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Original research article

One year quality of life measured with SEC-QoL in levonorgestrel 52 mg IUS users ☆

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Abstract

Objectives: The present study aims to prospectively evaluate quality of life (QoL) of women using 52-mg levonorgestrel intrauterine system (LNG-IUS) for contraception determined through the Sociedad Española de Contracepción (Spanish contraception Society) (SEC)-QoL, a questionnaire specifically designed to assess the impact of contraceptive methods on QoL of fertile women.
Study design: We conducted a prospective observational multicenter study of 201 reproductive age women who initiated the LNG-IUS for contraception. Sociodemographic and clinical data were collected at baseline and 12 months afterwards. Participants filled in the SEC-QoL questionnaire at both visits. SEQ-QoL scores range from 0 (*worst QoL*) to 100 (*best QoL*).
Results: Participants claimed an increased QoL 12 months after insertion in all five dimensions of SEC-QoL due to its high contraceptive efficacy and its capability to reduce other menstrual symptoms (e.g., heavy menstrual bleeding or dysmenorrhoea), overall exerting a positive impact on user's satisfaction. SEC-QoL general overall score went from a mean (S.D.) score of 46.3 (17.3) at baseline to 72.2 (14.8) 12 months afterwards ($p<.001$). Overall, 94.6% of women claimed having found additional benefits other than contraception. No pregnancies were reported during the 12 months of study duration, and only 14 women discontinued use of LNG-IUS (only two of them due to an adverse event), representing a continuation rate of 93%.
Conclusions: Women using LNG-IUS for contraception have an increased QoL after 12 months of use, demonstrated by the increased score in all dimensions of the SEC-QoL questionnaire.
Implications: The present study prospectively evaluated QoL of women using LNG-IUS for contraception through the SEC-QoL questionnaire. Participants claimed increased QoL 12 months afterwards, implying that women using LNG-IUS for contraception in usual clinical practise also benefit from the reduction of period-related symptoms, overall leading to very low discontinuation rates.

Keywords: Intrauterine system; Levonorgestrel; Quality of life; Contraception; SEQ-QoL questionnaire

1. Introduction

Levonorgestrel intrauterine system (LNG-IUS) exhibits a very low discontinuation rate and very good level of satisfaction within its users [1–3]. Particularly, several studies reveal that benefits associated to LNG-IUS are not only related to its contraception efficacy [4] but are also due to its capability to reduce other menstrual and premenstrual

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symptoms [5,6] which exert a negative impact on women's health-related quality of life (HRQoL) [7–10]. Given the benefit provided by LNG-IUS in the reduction of heavy menstrual bleeding (HMB), the National Institute for Health and Care Excellence (NICE) institute in the UK recommended it as first-line treatment for HMB in 2007 [11], and the Food and Drug Administration approved its use for this indication in 2009.

Several studies have been conducted to assess HRQoL in women using LNG-IUS to reduce HBM [12,13], as well as for women using it for contraception [14–16], in which HRQoL was assessed through generic questionnaires (i.e., EQ-5D or SF-36) [17].

However, to the best of our knowledge, there is a lack of studies aiming to determine the level of satisfaction and HRQoL of women using LNG-IUS for contraception, particularly, those in which HRQoL was assessed through questionnaires specifically designed for fertile women under contraception like the Sociedad Española de Contracepción (Spanish contraception Society)-quality of life (SEC-QoL) questionnaire [18].

In this context, the present study aims to assess the impact of 52-mg LNG-IUS used for contraception on HRQoL of women, after 12 months of use through the SEC-QoL questionnaire in Spain.

2. Material and methods

2.1. Study design

We conducted a prospective observational multicenter study of 201 reproductive age women who initiated the 52-mg LNG-IUS for contraception. The cohort included women aged from 18 to 49 who were recruited from 18 private gynaecological centres in Spain, after giving written informed consent. Women were eligible to participate in this study unless they (a) presented contraindications for LNG-IUS; (b) were using LNG-IUS for noncontraceptive purposes such as HMB; (c) had used any other kind of hormonal contraceptives 3 months prior to study inclusion; (d) were unable to fill in the study questionnaire; and (e) were participating in other clinical trials. The study was conducted following current Spanish regulations for post-authorization studies and was approved by the Spanish Agency of Medicine and Health Products and the Hospital *la Zarzuela* Research Ethic Committee.

The present study consisted of two visits: when starting use of LNG-IUS (baseline) and 12 months afterwards (final visit). Sociodemographic and clinical data were collected from medical charts or from the interviews conducted during the study visits. At baseline (when LNG-IUS was introduced), the following sociodemographic data were collected: age, level of education, employment status and marital status. Both at baseline and final visits, the following clinical data were collected: bleeding intensity, painful menstrual periods [measured through a visual analogue scale (VAS) ranging from 0: *no pain* to 10: *maximum pain*], menstrual and premenstrual breast symptoms and presence of non-contraception benefits from LNG-IUS (reduction of period-related symptoms, improvement of anaemia, improvement of skin and/or hair appearance, reduction of migraine episodes, others). Period-related symptoms were assessed on the basis of women's personal perception. In order to determine HRQoL evolution of included women, they were asked to fill in, both at baseline (straight after introducing LNG-IUS) and at final visits, the self-administered SEC-QoL questionnaire [18]: a specific HRQoL questionnaire for fertile women on contraception which consists of 19 items distributed in five dimensions: "social" (5 items), "menstrual symptoms" (4 items), "breast symptoms" (3 items), "psychological" (4 items) and "sexual" (3 items); each item allowing for five liker-type response choices (from "always" to "never" or from "totally agree" to "totally disagree", depending on the kind of statement). Overall scores were obtained by adding up the responses from the corresponding items, which were subsequently standardised to a scale ranging from 0 (*worst HRQoL*) to 100 (*best HRQoL*). In addition, at the final visit, women were asked about their general level of satisfaction with the method using a VAS graded from 0 (*not satisfied at all*) to 10 (*very satisfied*).

2.2. Sample size

Sample size was calculated in order to detect changes in terms of HRQoL measured through the SEC-QoL questionnaire at baseline and final visits. According to the validation study of the SEC-QoL questionnaire, in which women initiating contraception went from a mean (SD) score of 46.6 (17.8) to 57.0 (18.4) [18], a minimal important difference (MID), the smallest change in score at baseline and final visits required to be considered clinically relevant were established at 3.4 points. However, the SEC-QoL validation study included women using many different contraceptive methods, whereas in the present study, only women using LNG-IUS were included, thus a more conservative approach was considered for the sample size calculation. In this context, in order to detect changes ≥ 5 between scores reported at baseline and final visits, assuming a deviation of 18, a significance level of 0.05, a statistical power of 0.8 and at least 10% of dropouts, a minimum sample of 150 women was estimated.

2.3. Statistical analysis

All women fulfilling inclusion criteria were included in the analysis, except those who had not completed the SEC-QoL questionnaire at baseline. Women who discontinued the study and reason for discontinuation were also collected. A descriptive analysis of sociodemographic and clinical data and scores from the SEC-QoL questionnaire at baseline and final visits was conducted. Correlation between SEC-QoL results and sociodemographic and clinical variables was determined through the ANalysis Of VAriance