during period reduce to less than 30% of patients. Only 13% reported pain during intercourse.

3.4. One year after insertion.

Three women discontinued the LNG-IUS because of heavy bleeding leaving only a 7% reporting this symptom in the survey. Sixty-one percent of women reported regular menstrual periods after one year of LNG-IUS use. Less than a 9% used another contraceptive method but more than a half of them in order to prevent sexually transmitted diseases.

3.5. Satisfaction.

After six-months of use over 75% women reported to be "very satisfied" and "satisfied" for choosing the LNG-IUS as their contraceptive method (Figure 2-A). Less than 10% referred dissatisfaction and almost 90% of women wouldn´t choose another contraceptive method.



After a whole year of use, 95% of women were satisfied of choosing the LNG-IUS as their contraceptive method (figure 2-B) and more than 90% of all women stated that they wouldn't choose other contraceptive method with a 95% of women willing to recommend its use.

4. Discussion.

Our study contributes to the premise that intra-uterine contraception is safe and well tolerated not only in multiparous women but in nulliparous as well. Also, we obtained important information about experiences of women related to: the insertion procedure; one, six and 12 months of IUD use; that can be used for patient and provider information and education.

Our sample size is relatively small, but compared with the overall experience in other clinics in Spain; it provides a good estimation and representation of the women in our country. Our response rate was excellent and we thought this is due to the fact that all these women are regular patients in our clinic and it is also resulting in the majority having a private health insurance.

Overall the insertion procedure was well tolerated. There are some studies reporting a widely ranging pain scores from 2.7 to 6.8 out of 10 in nulliparous women (Allen, Carey, Raker, Goyal, & Matteson, 2014; Brown & Trouton, 2014; Dijkhuizen et al., 2011; Espey et al., 2014). These variations can be attributed to a variation of pain scores and are frequently inconsistent between populations (Hall & Kutler, 2016). We assessed the pain with categorical variables and not only on the day of the procedure but a complete week after it. Even though we didn't have any comparison or control, literature has

shown that there is no intervention that has been effective in reducing pain during IUD insertion [misoprostol (Espey et al., 2014; Ward, Jacobson, Turok, & Murphy, 2011), topical lidocaine (Allen, Raker, & Goyal, 2013; A. L. Nelson & Fong, 2013), ibuprofen (Hubacher et al., 2006)] so we attributed our relatively lower pain scores to: a) parity; and b) size of the IUD when compared to copper IUD.

When assessing effectiveness, a Phase III RCT including 1432 Jaydess users, has demonstrated a Pearl index of 0.41 (95% CI 0.13-0.96) at 1 year and a cumulative Pearl index after 3 years' use of 0.33 pregnancies per 100 woman-years (95% CI 0.16-0.60) (A. Nelson et al., 2013). The Kaplan-Meier estimate for the cumulative failure rate of Jaydess over 3 years was 0.9% (A. Nelson et al., 2013). We didn't have any pregnancies reported, but our sample is relatively small and our follow-up was limited to one year only.

The most common reasons for method-related discontinuations of the LNG-IUS are usually unacceptable bleeding patterns and hormonal side effects including: acne, mood changes and a decreased libido (Hall & Kutler, 2016). We found that the reason for discontinuation in our population was attributed to bleeding patterns. However, our findings showed that more than a half of women reported regular menstrual patterns after six-months of use, and more than 60% after a whole year of Jaydess use. This is similar to what has been reported by other authors in that there is a lower rate of amenorrhea in Jaydess users when compared with other methods such as Mirena (Gemzell-Danielsson et al., 2012). When a whole year has passed, the spotting or abnormal bleeding seemed to reduce and this could be the reason for a high satisfaction among users.

Jaydess is good contraceptive option because of many advantages: a) it is a long-acting reversible contraceptive; b) although amenorrhea may occur, Jaydess may appeal to women who prefer to have regular bleeding patterns; c) the smaller dimensions of Jaydess when compared to other IUD may conferred an advantage in terms of easy fitting and reduced pain scores associated with insertion.

Our study contributes to expand the literature regarding safety and comfort for the LNG-IUS. If providers and patients are better informed about symptoms and experiences, not only in terms of the insertion procedure but also during months of use, it is easy to help counseling, take a decision and, most important, to have a good overall satisfaction that provides higher continuation rates.

