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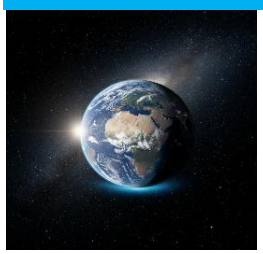

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Evening Primrose Oil (Oenothera biennis L.) in Women's Health: A Narrative Review of Clinical Evidence

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Abstract: Evening primrose oil (EPO), derived from the seeds of Oenothera biennis L., has been widely used as a complementary therapeutic agent in various female health conditions. Its biological activity is primarily attributed to its high content of essential omega-6 fatty acids, particularly linoleic acid and γ-linolenic acid, which serve as precursors of anti-inflammatory prostaglandins. Over recent decades, increasing clinical interest has focused on the potential role of EPO in the management of premenstrual syndrome, mastalgia, menopausal symptoms, polycystic ovary syndrome, and other inflammatory or hormone-related disorders affecting women.

The present narrative review aims to summarize current evidence regarding the phytochemical composition, proposed mechanisms of action, clinical efficacy, and safety profile of evening primrose oil in women's health. A comprehensive literature search of electronic databases was conducted, including randomized controlled trials, systematic reviews, meta-analyses, and observational studies.

Available evidence suggests that evening primrose oil may provide symptomatic relief in selected conditions, particularly mastalgia and certain menopausal symptoms, while results in premenstrual syndrome and other indications remain inconsistent. Overall, EPO appears to be well tolerated, although its therapeutic effectiveness varies depending on dosage, duration of use, and clinical indication. Further large-scale, well-designed clinical trials are required to establish clear recommendations for its use in general medical practice.

Background: Women's health disorders associated with hormonal fluctuations, inflammatory processes, and metabolic imbalance represent a substantial burden worldwide. Conditions such as premenstrual syndrome (PMS), mastalgia, menopausal symptoms, and polycystic ovary syndrome (PCOS) significantly impair quality of life and often require long-term management. Although conventional pharmacological therapies are widely available, their use may be limited by adverse effects, contraindications, or patient preference for non-synthetic treatment options. In recent years, complementary and alternative medicine has gained increasing acceptance among both patients and healthcare professionals. Herbal and plant-derived therapies are frequently perceived as safer alternatives with fewer side effects. Among these, evening primrose oil has attracted considerable attention due to its unique fatty acid composition and its potential influence on inflammatory mediators and hormonal pathways.

Evening primrose oil has been traditionally used for a variety of conditions, including dermatological, rheumatological, and gynaecological disorders. Its application in women's health has expanded, supported by a growing body of experimental and clinical research. However, the clinical evidence remains heterogeneous, and conclusions regarding its efficacy are often conflicting. A critical and structured evaluation of available data is therefore necessary to clarify the role of evening primrose oil in modern medical practice.

Aim: The aim of this review is to evaluate the current scientific evidence regarding the use of evening primrose oil (Oenothera biennis L.) in women's health, with particular emphasis on its phytochemical composition, mechanisms of action, clinical efficacy, and safety profile across various gynaecological and hormone-related conditions.

Material and Methods: This narrative review was conducted through a comprehensive analysis of published scientific literature focusing on evening primrose oil and its application in women's health. Electronic databases including PubMed, Scopus, Web of Science, ScienceDirect, and Google Scholar were systematically searched.

The search strategy employed combinations of the following keywords: evening primrose oil, Oenothera biennis, women's health, premenstrual syndrome, mastalgia, menopause, polycystic ovary syndrome, inflammatory diseases, and clinical trials.

Eligible publications included randomized controlled trials, systematic reviews, meta-analyses, observational studies, and relevant review articles published in English. Studies focusing exclusively on animal models or unrelated clinical indications were excluded unless they provided essential mechanistic insights. Data were extracted and synthesized qualitatively, with attention to study design, sample size, dosage and duration of evening primrose oil administration, clinical outcomes, and reported adverse effects.

