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First-Year Side Effect Rates in Nulliparous and Parous Levonorgestrel 52 mg Intrauterine System Users

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First-Year Side Effect Rates in Nulliparous and Parous Levonorgestrel 52mg Intrauterine System Users

INTRODUCTION (20)

We investigated the impact of parity on side effects during the first year after levonorgestrel 52mg intrauterine system (IUS) placement.

METHODS (99)

We evaluated data from the ongoing 10-year Phase 3 Liletta® study in which 1,714 women aged 16-45 years received an IUS. Subjects reported side effects during follow-up visit interviews. For this analysis, we only included women with at least one 28-day cycle of follow-up and excluded women using a levonorgestrel IUS in the month before enrollment. Side effects evaluated at six and 12 months included abdominal pain, acne, anxiety/panic issues, depression, diarrhea, dyspareunia, fatigue, gastritis/reflux, headache, mastalgia, mood changes, nausea or vomiting, orgasm/libido problems, pelvic pain, vaginal discharge/odor, and weight changes. We used Fisher's exact tests for all comparisons.

RESULTS (92)

The dataset included 931 nulliparous and 613 parous women. Over the first six and 12 months, the most common complaints were acne (158[10.2%] and 193[12.5%], respectively) and headache (87[5.6%] and 104[6.7%], respectively). Only acne differed by parity, being more common among nulliparous women at both six (112[12.0%] vs 46[7.5%], $P=.005$) and 12 months (134[14.4%] vs. 59[9.6%], $P=.006$). When evaluating only women who did not use combined hormonal contraception (CHC) in the month before enrollment, nulliparous ($n=445$) and parous ($n=414$) women had no significant difference in side effects at six or 12 months.

CONCLUSION/IMPLICATIONS (39)

Side effects did not differ by parity during the first year of levonorgestrel 52mg IUS use except acne reported more frequently by nulliparous than parous women. However, this difference may be more related to CHC discontinuation than IUS initiation.