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Endometrial safety with a low-dose intrauterine levonorgestrel-releasing system after three years of estrogen substitution therapy

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Abstract

Objective

To evaluate the pharmacodynamic effects of a novel intrauterine drug delivery system, FibroPlant-levonorgestrel (LNG), on the endometrium in 24 postmenopausal women using estrogen substitution therapy to suppress climacteric symptoms.

Design

A 3-year non-comparative prospective clinical trial.

Subjects

The treatment with the FibroPlant-LNG intrauterine system (IUS), releasing 14µg of LNG/day, was part of a regimen for estrogen substitution therapy (EST) in symptomatic postmenopausal women to prevent endometrial proliferation and bleeding. The majority of women received percutaneous 17β estradiol, 1.5 mg daily, or an equivalent dose by patch or orally, on a continuous basis.

Outcome measures

Menstrual pattern, endometrial histology and ultrasonographic evidence of endometrial suppression, after 3 years of use.

Results

The endometrial histology specimen showed profound endometrial suppression with glandular atrophy and stroma decidualization in all women. On transvaginal ultrasound, this corresponds with a thin endometrium (<5 mm) and clinically with a “bleed-free” menstrual pattern or amenorrhoea.

Conclusion

The results of this 3-year study in 24 postmenopausal women using EST suggest that the FibroPlant-LNG IUS is effective in causing strong suppression of the endometrium during the entire period of EST. Target delivery in the uterine cavity could be the preferred route of administering a progestin to oppose estrogen stimulation of the endometrium.