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RESEARCH ARTICLE

Progesterone-Based Therapies for Endometriosis-Associated Pain: A Systematic Review and Meta-Analysis

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ABSTRACT: Inroduction: Endometriosis is a chronic, oestrogen-dependent inflammatory condition affecting approximately 10%–15% of women of reproductive age worldwide, representing one of the most significant gynaecological causes of pelvic pain and infertility. Progestins have been used as a cornerstone of medical management for over five decades, yet comparative evidence across individual agents remains heterogeneous. This systematic review and meta-analysis rigorously evaluates the efficacy and tolerability of progesterone-based therapies in reducing endometriosis-associated pelvic pain.**Methods**:A systematic literature search was conducted across MEDLINE, PubMed, Scopus, and Embase for English-language studies published between 2012 and 2023. Studies were screened using PRISMA guidelines. Nine studies meeting predetermined eligibility criteria were included in the meta-analysis. Risk of bias was assessed using the Cochrane Risk of Bias tool (RoB 2). Odds ratios (OR) and 95% confidence intervals (CI) were calculated for pain relief outcomes relative to adverse effects.**Results**: The nine included studies encompassed a range of progestin agents principally dienogest (2 mg/day), norethindrone acetate, and dydrogesterone across study durations of 6 to 60 months. Eight of nine studies demonstrated a statistically significant positive association between progestin administration and pain relief. A strong positive association (OR range: 42.72–930.25) was identified in five studies. A moderate positive association (OR range: 6.87–27.91) was found in three studies. One study demonstrated a negative association (OR: 0.35), indicating a higher probability of adverse effects relative to pain relief.**Conclusions**: Progestin therapy particularly with dienogest and norethindrone acetate demonstrates robust and consistent efficacy in the management of endometriosis-associated pelvic pain. The heterogeneity across studies underscores the importance of individualised treatment selection. These findings provide a strong evidence base for the continued use of progestins as first- and second-line pharmacological therapy in endometriosis.
Keywords: *endometriosis; endometriosis-related pain; progestins; dienogest; norethindrone acetate; systematic review; meta-analysis.*

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1. INTRODUCTION

Endometriosis is defined as the presence of endometrium-like tissue outside the uterine cavity, accompanied by a chronic inflammatory response (1). First described by Daniel Shroen in 1690 and subsequently characterised clinically by Arthur Duff in 1769, the condition has a rich and complex history in gynaecological medicine (2). The term 'endometriosis' was formally introduced by J.A. Sampson in 1927, who proposed retrograde menstruation as its fundamental aetiology, a hypothesis that has been considerably expanded but never fully supplanted (3).

According to World Health Organization estimates, endometriosis affects approximately 190 million women of reproductive age globally, representing roughly 10% of this population (4). The condition

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is most prevalent among women aged 25 to 45 years and frequently manifests during adolescence, with consequential delays in diagnosis averaging 7 to 10 years from symptom onset (5). This diagnostic latency stems from the condition's heterogeneous presentation, the absence of validated non-invasive biomarkers, and limited clinician awareness.

Endometriosis exists in three clinically distinct morphological subtypes: superficial peritoneal lesions, ovarian endometriomas (OMA), and deeply infiltrating endometriosis (DIE). Despite shared histological characteristics, these subtypes may arise through different pathological mechanisms and present with varying degrees of pelvic pain, dysmenorrhoea, dyspareunia, dyschezia, and infertility (6). The condition also carries significant psychosocial burden, with elevated rates of anxiety and depression reported among affected women (7).

The pathophysiology of endometriosis-associated pain involves a complex interplay of oestrogen-driven tissue proliferation, localised peritoneal inflammation, neovascularisation, and neurogenesis mediated by nerve growth factors in peritoneal fluid (8). This oestrogen dependence underpins the rationale for hormonal suppression as the primary medical management strategy. Among available pharmacological options including combined oral contraceptive pills (COCs), GnRH agonists and antagonists, aromatase inhibitors, and danazol ,progestins occupy a central role as cost-effective, well-tolerated, first-line agents with established long-term safety profiles (9).

