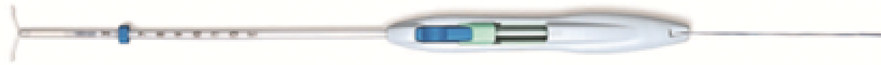
Relationship of obesity and intrauterine contraceptive expulsion



Lisa Harris, MD, PhD[1]; Angelina Gangestad, MD[2]; Paul Blumenthal, MD, MPH[3]; Melissa L. Gilliam, MD, MPH[4]; Jeffrey Jensen, MD, MPH[5]; Mitchell D. Creinin, MD[6]

[1]University of Michigan, Ann Arbor, MI; [2]Case Western Reserve University, Cleveland, OH; [3]Stanford University, Palo Alto, CA; [4]University of Chicago, Chicago, IL; [5]Oregon Health & Science University, Portland, OR; [6]University of California, Davis, Sacramento, CA

Introduction

Liletta®, a levonorgestrel 52 mg intrauterine system (IUS), is U.S. FDA approved for up to 6 years of use for contraception and is being investigated for up to 10 years of use.

Obese intrauterine contraceptive users have higher expulsion rates than non-obese users.

Objective

Investigate the association of increasing obesity and expulsion risk with levonorgestrel 52 mg IUS use.

Study Design

ACCESS IUS (**A C**ontraceptive **C**linical **E**fficacy and **S**afety **S**tudy of an **IUS**): a prospective, multi-center, Phase 3, open-label study at 29 U.S. sites.

- Entry criteria:
  - Age 16-45 years
  - Regular menstrual cycles (21-35 days when not using hormones; typical variation ≤5 days)
  - Sexually active, plan IUS as primary contraceptive
- No limits on weight, BMI or parity
- Total Liletta enrollment: n=1,751
- Successful placement: n=1,714 (97.9%)
- Follow-up visits scheduled at 1, 3, 6 and every 6 months thereafter during which Investigators confirmed IUS presence.

Study Analysis

- Study population for this analysis:
  - Body mass index (BMI) ≥30 kg/m^2
  - At least one follow-up contact after IUS insertion
- Evaluations:
  - Expulsion rates over time through 6 years in persons with BMI 30.0-39.9 kg/m^2 and ≥40 kg/m^2 using Fisher exact tests
  - Multivariable model to assess expulsion association in obese users (with BMI and parity as continuous variables); included BMI, Age, Race (white v. non-white), Ethnicity, Parity, Marital Status, History of Miscarriage, Baseline subjective heavy menstrual bleeding (HMB), Hormonal contraceptive use at enrollment

Results

Participant Characteristics

	Obese BMI ≥ 30 kg/m^2 N=431
BMI at enrollment (kg/m^2)	36.4 ±5.9
>40	92 (21.3)
Age at enrollment (years)	28.5 ±6.1
<25	125 (29.0)
25-45	306 (71.0)
Race	
White	297 (68.9)
Black	106 (24.6)
Other	28 (6.5)
Ethnicity	
Hispanic/Latina	73 (16.9)
Nulliparous	174 (40.4)
Marital status	
Never married	253
Married/ever married	178
History of Miscarriage	71 (16.5)
Baseline HMB	54 (12.5)
Contraceptive at enrollment	
Levonorgestrel IUS	42 (9.7)
Copper IUD	9 (2.1)
Implant	2 (0.5)
CHC	130 (30.2)
POP	11 (2.6)
Non-hormonal/Non-IUD	193 (44.8)
None	44 (10.2)

Data are presented as n (%) or mean ± standard deviation
BMI: Body Mass Index; IUD: intrauterine device; CHC: combined hormonal contraceptive; POP: progestin-only pill

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Expulsion rates

	Total N=431	BMI 30.0-39.9 kg/m^2 n=339	BMI ≥ 40 kg/m^2 n=92	P-value
Expulsion Rate (cumulative)				
One year	22 (5.1)	15 (4.4)	7 (7.6)	0.28
Six years	31 (7.2)	21 (6.2)	10 (10.9)	0.17

Multivariable Analysis No factors significant - 3 highest odds ratios presented:

Variable	N	Expulsion	Odds Ratio	Adjusted Odds Ratio
BMI at enrollment (continuous)				1.05 (95% CI 0.99-1.11)
30.0-39.9 kg/m^2	339	21 (6.2)	referent	
≥40.0 kg/m^2	92	10 (10.9)	1.85 (95% CI 0.84-4.07)	
Parity (continuous)				1.33 (95% CI 0.98-1.81)
Nulliparous	174	8 (4.6)	referent	
Parous	257	23 (8.9)	2.04 (95% CI 0.89-4.67)	
Baseline HMB (categorical)				
No	377	24 (6.4)	referent	referent
Yes	54	7 (13.0)	2.19 (95% CI 0.89-5.36)	2.09 (95% CI 0.82-5.33)

Conclusions

- Although obese levonorgestrel 52 mg IUS users experience higher expulsion rates than non-obese users, **we did not identify a significant difference in expulsion risk as BMI increases <u>when evaluating just obese women</u>**
- Baseline HMB, parity and ≥40.0 kg/m2 may be associated with expulsion among obese levonorgestrel 52 mg IUS users; studies with even more obese participants are needed to further evaluate these potential associations