

REVIEW ARTICLE

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Should the Mirena intrauterine system be offered (unless contraindicated) to women presenting with postmenopausal bleeding at the time of endometrial sampling?

Nader Gad

ABSTRACT

Postmenopausal bleeding (PMB) is a common but potentially serious clinical presentation, with 5–10% of women ultimately diagnosed with endometrial carcinoma. Although most causes are benign, histological assessment remains essential, as imaging alone cannot reliably exclude premalignant or malignant pathology. Increasing evidence demonstrates that proliferative endometrium and endometrial hyperplasia carry measurable risks of progression to carcinoma, and that the levonorgestrel-releasing intrauterine system (LNG-IUS; Mirena) achieves high rates of histological regression while providing durable endometrial suppression. This review examines whether Mirena should be routinely offered, unless contraindicated, at the time of endometrial sampling in women presenting with PMB. The uterine causes of PMB, including atrophic endometrium, endometrial polyps, proliferative endometrium, endometrial hyperplasia with or without atypia, and endometrial carcinoma, are reviewed with particular emphasis on the effects of levonorgestrel released by LNG-IUS on endometrial proliferation and hyperplasia. Evidence demonstrates suppression of proliferative activity in most treated women and regression rates exceeding 90% in non-atypical hyperplasia and approximately 70–90% in atypical hyperplasia, with additional roles in temporizing management of selected early-stage carcinoma.

Cervical stenosis is a common finding in postmenopausal women. To obtain an endometrial biopsy, these women may require general anesthesia, cervical dilatation, and hysteroscopy. Under these circumstances, LNG-IUS insertion during the initial hysteroscopy would avoid women undergoing repeat procedures should progesterone treatment be required. Current evidence supports consideration of offering LNG-IUS insertion, unless contraindicated, at the time of endometrial biopsy in appropriately selected patients. This approach would combine diagnosis and treatment in women with proliferative endometrium and endometrial hyperplasia.

Keywords: Endometrial hyperplasia, LNG-IUS, Mirena, Postmenopausal bleeding, Proliferative endometrium

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INTRODUCTION

Postmenopausal bleeding (PMB) accounts for approximately 5–10% of gynecological consultations in postmenopausal women and mandates investigation due to the risk of endometrial cancer [1, 2]. Although most women presenting with PMB have a benign etiology, approximately 5–10% are diagnosed with endometrial carcinoma [1].

Standard care for women presenting with PMB includes transvaginal ultrasound for endometrial assessment. The majority of these women would also

require endometrial sampling. The women who require endometrial sampling include those with abnormally thickened endometrium measuring more than 4 mm, an irregular endometrial appearance, or cystic spaces. Women with an endometrial thickness of 4 mm or less but with persistent or recurrent bleeding as well as women at high risk for endometrial carcinoma, such as those with obesity, nulliparity, diabetes mellitus, Lynch syndrome and those on unopposed estrogen, tamoxifen or selective estrogen receptor modulators, also require endometrial sampling [2, 3].

The most recent update is the recommendation by the American College of Obstetricians and Gynecologists (ACOG) to perform both transvaginal ultrasound (TVUS) and endometrial biopsy as part of the initial evaluation of the endometrium. This is a change from prior guidance, which permitted the use of TVUS as an alternative to endometrial sampling in most patients, if the endometrial thickness was <4 mm. Due to the rising rates of endometrial cancer, the potential for a false-negative result on TVUS, and the presence of high-risk cancers (which often present with thin endometrium), ACOG now recommends both tests with few exceptions. The exceptions are the women who meet all the following criteria: a single episode of PMB, full visualization of the endometrium by TVUS, endometrial thickness of 4 mm or less, no strong risk factors for endometrial carcinoma, appropriate counseling that recurrence of PMB requires immediate reassessment, and no barrier for prompt attendance to the gynecology clinic if bleeding recurs [4].