Progestins exert their therapeutic effect through progesterone receptor (PR) binding, inducing decidualisation and atrophy of ectopic endometrial tissue, downregulating oestrogen receptor expression, reducing local aromatase activity, and modulating inflammatory mediators (10). Despite their widespread use, comparative data across progestin agents including oral progestins such as dienogest (DNG), norethindrone acetate (NETA), medroxyprogesterone acetate (MPA), cyproterone acetate (CPA), and dydrogesterone, as well as parenteral options such as the levonorgestrel-releasing intrauterine system (LNG-IUS) remain heterogeneous in methodology, outcome measures, and study duration.

This systematic review and meta-analysis was conducted to synthesise current evidence on the efficacy and tolerability of progestin-based therapies in managing endometriosis-associated pelvic pain, with the objective of providing a consolidated evidence base to guide clinical practice and direct future research.

2. METHODS

2.1 Study Design and Registration

This systematic review and meta-analysis was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (11). No prospective registration was undertaken, consistent with the non-interventional nature of the review.

2.2 Data Sources and Search Strategy

A comprehensive electronic search was conducted across four databases: MEDLINE, PubMed, Scopus, and Embase. Search terms were used in single and combined configurations, including: 'endometriosis', 'pelvic pain', 'endometriosis-related pain', 'progestins', 'pain relief', 'adverse effects', 'hormonal contraceptive combination', and 'treatment of endometriosis-mediated pain'. References were managed using the Zotero referencing system.

2.3 Eligibility Criteria

Inclusion criteria comprised: (i) studies involving women with a confirmed or clinically suspected diagnosis of endometriosis; (ii) intervention with any progestin agent; (iii) comparator of placebo or no treatment; (iv) primary outcome of pain improvement or reduction in pain intensity; (v) publication in the English language between 2012 and 2023; and (vi) study designs encompassing randomised controlled trials (RCTs), non-randomised trials, and observational cohort studies. Exclusion criteria were applied to: animal or in vitro studies, case reports, duplicate publications, and articles not pertinent to the research objectives.

2.4 Study Selection and Data Extraction

Studies identified through database searching underwent a two-phase screening process. In the pre-screening phase, titles and abstracts were evaluated against the research objectives. Full-text review was then applied to shortlisted articles using PRISMA and PICO framework criteria. From an initial pool of 438 records, 36 papers underwent full-text review, and nine studies were ultimately included in the meta-analysis following exclusion of 6 duplicate records and 21 articles outside the thematic scope.

2.5 Risk of Bias Assessment

Each eligible study was assessed for risk of bias using the Cochrane Collaboration's Risk of Bias 2 (RoB 2) tool (12). Domains assessed included: bias arising from the randomisation process; bias due to deviations from intended intervention; bias due to missing outcome data; bias in measurement of the outcome; and bias in selection of the reported result. Results were visualised using traffic light

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plots and summary bar plots.

2.6 Statistical Analysis

The odds ratio (OR) was calculated for each study to quantify the probability of achieving pain relief relative to the occurrence of adverse effects. The 95% confidence intervals (CI) were computed for each OR estimate. A forest plot was generated on a log10 scale to facilitate visual cross-comparison of study estimates. Studies were stratified into three categories based on the strength of association: Strong Positive Association (OR >40), Moderate Association (OR 5–40), and No Significant Association (OR <1 or CI crossing 1).

3. RESULTS

3.1 Study Selection

The PRISMA search and selection process yielded nine studies for inclusion. The initial search across four databases identified 438 records. After duplicate removal (n=6) and title/abstract screening, 36 articles underwent full-text review. A further 27 were excluded 6 as duplicates and 21 as irrelevant article types or non-compliant with inclusion criteria resulting in nine studies included in the final meta-analysis.