5. Conclusion.

Our survey indicates that the LNG-IUS Jaydess is a good and safety option for contraceptive method in women despite their parity and age. It is safe, effective and well tolerated and has higher satisfaction and continuation rates.

6. REFERENCES:

1. Allen, R. H., Carey, M. S., Raker, C., Goyal, V., & Matteson, K. (2014). A prospective cohort study of pain with intrauterine device insertion among women with and without vaginal deliveries. J Obstet Gynaecol, 34(3), 263-267. doi:10.3109/01443615.2013.868424
2. Allen, R. H., Raker, C., & Goyal, V. (2013). Higher dose cervical 2% lidocaine gel for IUD insertion: a randomized controlled trial. Contraception, 88(6), 730-736. doi:10.1016/j.contraception.2013.07.009
3. Brown, W. M., & Trouton, K. (2014). Intrauterine device insertions: which variables matter? J Fam Plann Reprod Health Care, 40(2), 117-121. doi:10.1136/jfprhc-2012-100383
4. Committee on Adolescent Health Care Long-Acting Reversible Contraception Working Group, T. A. C. o. O., & Gynecologists. (2012). Committee opinion no. 539: adolescents and long-acting reversible contraception: implants and intrauterine devices. Obstet Gynecol, 120(4), 983-988. doi:10.1097/AOG.0b013e3182723b7d
5. Dijkhuizen, K., Dekkers, O. M., Holleboom, C. A., de Groot, C. J., Hellebrekers, B. W., van Roosmalen, G. J., . . . Helmerhorst, F. M. (2011). Vaginal misoprostol prior to insertion of an intrauterine device: an RCT. Hum Reprod, 26(2), 323-329. doi:10.1093/humrep/deq348
6. Espey, E., Singh, R. H., Leeman, L., Ogburn, T., Fowler, K., & Greene, H. (2014). Misoprostol for intrauterine device insertion in nulliparous women: a randomized controlled trial. Am J Obstet Gynecol, 210(3), 208 e201-205. doi:10.1016/j.ajog.2013.11.018
7. Gemzell-Danielsson, K., Schellschmidt, I., & Apter, D. (2012). A randomized, phase II study describing the efficacy, bleeding profile, and safety of two low-dose levonorgestrel-releasing intrauterine contraceptive systems and Mirena. Fertil Steril, 97(3), 616-622 e611-613. doi:10.1016/j.fertnstert.2011.12.003
8. Hall, A. M., & Kutler, B. A. (2016). Intrauterine contraception in nulliparous women: a prospective survey. J Fam Plann Reprod Health Care, 42(1), 36-42. doi:10.1136/jfprhc-2014-101046
9. Hubacher, D., Reyes, V., Lillo, S., Zepeda, A., Chen, P. L., & Croxatto, H. (2006). Pain from copper intrauterine device insertion: randomized trial of prophylactic ibuprofen. Am J Obstet Gynecol, 195(5), 1272-1277. doi:10.1016/j.ajog.2006.08.022
10. Melvin, L., Scott, J., & Craik, J. (2014). Jaydess(R) levonorgestrel intrauterine system. J Fam Plann Reprod Health Care, 40(3), 165-169. doi:10.1136/jfprhc-2014-100980
11. Nelson, A., Apter, D., Hauck, B., Schmelter, T., Rybowski, S., Rosen, K., & Gemzell-Danielsson, K. (2013). Two low-dose levonorgestrel intrauterine contraceptive systems: a randomized controlled trial. Obstet Gynecol, 122(6), 1205-1213. doi:10.1097/AOG.0000000000000019
12. Nelson, A. L., & Fong, J. K. (2013). Intrauterine infusion of lidocaine does not reduce pain scores during IUD insertion. Contraception, 88(1), 37-40. doi:10.1016/j.contraception.2012.12.009
13. Ward, K., Jacobson, J. C., Turok, D. K., & Murphy, P. A. (2011). A survey of provider experience with misoprostol to facilitate intrauterine device insertion in nulliparous women. Contraception, 84(6), 594-599. doi:10.1016/j.contraception.2011.03.011