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EFFECT OF ORAL SPIRONOLACTONE IN THE TREATMENT OF ACNE IN ADULT WOMEN: A SYSTEMATIC REVIEW

EFEITO DA ESPIRONOLACTONA ORAL NO TRATAMENTO DA ACNE EM MULHERES ADULTAS: UMA REVISÃO SISTEMÁTICA

EFECTO DE LA ESPIRONOLACTONA ORAL EN EL TRATAMIENTO DEL ACNÉ EN MUJERES ADULTAS: UNA REVISIÓN SISTEMÁTICA

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ABSTRACT

Introduction: Acne vulgaris in adult women represents a frequent, chronic, and therapeutically challenging dermatological condition that is often associated with hormonal influences and reduced responsiveness to conventional treatments. Oral spironolactone has emerged as a widely used off-label therapy due to its antiandrogenic properties, yet its efficacy and safety profile continue to be debated in clinical practice.

Objective: The main objective of this systematic review was to evaluate the effectiveness of oral spironolactone in the treatment of acne in adult women. Secondary objectives included assessing dose–response relationships, safety and tolerability profiles, comparative effectiveness with other systemic therapies, patient-reported outcomes, and gaps in current evidence.

Methods: A systematic search was conducted across PubMed, Scopus, Web of Science, Cochrane Library, LILACS, ClinicalTrials.gov, and ICTRP. Eligible studies included randomized controlled trials and observational studies evaluating oral spironolactone in adult women with acne, published within the last five years, with an extension to ten years if fewer than ten eligible studies were identified. Data were synthesized qualitatively following PRISMA guidelines.

Results and Discussion: A total of 20 studies met the inclusion criteria and were included in the final analysis. The evidence consistently demonstrated that oral spironolactone was

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associated with significant reductions in acne lesion counts and severity scores, particularly in hormonally mediated acne phenotypes, with an acceptable safety profile. Variability in dosing regimens and outcome measures contributed to moderate heterogeneity across studies.

Conclusion: Current evidence supports oral spironolactone as an effective and generally well-tolerated therapeutic option for acne in adult women, especially in cases resistant to conventional therapies. Its use should be individualized, considering patient characteristics, comorbidities, and reproductive considerations.

Keywords: Acne Vulgaris. Spironolactone. Anti-Androgen Therapy. Women.

RESUMO

Introdução: A acne vulgar em mulheres adultas representa uma condição dermatológica frequente, crônica e terapeuticamente desafiadora, frequentemente associada a influências hormonais e à menor responsividade aos tratamentos convencionais. A espironolactona oral tem emergido como uma terapia off-label amplamente utilizada devido às suas propriedades antiandrogênicas; entretanto, sua eficácia e perfil de segurança ainda são debatidos na prática clínica.

Objetivo: O principal objetivo desta revisão sistemática foi avaliar a eficácia da espironolactona oral no tratamento da acne em mulheres adultas. Os objetivos secundários incluíram a análise da relação dose–resposta, dos perfis de segurança e tolerabilidade, da eficácia comparativa com outras terapias sistêmicas, dos desfechos relatados pelas pacientes e das lacunas existentes na evidência científica atual.

Métodos: Foi realizada uma busca sistemática nas bases de dados PubMed, Scopus, Web of Science, Cochrane Library, LILACS, ClinicalTrials.gov e ICTRP. Foram incluídos ensaios clínicos randomizados e estudos observacionais que avaliaram o uso de espironolactona oral em mulheres adultas com acne, publicados nos últimos cinco anos, com extensão para até dez anos caso fossem identificados menos de dez estudos elegíveis. Os dados foram sintetizados de forma qualitativa, seguindo as diretrizes PRISMA.

Resultados e Discussão: Um total de 20 estudos atendeu aos critérios de inclusão e foi incorporado à análise final. As evidências demonstraram de forma consistente que a espironolactona oral esteve associada a reduções significativas no número de lesões acneicas e nos escores de gravidade, especialmente em fenótipos de acne mediados por fatores hormonais, apresentando um perfil de segurança aceitável. A variabilidade nos esquemas posológicos e nas medidas de desfecho contribuiu para uma heterogeneidade moderada entre os estudos.

Conclusão: As evidências atuais sustentam a espironolactona oral como uma opção terapêutica eficaz e geralmente bem tolerada para o tratamento da acne em mulheres adultas, especialmente nos casos resistentes às terapias convencionais. Seu uso deve ser individualizado, considerando as características da paciente, comorbidades e aspectos reprodutivos.

Palavras-chave: Acne Vulgar. Espironolactona. Terapia Antiandrogênica. Mulheres.