Results: The analysis of available literature revealed a substantial number of clinical studies evaluating the use of evening primrose oil (EPO) in various conditions related to women's health. Most publications consisted of randomized controlled trials, systematic reviews, and narrative reviews, with considerable heterogeneity regarding study design, dosage regimens, treatment duration, and outcome measures.

Clinical trials investigating the efficacy of EPO in premenstrual syndrome reported mixed results. Several randomized and placebo-controlled studies demonstrated a reduction in the severity and duration of physical, psychological, and behavioural symptoms, particularly when EPO was administered for at least three consecutive menstrual cycles. Improvements were most frequently observed in breast tenderness, irritability, fatigue, and overall symptom scores.

Conversely, meta-analyses and systematic reviews highlighted limitations in study quality, including small sample sizes and inconsistent outcome measures, which restricted definitive conclusions regarding its effectiveness in PMS. Nevertheless, EPO was consistently reported as safe and well tolerated at commonly used doses.

Mastalgia represented the most extensively studied indication for EPO use. Multiple clinical trials reported significant reductions in pain intensity, especially in cyclical mastalgia, following prolonged administration of evening primrose oil. In comparative studies, EPO demonstrated similar efficacy to certain pharmacological treatments, with a lower incidence of adverse effects.

However, several large randomized controlled trials and factorial studies did not identify statistically significant differences between EPO and placebo. Despite these conflicting findings, most studies supported a favourable safety profile and suggested potential benefit, particularly with long-term use.

Evidence regarding the role of EPO in managing menopausal symptoms focused primarily on vasomotor complaints such as hot flashes and night sweats. Some randomized trials reported significant improvements in symptom severity and quality-of-life measures, while others observed only modest or non-significant effects compared to placebo.

Systematic reviews and meta-analyses indicated that while EPO may offer symptomatic relief for certain individuals, the overall evidence remains inconclusive due to heterogeneity among studies and reliance on subjective outcome measures.

Emerging evidence suggested potential benefits of EPO in conditions such as polycystic ovary syndrome, gestational diabetes, cervical ripening, and selected inflammatory disorders. In PCOS, EPO supplementation was associated with improvements in hormonal parameters and menstrual regularity in limited clinical trials. In inflammatory conditions, reductions in inflammatory markers were reported in some studies; however, clinical outcomes were inconsistent.

Overall, these findings were based on a relatively small number of studies, precluding strong clinical recommendations.

Across all reviewed studies, evening primrose oil was generally well tolerated. Reported adverse effects were mild and infrequent, most commonly including gastrointestinal discomfort, nausea, and headache. Serious adverse events were rare. Caution was advised in patients using anticoagulant or antiplatelet medications and in those with specific neurological conditions.

Conclusions: The present review highlights the extensive but heterogeneous body of evidence regarding the use of evening primrose oil in women's health. Clinical data suggest that EPO may offer symptomatic benefit in certain conditions, particularly cyclical mastalgia and selected menopausal symptoms, while its effectiveness in premenstrual syndrome and other indications remains inconsistent.

Evening primrose oil appears to have a favourable safety profile, supporting its use as a complementary therapeutic option for women seeking alternatives to conventional pharmacological treatments. However, variability in study design, dosing strategies, and outcome assessment limits the generalizability of current findings.

Further large-scale, well-designed randomized controlled trials with standardized outcome measures are necessary to clarify the clinical role of evening primrose oil and to establish evidence-based recommendations for its use in general medical practice.

Key words: Evening primrose oil; Oenothera biennis; premenstrual syndrome; mastalgia; menopause; gamma-linolenic acid.