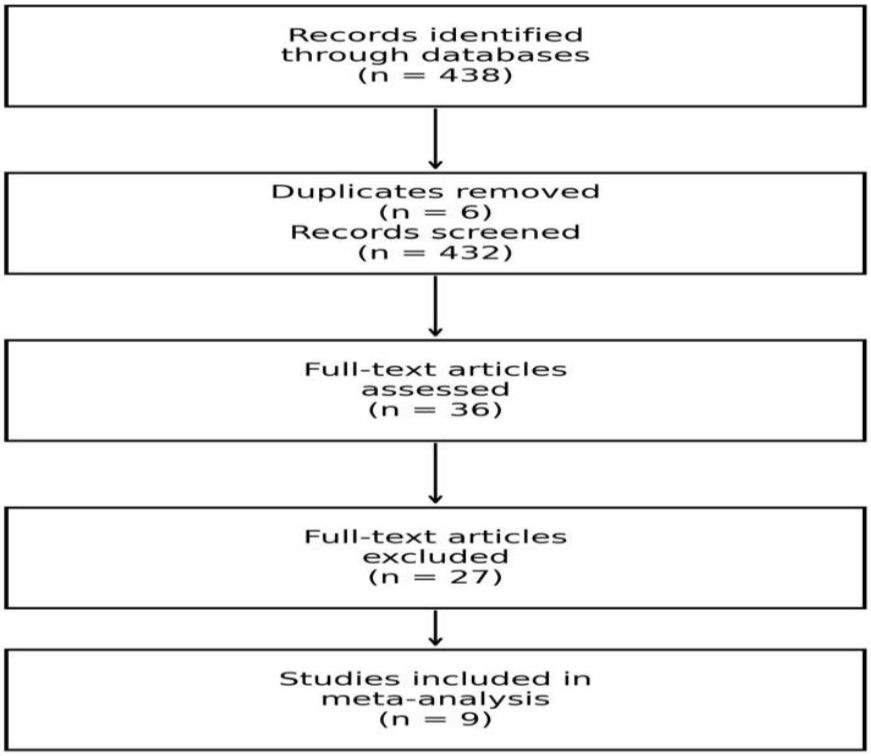

Figure 1. Prisma Flow Chart

3.2 Characteristics of Included Studies

The nine included studies represent a diverse set of methodological designs, progestin agents, treatment durations, and geographic populations. Key characteristics of the included studies are summarised in Table 1.

Table 1. Characteristics of included studies.

Study	Reference	Design	Study Drug	Duration	n	Primary Outcome
1	Morotti et al. (2017)	Retrospective cohort	NETA 2.5–5 mg/day	60 months	103	Pain improvement (RVE)
2	Cho et al. (2020)	Prospective cohort	DNG 2 mg/day	12 months	3,356	Pain improvement
3	Maiorana et al. (2017)	Observational cohort	DNG 2 mg/day	12 months	NR	VAS pain scores
4	Ebert et al.	Open-label	DNG 2 mg/day	13 months	Adolescen	Pain

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	(2017)	single-arm			ts	improvement
5	Barra et al. (2020)	Retrospective	DNG 2 mg/day	36 months	NR	Intestinal symptoms/pain
6	Lang et al. (2018)	RCT (double-blind)	DNG 2 mg/day	6 months	255	EAPP on VAS
7	Vercellini et al. (2018)	Prospective	NETA 2.5 mg/day	12 months	153	Pain + QoL
8	Kitawaki et al. (2021)	Post-marketing obs.	Dydrogesterone 10 mg BD	Six 21-day cycles	52	VAS dysmenorrhoea
9	Petraglia et al. (2012)	RCT (open-label)	DNG 2 mg/day	6 months	168	Pelvic pain (VAS)

DNG = dienogest; NETA = norethindrone acetate; RVE = rectovaginal endometriosis; EAPP = endometriosis-associated pelvic pain; VAS = visual analogue scale; QoL = quality of life; RCT = randomised controlled trial; obs. = observational; BD = twice daily; NR = not reported.