The levonorgestrel-releasing intrauterine system (LNG-IUS) releases continuous levonorgestrel directly into the uterine cavity with minimal systemic absorption. Levonorgestrel induces decidualization of the endometrial stroma and suppresses endometrial glandular proliferation, causing glandular atrophy and thinning of the endometrium. It also downregulates endometrial estrogen receptors, thereby suppressing proliferative activity induced by estrogen. Levonorgestrel decreases mitotic activity, reduces endometrial vascularity, thereby creating a relatively inactive endometrium. These mechanisms of action explain how the LNG-IUS suppresses proliferative endometrium, induces regression of endometrial hyperplasia in most women, and, in selected women, may reduce progression of endometrial carcinoma [5–9].

This review evaluates whether the LNG-IUS should be considered for routine offering at the time of endometrial sampling in women presenting with PMB, unless contraindicated.

DISCUSSION

The differential diagnosis of PMB is less broad than that for abnormal bleeding in premenopausal patients, since the various causes of anovulation relevant to premenopausal women are not applicable after menopause. In a prospective study that included

454 postmenopausal women with uterine bleeding, the frequency of endometrial pathology was as follows: endometrial polyps (37.7%), endometrial atrophy (30.8%), proliferative or secretory endometrium (14.5%), endometrial carcinoma (6.6%), fibroids (6.2%), endometrial hyperplasia without atypia (2%), and endometrial hyperplasia with atypia (0.2%) [10].

Atrophic Endometrium

Endometrial atrophy represents one of the most common causes of PMB [2, 10]. Hypoestrogenism results in a thin, fragile endometrium prone to bleeding. The LNG-IUS is not required for isolated atrophic bleeding. However, it is not uncommon for an endometrium that appears atrophic during hysteroscopy to subsequently reveal endometrial proliferation, hyperplasia, or carcinoma on histological examination. If histological diagnosis confirms atrophic endometrium, the LNG-IUS may become clinically valuable in women planning systemic menopause hormone therapy (MHT), providing reliable endometrial protection against hyperplasia and carcinoma [11]. In women with confirmed atrophic endometrium who do not intend to use MHT, the LNG-IUS can be removed in the outpatient clinic. Pre-insertion counselling regarding this clinical possibility and shared decision-making are essential, especially in women at increased risk of requiring progestogen therapy.

Endometrial Polyps

It is uncommon for transvaginal ultrasound assessment to miss endometrial polyps; however, false-negative results may occur, particularly with small or focal lesions [2]. Polyps account for approximately 10–38% of PMB cases [2, 3, 10]. Although usually benign, malignant transformation occurs in 2–5% of postmenopausal polyps [3]. Following hysteroscopic polypectomy, the LNG-IUS suppresses endometrial proliferation and may reduce recurrence of polyps and subsequent abnormal bleeding [5, 6].

Proliferative Endometrium in Postmenopausal Women

Women presenting with PMB, where their endometrial biopsy reveals proliferative endometrium, are very likely to have relatively increased estrogen levels causing stimulation of the endometrium [1]. The proliferative endometrium may progress to endometrial hyperplasia or malignancy.

Long-term cohort data demonstrate that postmenopausal women with proliferative endometrium have a significantly increased risk of subsequent endometrial hyperplasia or carcinoma compared with women with atrophic endometrium. In a cohort with approximately 11 years of follow-up, progression to hyperplasia or cancer occurred in 11.9% of women with proliferative endometrium compared with 2.9% in women with atrophic endometrium; the incidence of

carcinoma alone was 5.8% versus 1.8%, respectively [12, 13].

The LNG-IUS induces histological endometrial atrophy and provides continuous local progesterone opposition. Although trials specifically evaluating proliferative endometrium in postmenopausal women are limited, studies of the LNG-IUS for endometrial protection in women receiving estrogen therapy demonstrate suppression of proliferative activity at 6–12 months in most treated women [14]. This supports a high likelihood of regression to a non-proliferative or atrophic endometrium following LNG-IUS insertion.