1. Introduction

Women's health disorders related to hormonal regulation, inflammatory mechanisms, and metabolic disturbances constitute a major public health concern worldwide. Premenstrual syndrome (PMS), mastalgia, menopausal symptoms, polycystic ovary syndrome (PCOS), and inflammatory conditions disproportionately affect women across the lifespan and often result in reduced quality of life, impaired daily functioning, and increased healthcare utilization. Although pharmacological interventions such as non-steroidal anti-inflammatory drugs, hormonal therapies, and selective serotonin reuptake inhibitors are commonly prescribed, their long-term use is frequently limited by adverse effects, contraindications, and patient preference. As a result, there has been a growing interest in complementary and alternative medicine, particularly plant-derived therapies with perceived safety and tolerability. Evening primrose oil (EPO), obtained from the seeds of Oenothera biennis L., has been widely used for decades in women's health. EPO is rich in essential omega-6 fatty acids, mainly linoleic acid and γ-linolenic acid (GLA), which are not synthesized endogenously and play a crucial role in cell membrane integrity and eicosanoid metabolism.

Gamma-linolenic acid is metabolized to dihomo-γ-linolenic acid, a precursor of prostaglandin E1, an anti-inflammatory and vasodilatory mediator. Dysregulation of prostaglandin synthesis and essential fatty acid metabolism has been implicated in the pathophysiology of PMS, mastalgia, inflammatory pain, and menopausal vasomotor symptoms. This biochemical rationale has supported extensive clinical investigation of EPO in women's health.

Despite widespread clinical use, evidence regarding the efficacy of evening primrose oil remains inconsistent. While some randomized controlled trials and observational studies report clinically relevant benefits, others fail to demonstrate superiority over placebo. Given the expanding body of literature and the continued popularity of EPO, a comprehensive synthesis of current evidence is required to clarify its therapeutic role.

2.Research materials and methods

This narrative review was conducted through a comprehensive analysis of peer-reviewed literature addressing the use of evening primrose oil in women's health. Electronic databases including PubMed, Scopus, Web of Science, ScienceDirect, SpringerLink, Wiley Online Library, and Google Scholar were systematically searched.

The search strategy included combinations of the following keywords: evening primrose oil, Oenothera biennis, gamma-linolenic acid, women's health, premenstrual syndrome, mastalgia, menopause, hot flashes, polycystic ovary syndrome, inflammation, clinical trial, systematic review, and meta-analysis. Manual searches of reference lists were also performed.

Eligible studies included randomized controlled trials, double- and triple-blind clinical trials, systematic reviews, meta-analyses, and observational studies published in English. Mechanistic studies and phytochemical analyses were included when relevant to clinical interpretation. Studies exclusively involving animal models or unrelated indications were excluded unless they provided essential pharmacological insight. Due to heterogeneity of study designs and outcomes, data were synthesized qualitatively rather than quantitatively.

3. Research results

3.1. Premenstrual Syndrome

Premenstrual syndrome was among the most frequently investigated indications for EPO use. Several randomized controlled trials reported statistically significant reductions in total symptom severity scores following EPO supplementation, particularly when administered for at least three consecutive menstrual cycles. Improvements were most consistently observed in somatic symptoms such as breast tenderness, bloating, headache, and fatigue. Psychological and behavioural symptoms, including irritability, anxiety, and mood fluctuations, also demonstrated improvement in some studies.

Biochemical studies accompanying clinical trials reported increases in plasma levels of γ-linolenic acid and dihomo-γ-linolenic acid following EPO administration, supporting the proposed mechanism involving prostaglandin E1 synthesis. However, systematic reviews and meta-analyses emphasized that many PMS trials were limited by small sample sizes, short follow-up periods, and inconsistent diagnostic frameworks. As a result, pooled analyses failed to demonstrate uniform efficacy across studies. Despite these limitations, EPO was consistently reported to be safe, with no serious adverse events associated with its use in PMS populations.

3.2. Mastalgia

Mastalgia represented the most extensively studied clinical indication for evening primrose oil. Numerous trials investigated its effects in women with cyclical and non-cyclical breast pain. Several studies reported significant reductions in pain intensity and frequency, particularly in cyclical mastalgia, following EPO administration for periods ranging from three to six months. Comparative clinical trials evaluated EPO against pharmacological agents such as danazol, bromocriptine, vitamin E, topical non-steroidal anti-inflammatory drugs, and hormonal modulators. In many of these studies, EPO demonstrated comparable efficacy in pain reduction, with a notably lower incidence of adverse effects. However, results were not uniform. Large multicentred randomized controlled trials and factorial studies failed to show statistically significant differences between EPO and placebo groups, despite overall improvements observed in all treatment arms.