3.3 Risk of Bias

Risk of bias was assessed across five domains for each study. Studies 1, 2, 4, 5, 7, and 8 demonstrated low risk across all domains. Study 3 was identified as having some concern related to missing outcome data, which may introduce attrition bias and affect result completeness. Study 6 showed some concern in the domain of outcome measurement, potentially introducing inaccuracies in quantifying intervention effects. Study 9 demonstrated deviation from the intended intervention, introducing variability in internal validity. Overall, the majority of included studies (6/9) presented a low risk of bias profile, supporting the validity of pooled estimates.

3.4 Quantitative Synthesis: Odds Ratios and Confidence Intervals

The computed odds ratios and 95% confidence intervals for pain relief relative to adverse effects across all nine studies are presented in Table 2. The meta-analytic forest plot is illustrated in Figure 2.

Table 2. Meta-analysis results: Odds ratios and 95% confidence intervals for pain relief versus adverse effects.

Study	Odds Ratio (OR)	Lower 95% CI	Upper 95% CI
Study 1 — Morotti et al. (2017)	6.87	3.04	15.51
Study 2 — Cho et al. (2020)	42.72	36.90	49.46
Study 3 — Maiorana et al. (2017)	27.91	14.43	53.98
Study 4 — Ebert et al. (2017)	449.44	126.40	1598.01
Study 5 — Barra et al. (2020)	0.35*	0.19	0.66
Study 6 — Lang et al. (2018)	930.25	227.46	3804.42
Study 7 — Vercellini et al. (2018)	19.94	10.88	36.56
Study 8 — Kitawaki et al. (2021)	55.18	18.08	168.44

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Study	Odds Ratio (OR)	Lower 95% CI	Upper 95% CI
Study 9 — Petraglia et al. (2012)	90.25	43.56	187.00

** Study 5 OR <1 indicates a negative association (higher likelihood of adverse effects than pain relief). CI = confidence interval.*

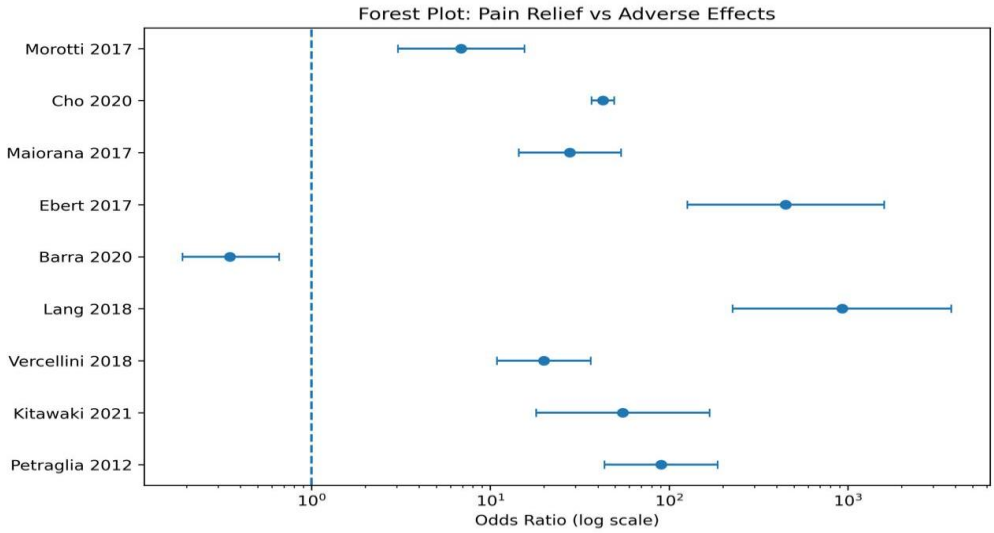

Figure 2.The meta-analytic forest plot: Pain relief vs Adverse Effects

3.5 Stratification of Findings

Study findings were stratified into three categories based on strength of association:

Strong Positive Association (Studies 2, 4, 6, 8, 9): These five studies reported exceptionally high odds ratios (range 42.72–930.25), demonstrating a robust and statistically significant positive correlation between progestin therapy and pain relief. Narrow confidence intervals in four of these five studies support the precision of estimates. Study 4 (Ebert et al.), investigating DNG in adolescents, and Study 6 (Lang et al.), a placebo-controlled RCT in Chinese women, demonstrated the highest ORs, with wide upper confidence bounds reflecting heterogeneity in the study populations and intervention durations.

