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BLEEDING PATTERNS FROM MONTHS 60 TO 72 WITH USE OF A LEVONORGESTREL 52 MG INTRAUTERINE SYSTEM

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OBJECTIVE: Evaluate bleeding patterns during levonorgestrel (LNG) 52 mg intrauterine system (IUS) use beyond 5 years.

DESIGN: Prospective clinical trial.

MATERIALS AND METHODS: Nulliparous and parous women 16-45 years old received the Liletta® LNG 52 mg IUS in an IRB-approved multicenter trial to evaluate efficacy and safety for up to 10 years. Bleeding assessments after 24 months of IUS use occurred every 3 months, including subjective flow evaluation and how the bleeding compared to pre-insertion frequency or flow. For this analysis, we evaluated reported bleeding patterns (none, “just spotting,” irregular or regular), comparison of frequency or flow to baseline, and discontinuation for bleeding complaints over 3-month intervals beginning at 60 months (5 years) and then for the following year (months 63 to 72). We performed chi-square test for trend to evaluate changes in patterns over time.

RESULTS: The dataset included 707, 645, 563, 477 and 349 women with bleeding pattern reports for months 58-60, 61-63, 64-66, 67-69, and 70-72 at the time of the

data cut. The heaviest flow in the prior 3 months is reported in the Table. Amenorrhea rates remained around 40%, ranging from 39.1-43.2% (p=0.75). Most women reported their heaviest flow as none (amenorrhea) or spotting during each interval (69.8-72.6%, p=0.30). Approximately 90% of women (87.2-90.4%, p=0.58) reported their heaviest bleeding as none (amenorrhea), spotting, or light bleeding per interval. Among women with any bleeding, most reported spotting as the main pattern, ranging from 29.8-35.3% (p=0.41); the remainder reported the main pattern as irregular (6.4-7.7%, p=0.84) or regular (16.6-19.5%, p=0.52) during each interval. Approximately 1-1.5% of users reported frequency or flow worse than pre-insertion patterns and only 1 woman during months 58-60 and 1 during months 70-72 discontinued for a bleeding complaint considered an adverse event. Additionally, beginning after month 60, 1-2 persons per 3-month period discontinued because of reduced menstrual suppression.

CONCLUSIONS: Bleeding patterns remain consistent in LNG 52 mg IUS users from months 60 through 72 of use, with most women experiencing amenorrhea, spotting or light bleeding. Discontinuation for a bleeding complaint occurred in only 2/707 (0.3%) women during this period, and another 6 (0.9%) discontinued for reduced menstrual suppression. Providers and patients can be informed by this data that bleeding patterns remain favorable with use beyond 5 years.

	Heaviest flow in prior 3 months				
	Month 60 n=707	Month 63 n=645	Month 66 n=563	Month 69 n=477	Month 72 n=349
None	40.2%	40.8%	39.1%	43.2%	40.4%
Spotting	30.8%	31.8%	32.0%	26.6%	31.2%
Light	18.0%	17.8%	18.1%	17.4%	17.8%
Normal	9.2%	8.8%	9.2%	11.1%	9.5%
Heavy	1.8%	0.8%	1.6%	1.7%	1.1%