RESUMEN

Introducción: El acné vulgar en mujeres adultas representa una condición dermatológica frecuente, crónica y terapéuticamente desafiante, a menudo asociada a influencias hormonales y a una menor respuesta a los tratamientos convencionales. La espironolactona

oral ha surgido como una terapia off-label ampliamente utilizada debido a sus propiedades antiandrogénicas; sin embargo, su eficacia y perfil de seguridad continúan siendo objeto de debate en la práctica clínica.

Objetivo: El objetivo principal de esta revisión sistemática fue evaluar la eficacia de la espironolactona oral en el tratamiento del acné en mujeres adultas. Los objetivos secundarios incluyeron la evaluación de la relación dosis–respuesta, los perfiles de seguridad y tolerabilidad, la eficacia comparativa frente a otras terapias sistémicas, los resultados reportados por las pacientes y las lagunas existentes en la evidencia científica actual.

Métodos: Se realizó una búsqueda sistemática en las bases de datos PubMed, Scopus, Web of Science, Cochrane Library, LILACS, ClinicalTrials.gov e ICTRP. Se incluyeron ensayos clínicos aleatorizados y estudios observacionales que evaluaron el uso de espironolactona oral en mujeres adultas con acné, publicados en los últimos cinco años, con una extensión de hasta diez años en caso de identificarse menos de diez estudios elegibles. Los datos se sintetizaron de manera cualitativa, siguiendo las directrices PRISMA.

Resultados y Discusión: Un total de 20 estudios cumplió con los criterios de inclusión y fue incorporado en el análisis final. La evidencia demostró de forma consistente que la espironolactona oral se asoció con reducciones significativas en el número de lesiones acneicas y en los puntajes de gravedad, especialmente en los fenotipos de acné mediados por factores hormonales, con un perfil de seguridad aceptable. La variabilidad en los esquemas de dosificación y en las medidas de resultado contribuyó a una heterogeneidad moderada entre los estudios.

Conclusión: La evidencia actual respalda la espironolactona oral como una opción terapéutica eficaz y generalmente bien tolerada para el tratamiento del acné en mujeres adultas, especialmente en casos resistentes a las terapias convencionales. Su uso debe individualizarse, considerando las características de la paciente, las comorbilidades y los aspectos reproductivos.

Palabras clave: Acné Vulgar. Espironolactona. Terapia Antiandrogénica. Mujeres.

1 INTRODUCTION

Acne vulgaris persisting or emerging in adulthood is increasingly recognized as a distinct clinical entity, particularly among women, with significant physical and psychosocial consequences.[1] Adult female acne frequently differs from adolescent acne in terms of lesion distribution, chronicity, and recurrence patterns, often involving the lower face and jawline.[1] Epidemiological studies indicate that a substantial proportion of women continue to experience acne beyond the age of 25 years, challenging the traditional perception of acne as a self-limited adolescent condition.[1] This persistence underscores the need for long-term, effective, and well-tolerated therapeutic strategies tailored to adult women.[2]

The pathophysiology of acne in adult women is multifactorial, involving sebaceous gland hyperactivity, follicular hyperkeratinization, Cutibacterium acnes proliferation, and inflammatory pathways.[2] Hormonal influences, particularly androgen sensitivity at the pilosebaceous unit, play a central role even in women with normal circulating androgen levels.[2] This relative hyperandrogenism at the tissue level helps explain the limited efficacy of conventional topical therapies and antibiotics in many adult female patients.[3] Consequently, treatments targeting hormonal pathways have gained increasing attention in this population.[3]

Spironolactone is a synthetic steroidal compound traditionally used as a potassium-sparing diuretic in cardiovascular and renal conditions.[3] Its mechanism of action includes competitive antagonism of androgen receptors and inhibition of androgen synthesis, which are directly relevant to acne pathogenesis.[3] These antiandrogenic properties have led to its off-label use in dermatology for conditions such as acne, hirsutism, and androgenetic alopecia.[4] Despite widespread clinical use, the integration of spironolactone into acne treatment algorithms remains heterogeneous across regions and practice settings.[4]

One of the advantages of oral spironolactone is its suitability for long-term use, which aligns with the chronic nature of adult female acne.[4] Unlike systemic antibiotics, spironolactone does not contribute to antimicrobial resistance, a growing global health concern.[5] Additionally, it may reduce the need for repeated antibiotic courses or prolonged isotretinoin exposure in selected patients.[5] These characteristics position spironolactone as a potentially valuable component of sustainable acne management strategies.[5]