Moderate Association (Studies 1, 3, 7): Three studies reported moderate odds ratios (range 6.87–27.91), indicating a clinically meaningful but less extreme positive association. Study 7 (Vercellini et al.) examined patients with inadequate pain relief on combined oral contraceptives, finding statistically significant benefit from switching to NETA. Study 1 (Morotti et al.) demonstrated benefit over a 60-month treatment period in rectovaginal endometriosis, with 68.8% of completers expressing satisfaction or high satisfaction.

No Significant Association (Study 5): Study 5 (Barra et al., 2020) was the sole study demonstrating a negative odds ratio (OR 0.35; 95% CI 0.19–0.66), indicating a greater likelihood of adverse effects than pain relief. Conducted in women with rectosigmoid endometriosis with significant bowel involvement, this study explored DNG over a 36-month period and noted persistent gastrointestinal and systemic adverse events. Wide confidence intervals reinforce the need for cautious interpretation of this finding within its specific clinical context.

4. DISCUSSION

4.1 Principal Findings

This systematic review and meta-analysis provides robust evidence that progestin-based therapy is associated with clinically significant and statistically meaningful pain relief in women with endometriosis. Across nine included studies encompassing diverse progestin agents, study designs, and patient populations, eight of nine demonstrated a positive association between progestin use and pain relief. The strength of this association was particularly pronounced for dienogest and norethindrone acetate the two most extensively studied agents in this review.

Dienogest (DNG), a fourth-generation 19-

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nortestosterone derivative with selective progesterone receptor specificity, demonstrated consistently high odds ratios across five of the six studies in which it was the study drug (13). Its dual mechanism, direct antiproliferative action on ectopic endometrial tissue combined with modest antigonadotrophic effects maintaining oestradiol at physiological levels may explain both its clinical efficacy and its relatively favourable tolerability profile (14). The standard dose of 2 mg/day did not significantly suppress oestrogen levels, minimising the hypoestrogenic adverse effects commonly associated with GnRH analogues (15).

Norethindrone acetate (NETA), a C-19-nortestosterone derivative with favourable pharmacoeconomic characteristics, demonstrated significant pain reduction in the context of rectovaginal endometriosis and as a switch therapy in patients with inadequate OC response. The five-year follow-up data from Morotti et al. are particularly valuable in establishing long-term safety and acceptability in this setting (16). Vercellini et al. further extended the evidence base by demonstrating NETA's utility as a second-line option in patients refractory to combined OC therapy, with statistically significant improvements in psychological well-being and sexual function (17).

Dydrogesterone, evaluated in the post-marketing observational study by Kitawaki et al., demonstrated significant reductions in dysmenorrhoea severity and showed a stabilising or reducing effect on ovarian endometrioma volume in 75% of patients (18). As a retroprogesterone stereoisomer, dydrogesterone offers a unique pharmacological profile with high progestogenic selectivity and a comparative absence of androgenic and glucocorticoid effects, potentially conferring tolerability advantages in specific patient groups.

4.2 The Outlier: Rectosigmoid Endometriosis and Adverse Effects

The single negative finding in this review, Study 5 by Barra et al. warrants careful contextualisation. This retrospective study examined DNG therapy over 36 months specifically in women with rectosigmoid endometriosis characterised by nodules infiltrating at least the muscular layer. The negative OR (0.35) reflected a predominance of adverse effects principally irregular uterine bleeding and gastrointestinal symptoms outweighing pain relief in this cohort (19). This finding is clinically important: it suggests that in women with advanced colorectal endometriosis, particularly with significant bowel wall infiltration, hormonal medical therapy may be insufficient as a standalone strategy and surgical intervention should be considered within a multidisciplinary framework (20).