Endometrial Hyperplasia without Atypia

Endometrial hyperplasia without atypia carries a relatively low malignant progression risk but frequently causes persistent bleeding [5]. The cumulative long-term risk of progression to endometrial carcinoma is reported to be less than 5% over 20 years [5].

Randomized trials demonstrate superior regression rates with the LNG-IUS compared with oral progestogens, exceeding 90% at 6–12 months [7–9]. Meta-analysis data report regression rates of approximately 92% for complex hyperplasia treated with the LNG-IUS compared with 66% with oral progestogens [7]. Current international guidelines recommend the LNG-IUS as first-line therapy [5].

Endometrial Hyperplasia with Atypia

Atypical hyperplasia, or endometrial intraepithelial neoplasia (EIN), carries a significant risk of concurrent carcinoma [1]. At hysterectomy performed for EIN, concurrent endometrial carcinoma is identified in approximately 30–50% of cases [15]. While hysterectomy remains definitive treatment, the LNG-IUS provides effective conservative therapy in women who decline surgery, are medically unfit, or are awaiting definitive treatment. Regression rates of 70–90% have been reported [8, 9], with meta-analysis demonstrating higher regression rates with the LNG-IUS compared with oral progestogens (approximately 90% vs 69%) [7].

Endometrial Carcinoma

Endometrial carcinoma represents the most serious cause of PMB. Standard management involves surgical staging and hysterectomy [1]. The LNG-IUS has a valuable role in reducing tumor proliferation and uterine bleeding while awaiting definitive surgery. In surgically unfit postmenopausal women, it also controls uterine bleeding and may serve as definitive conservative hormonal management in selected cases of early-stage endometrioid carcinoma. Local progestogenic effects reduce cellular proliferation and may suppress tumor progression in selected cases [12].

Thus, LNG-IUS insertion at the time of endometrial biopsy may provide therapeutic benefit before definitive management.

Special Clinical Scenario: Cervical Stenosis

Cervical stenosis is common in postmenopausal women due to estrogen deficiency. Adequate sampling often requires hysteroscopy and dilation and curettage under general anesthesia. If the LNG-IUS is not inserted during the initial procedure and histology subsequently demonstrates proliferative endometrium or hyperplasia requiring progestogen therapy, patients frequently require repeat general anesthesia for device insertion.

Concurrent LNG-IUS insertion during the initial procedure would avoid repeat anesthesia, provide immediate therapeutic intervention, reduce healthcare costs, improve patient compliance, and reduce morbidity associated with repeat procedures.

Contraindications to LNG-IUS Insertion

In postmenopausal women, the LNG-IUS should be avoided in the presence of active pelvic infection. Insertion is generally contraindicated in women with progestogen-sensitive breast cancer. Insertion may be unsafe in women with a uterine cavity too small to appropriately accommodate the device as this may increase the risk of uterine perforation, device malposition or expulsion, or chronic pelvic pain. Similarly, congenital uterine abnormalities may prevent correct placement, thereby compromising the safety and therapeutic efficacy of the device. Finally, insertion of the LNG-IUS should be avoided in women with known previous intolerance or significant adverse reaction to the LNG-IUS.

CONCLUSION

The LNG-IUS may be considered for routine offering, unless contraindicated, in appropriately selected women undergoing endometrial sampling for postmenopausal bleeding. Insertion of the LNG-IUS at the time of endometrial biopsy uniquely combines diagnosis and treatment in PMB management. The levonorgestrel released within the uterine cavity suppresses proliferative endometrium, may reduce the risk of recurrence of endometrial polyps, and may induce regression of endometrial hyperplasia.

In women presenting with PMB, particularly those with cervical stenosis requiring cervical dilatation and hysteroscopy under general anesthesia, insertion of the LNG-IUS at the time of endometrial biopsy may avoid repeat procedures if histological examination subsequently confirms proliferative endometrium or endometrial hyperplasia.