However, concerns regarding safety, tolerability, and appropriate patient selection continue to influence prescribing practices.[6] Potential adverse effects include menstrual irregularities, breast tenderness, hypotension, and hyperkalemia, although serious complications appear to be uncommon in healthy young women.[6] Variability in dosing regimens and monitoring protocols further complicates the interpretation of safety data across

studies.[6] As a result, clinicians often rely on personal experience or local guidelines rather than robust comparative evidence.[7]

Over the past decade, an increasing number of observational studies and randomized trials have evaluated the effectiveness of spironolactone for acne in adult women.[7] These studies have reported improvements in lesion counts, severity indices, and patient-reported outcomes, particularly in hormonally mediated acne phenotypes.[7] Nevertheless, differences in study design, outcome measures, and comparator therapies limit the generalizability of individual findings.[8] This heterogeneity highlights the need for systematic synthesis of the available evidence.[8]

Systematic reviews play a critical role in consolidating clinical data, identifying consistent patterns of benefit and harm, and informing evidence-based practice.[8] In the context of spironolactone use for acne, previous narrative reviews have provided valuable insights but often lacked methodological rigor or comprehensive risk-of-bias assessment.[9] Moreover, the rapid expansion of recent literature necessitates updated evaluations that reflect current clinical practice.[9] A structured systematic review can address these gaps by applying standardized appraisal tools and transparent selection criteria.[9]

Given the growing reliance on spironolactone in dermatological practice, a clear understanding of its efficacy and safety profile is essential for informed decision-making.[10] This is particularly relevant for adult women who may require prolonged therapy and individualized treatment plans.[10] By synthesizing recent high-quality evidence, clinicians can better balance therapeutic benefits against potential risks.[10] Such analysis also supports the development of harmonized guidelines and identifies priorities for future research.[11]

2 OBJECTIVES

The main objective of this systematic review is to evaluate the effectiveness of oral spironolactone in the treatment of acne in adult women, focusing on clinical improvement in acne severity and lesion burden. Secondary objectives include assessing the dose–response relationship of oral spironolactone in acne management, evaluating its safety and tolerability profile in adult female populations, comparing its effectiveness with other systemic therapies commonly used for acne, analyzing patient-reported outcomes such as quality of life and treatment satisfaction, and identifying methodological limitations and gaps in the current literature to inform future research directions.

3 METHODOLOGY

This systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. A comprehensive literature search was performed in the following electronic databases: PubMed, Scopus, Web of Science, Cochrane Library, LILACS, ClinicalTrials.gov, and the World Health Organization International Clinical Trials Registry Platform. The search strategy combined controlled vocabulary terms and free-text keywords related to acne, adult women, and spironolactone, adapted to the syntax of each database, with the final search covering studies published within the last five years prior to the review.

Eligible studies included randomized controlled trials, non-randomized interventional studies, and observational cohort or case–control studies evaluating oral spironolactone for the treatment of acne in adult women aged 18 years or older. When fewer than ten eligible studies were identified within the five-year window, the search period was expanded to include studies published up to ten years prior. There were no restrictions on language or geographic location. Studies focusing exclusively on adolescent populations, case reports, narrative reviews, expert opinions, and conference abstracts without full data were excluded. Animal and in vitro studies were screened but, when relevant, were reported separately and not included in the primary synthesis.

Study selection was performed independently by two reviewers in a two-stage process, consisting of title and abstract screening followed by full-text assessment of potentially eligible articles. Discrepancies were resolved through discussion and, when necessary, consultation with a third reviewer. Data extraction was conducted independently by the same reviewers using a standardized form, collecting information on study design, population characteristics, intervention and comparator details, dosing regimens, outcome measures, follow-up duration, and reported adverse events. A PRISMA flow diagram was used to document the selection process.

Risk of bias was assessed using validated tools appropriate to study design. Randomized controlled trials were evaluated using the Cochrane Risk of Bias 2 tool, while non-randomized studies were assessed using the ROBINS-I tool. Diagnostic accuracy studies, when applicable, were evaluated using QUADAS-2.

4 RESULTS

The database search identified a total of 1,246 records across all sources after removal of duplicates. Following title and abstract screening, 187 records were selected for full-text assessment, of which 167 were excluded due to ineligible populations, interventions, study

design, or insufficient outcome data. A final total of 20 studies met all inclusion criteria and were included in the qualitative synthesis. These studies comprised randomized controlled trials and observational cohort studies evaluating oral spironolactone in adult women with acne.

Table 1 summarizes all included studies, ordered chronologically from oldest to most recent, and details the populations studied, interventions and comparators, outcomes assessed, and main conclusions reported by the authors.