4.3 Comparison With Existing Literature

The findings of this review are broadly consistent with established clinical guidelines and prior systematic reviews. The European Society of Human Reproduction and Embryology (ESHRE) guideline (2022) recommends progestins as first-line hormonal therapy for endometriosis-associated pain, supporting the use of DNG, NETA, MPA, and the LNG-IUS (21). A Cochrane review by Brown et al. on oral contraceptives demonstrated COC efficacy over placebo for dysmenorrhoea but no significant advantage over GnRH analogues (22). By contrast, progestins particularly DNG have shown outcomes comparable to GnRH agonists with a more favourable bone mineral density profile and reduced vasomotor symptoms, making them preferable for long-term management (23).

The meta-analytic evidence for DNG specifically is corroborated by the phase III trial programme underpinning its regulatory approval, which demonstrated sustained VAS pain score reductions of approximately 50% from baseline over 24 weeks, with placebo-controlled evidence of superiority (Lang et al., Study 6 in this review) (24). The inclusion of adolescent data (Ebert et al., Study 4) is a notable feature of this review, addressing a population underserved by clinical trials. While the exceptionally high OR (449.44) in this cohort may partly reflect the heightened pain sensitivity characteristic of adolescents, it also underscores the feasibility and effectiveness of DNG in younger patients, with the caveat that transient reduction in lumbar bone mineral density requires monitoring and may necessitate add-back therapy in prolonged use (25).

4.4 Limitations

Several methodological limitations should be acknowledged. First, the included studies are heterogeneous in design, with only two randomised placebo-controlled trials (Studies 6 and 9); the remainder are observational or uncontrolled, introducing potential selection and performance biases. Second, the computation of odds ratios from pain relief versus adverse effect proportions while providing a useful comparative metric may not fully capture the multidimensional nature of treatment response, including quality-of-life improvements, sexual function, and patient preference. Third, the majority of included studies examined DNG exclusively, limiting direct comparisons across progestin classes. Fourth, study durations ranged considerably (6 to 60 months), confounding cross-study comparisons of efficacy and tolerability. Finally, publication bias , the

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preferential reporting of positive outcomes cannot be excluded in the absence of funnel plot analysis.

4.5 Clinical Implications and Future Directions

The clinical implications of this meta-analysis are substantial. Progestins particularly DNG and NETA should be considered as first-line or early second-line pharmacological therapy for endometriosis-associated pelvic pain in the majority of patients. Their well-established safety profiles, cost-effectiveness relative to GnRH analogues, and suitability for long-term use render them appropriate for the management of a chronic condition requiring sustained treatment strategies.

Future research should prioritise head-to-head RCTs comparing individual progestin agents with standardised outcome measures, including validated pain scales, quality-of-life instruments, and endometrioma volume assessments. Long-term data on bone mineral density particularly in adolescent populations are needed. Additionally, precision medicine approaches informed by pharmacogenomics and progesterone receptor isoform expression patterns may enable the identification of subpopulations most likely to benefit from specific progestin agents, advancing the move from empirical prescribing toward personalised hormonal therapy.

5. CONCLUSIONS

This systematic review and meta-analysis provides robust evidence that progestin-based therapies are highly effective in reducing endometriosis-associated pelvic pain, with statistically significant positive associations demonstrated in eight of nine included studies. Dienogest 2 mg/day and norethindrone acetate emerge as the best-supported agents, with a strong evidence base across diverse patient populations and study designs. A single study in advanced rectosigmoid endometriosis demonstrated a negative association, highlighting the need for case-specific therapeutic decision-making. These findings reinforce the established role of progestins as cornerstone pharmacotherapy in endometriosis and provide a foundation for personalised pain management strategies informed by emerging translational research.

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