Long-term observational and open-label studies suggested that prolonged use of EPO was associated with gradual symptom improvement in a substantial proportion of patients. Across studies, tolerability was consistently high, and adverse effects were generally mild and transient.

3.3. Menopausal Symptoms

Clinical trials assessing EPO in menopausal women primarily focused on vasomotor symptoms, including hot flashes and night sweats. Several randomized controlled trials reported statistically significant reductions in hot flash severity and improvements in quality-of-life measures, particularly in domains related to sleep, social functioning, and daily activities.

However, other studies reported only modest improvements or no significant differences compared with placebo. Meta-analyses and systematic reviews highlighted substantial heterogeneity in study methodologies, reliance on self-reported symptom scales, and relatively short intervention durations. While some evidence supported a potential benefit of EPO in

reducing the intensity of vasomotor symptoms, the overall findings were inconsistent, and definitive conclusions could not be drawn.

3.4. Polycystic Ovary Syndrome

Evidence regarding the use of EPO in polycystic ovary syndrome was limited but emerging. Small randomized controlled trials evaluated the effects of EPO supplementation on hormonal and metabolic parameters. Reported outcomes included reductions in serum insulin levels, testosterone concentrations, and free androgen index, along with increases in sex hormone-binding globulin levels. Improvements in menstrual cycle regularity were also observed in some studies.

Despite these findings, changes in ovarian morphology assessed by ultrasonography were generally not statistically significant. The limited number of studies and relatively small sample sizes restricted the generalizability of these results.

3.5. Pregnancy-Related and Gynecological Applications

Several studies investigated EPO in pregnancy-related conditions and gynaecological procedures. In gestational diabetes, supplementation with EPO, often in combination with vitamin D, was associated with reductions in inflammatory and oxidative stress markers. Studies examining pre-eclampsia prevention reported mixed results, with some improvements in edema and blood pressure-related outcomes.

EPO was also evaluated as an agent for cervical ripening and dilation prior to labour induction or gynaecological procedures. Some trials reported significant improvements in Bishop scores, cervical effacement, and dilation following intravaginal administration of EPO. However, other studies raised concerns regarding prolonged labour or increased obstetric interventions when EPO was administered orally. These findings indicated variability depending on route of administration and clinical context.

3.6. Inflammatory and Other Conditions

Systematic reviews investigating the role of EPO in inflammatory diseases reported mixed outcomes. Some studies demonstrated reductions in inflammatory markers and symptom severity in conditions such as atopic dermatitis, rheumatoid arthritis, and menopausal vasomotor symptoms, while others found no significant clinical benefit. Evidence supporting EPO use in broader inflammatory or dermatological conditions remained inconclusive.

3.7. Safety and Tolerability

Across all reviewed indications, evening primrose oil demonstrated a favourable safety profile. Adverse effects were generally mild and included gastrointestinal discomfort, nausea, headache, bloating, and altered taste. Serious adverse events were rare. Long-term toxicity studies and clinical trials did not identify significant safety concerns at commonly used doses. Caution was advised in patients using anticoagulant or antiplatelet medications and in individuals receiving phenothiazine therapy.

4. Discussion

The present review synthesizes a broad and heterogeneous body of literature examining the role of evening primrose oil in women's health. Overall, the findings indicate that while evening primrose oil is biologically plausible and generally safe, its clinical efficacy varies substantially across indications and study designs.

One of the most consistent observations across the reviewed literature is the favourable safety and tolerability profile of evening primrose oil. Adverse effects reported in clinical trials were predominantly mild and transient, most commonly involving gastrointestinal discomfort, headache, or nausea. Serious adverse events were rare, and long-term toxicity studies did not demonstrate clinically relevant safety concerns at commonly used doses. This safety profile likely contributes to the widespread and sustained use of evening primrose oil as a complementary therapy among women.