Although atrophic endometrium does not require LNG-IUS treatment, some of these women may later wish to commence systemic MHT. In such cases, the LNG-IUS may provide endometrial protection as part of MHT. If the LNG-IUS is ultimately not required, it can be removed easily in the outpatient clinic.

Routine offering of the LNG-IUS during endometrial sampling aligns with principles of evidence-based,

patient-centered care and may help reduce avoidable repeat procedures, particularly in women requiring operative hysteroscopy for cervical stenosis.

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Author Contributions

Nader Gad – Conception of the work, Design of the work, Acquisition of data, Analysis of data, Interpretation of data, Drafting the work, Revising the work critically for important intellectual content, Final approval of the version to be published, Agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

Guarantor of Submission

The corresponding author is the guarantor of submission.

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Conflict of Interest

Author declares no conflict of interest.

Data Availability

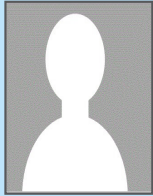
All relevant data are within the paper and its Supporting Information files.

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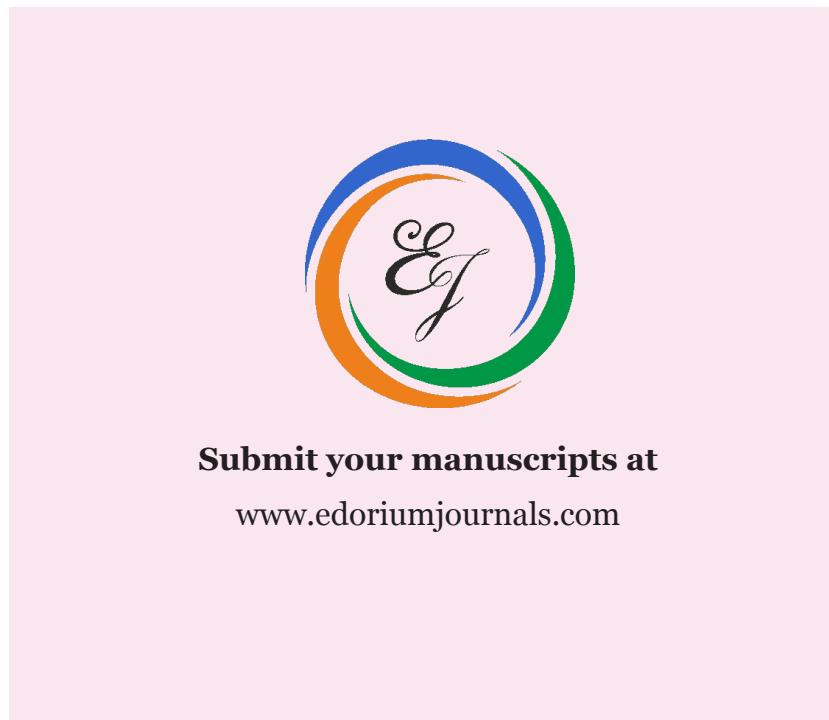
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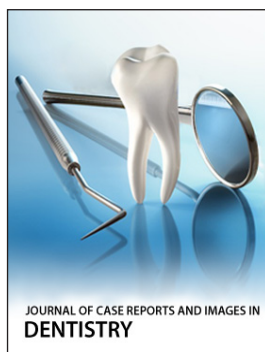
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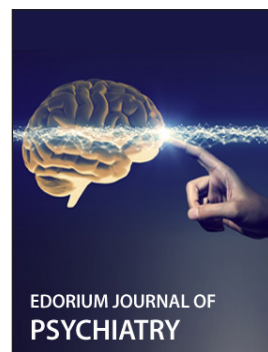
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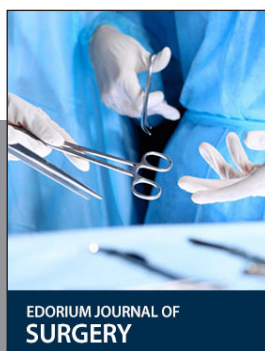
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