From an efficacy perspective, the strongest and most reproducible evidence was observed in cyclical mastalgia. A considerable number of clinical trials demonstrated reductions in breast pain severity following prolonged administration of evening primrose oil, often comparable to pharmacological treatments such as danazol or bromocriptine, but with fewer adverse effects. Nevertheless, several large randomized controlled trials and multicentred studies failed to show statistically significant superiority over placebo. These discrepancies may be explained by differences in baseline symptom severity, duration of treatment, and outcome assessment tools, as well as by the natural fluctuation of symptoms over time.

Evidence regarding the use of evening primrose oil in premenstrual syndrome remains inconsistent. While multiple trials reported improvements in both somatic and psychological symptoms, systematic reviews and meta-analyses emphasized significant methodological

limitations. These included small sample sizes, variable diagnostic criteria, and reliance on subjective symptom reporting. As a result, pooled analyses did not provide conclusive support for routine use of evening primrose oil in PMS, despite its apparent safety.

Similarly, studies evaluating menopausal symptoms, particularly vasomotor complaints, yielded mixed results. Some randomized controlled trials reported meaningful reductions in hot flash severity and improvements in quality-of-life measures, whereas others found no significant differences compared with placebo. The high placebo response commonly observed in menopausal symptom trials, combined with subjective outcome measures and short intervention periods, likely contributed to inconsistent findings. Meta-analyses suggested that evening primrose oil may offer modest benefit for selected individuals, but the evidence does not support strong clinical recommendations.

Emerging research has explored the role of evening primrose oil in other female health conditions, including polycystic ovary syndrome, gestational diabetes, cervical ripening, and inflammatory disorders. In PCOS, small clinical trials reported favourable changes in hormonal and metabolic parameters; however, the limited number of studies and small sample sizes preclude firm conclusions. Pregnancy-related and gynaecological applications showed variable outcomes depending on dosage, route of administration, and clinical context, highlighting the need for caution in interpreting these findings.

The biological plausibility of evening primrose oil's effects is supported by its influence on essential fatty acid metabolism and prostaglandin synthesis. Gamma-linolenic acid serves as a precursor to prostaglandin E1, which exhibits anti-inflammatory and vasodilatory properties. Dysregulation of these pathways has been implicated in several women's health disorders. However, clinical outcomes do not consistently mirror mechanistic expectations, underscoring the complexity of translating biochemical effects into measurable clinical benefit.

Overall, the heterogeneity of the existing literature represents a major limitation. Variability in study design, dosing regimens, treatment duration, outcome measures, and patient populations complicates comparison across studies and weakens the strength of conclusions. Future research should prioritize well-designed, adequately powered randomized controlled trials with standardized diagnostic criteria and validated outcome measures.

5. Conclusions

Evening primrose oil remains one of the most widely used complementary therapies in women's health. The available evidence suggests potential benefit in cyclical mastalgia and

selected menopausal symptoms, while results in premenstrual syndrome, polycystic ovary syndrome, and other indications remain inconsistent and inconclusive.

The consistently favorable safety profile supports the cautious use of evening primrose oil as an adjunctive therapeutic option, particularly for women seeking non-pharmacological or complementary approaches. However, current evidence does not justify its routine recommendation as a first-line therapy in most conditions.

High-quality, large-scale randomized controlled trials with standardized methodologies are required to clarify the clinical role of evening primrose oil and to establish evidence-based recommendations. Until such data are available, its use should be individualized, guided by patient preference, symptom severity, and clinical judgment.

Disclosure

Author's contribution

Conceptualization: [TS], [KW]
Methodology: [AB], [EC] [JB]
Check: [KW], [TS], [KW_2]
Investigation: [JB], [AB], [EC]
Data curation: [KW], [WW], [JB], [TS]
Writing - rough preparation: [KW_2], [TS], [WW], [EC]
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The authors declare no conflict of interest.

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