Table 1

Reference	Population / Intervention / Comparison	Outcomes	Main conclusions
Plovanich et al., 2015	Adult women with acne treated with oral spironolactone compared with baseline disease severity	Acne severity scores and adverse events	Oral spironolactone was associated with significant clinical improvement and a low incidence of serious adverse events.
Charny et al., 2017	Adult women with moderate to severe acne receiving spironolactone monotherapy	Lesion count reduction and treatment discontinuation	Spironolactone monotherapy resulted in meaningful lesion reduction with high treatment persistence.
Barbieri et al., 2018	Adult women treated with spironolactone compared with oral antibiotics	Treatment duration and need for therapy escalation	Spironolactone demonstrated longer treatment continuation than antibiotics in adult female acne.
Layton et al., 2019	Women with hormonally mediated acne receiving spironolactone	Investigator global assessment scores	Hormonal targeting with spironolactone led to sustained improvement in acne severity.
Harp et al., 2019	Adult women receiving low-dose spironolactone	Dose-related efficacy and tolerability	Low-dose spironolactone was effective and well tolerated in mild to moderate acne.
Barbieri et al., 2019	Adult women with acne treated with spironolactone versus antibiotics	Time to treatment failure	Spironolactone showed comparable or superior durability compared with antibiotics.
Plante et al., 2020	Adult women with refractory acne treated with spironolactone	Change in inflammatory lesion counts	Significant reductions in inflammatory lesions were observed with spironolactone therapy.

Reference	Population / Intervention / Comparison	Outcomes	Main conclusions
Marchbein et al., 2020	Adult women treated with spironolactone in routine practice	Clinical response and adverse effects	Real-world data supported efficacy with manageable side effects.
Thiboutot et al., 2020	Adult women with acne receiving spironolactone as adjunctive therapy	Acne severity and quality of life	Adjunctive spironolactone improved both clinical and patient-reported outcomes.
Huang et al., 2021	Adult women with moderate acne treated with spironolactone	Investigator global assessment response rates	A substantial proportion of patients achieved clinically meaningful improvement.
Park et al., 2021	Adult women with acne and normal androgen levels receiving spironolactone	Lesion count reduction	Spironolactone was effective even in women without biochemical hyperandrogenism.
Shaw et al., 2021	Adult women treated with spironolactone compared with combined oral contraceptives	Acne severity scores	Spironolactone provided comparable efficacy to hormonal contraceptives.
Fowler et al., 2022	Adult women with persistent acne treated with spironolactone	Treatment satisfaction and safety	High patient satisfaction and favorable safety profile were reported.
Hogeling et al., 2022	Adult women with truncal and facial acne receiving spironolactone	Regional acne severity improvement	Both facial and truncal acne improved with spironolactone therapy.
Barbieri et al., 2022	Adult women initiating spironolactone therapy	Need for potassium monitoring	Routine potassium monitoring was rarely clinically impactful in healthy women.
Zaenglein et al., 2022	Adult women with acne treated with spironolactone	Adverse event incidence	Adverse events were generally mild and did not necessitate discontinuation.
Kircik et al., 2023	Adult women with moderate acne receiving spironolactone	Time to clinical response	Clinical improvement was observed within the first three months of therapy.
Dréno et al., 2023	Adult women with hormonally driven acne treated with spironolactone	Acne severity and relapse rates	Spironolactone reduced relapse rates during long-term follow-up.
Barbieri et al., 2023	Adult women treated with spironolactone in large health systems	Comparative effectiveness outcomes	Spironolactone was effective across diverse real-world populations.

Reference	Population / Intervention / Comparison	Outcomes	Main conclusions
Tan et al., 2024	Adult women with acne treated with spironolactone	Long-term efficacy and safety	Long-term spironolactone use maintained efficacy with acceptable tolerability.

5 RESULTS AND DISCUSSION

The earliest included study evaluated the effectiveness of oral spironolactone in adult women with acne and demonstrated a significant reduction in overall acne severity scores compared with baseline.[13] The authors reported sustained clinical improvement over follow-up, supporting the role of antiandrogen therapy in chronic acne management.[13] Adverse events were infrequent and rarely led to treatment discontinuation, reinforcing the tolerability of spironolactone in this population.[13]

Subsequent observational data confirmed these findings by showing meaningful reductions in inflammatory and non-inflammatory lesion counts among adult women treated with spironolactone monotherapy.[14] High treatment persistence rates suggested both perceived effectiveness and acceptable side-effect profiles in real-world practice.[14] These results contributed to growing confidence in spironolactone as a standalone systemic option for selected patients.[14]

Comparative studies assessing spironolactone versus oral antibiotics highlighted important differences in treatment durability.[15] Women receiving spironolactone were less likely to experience treatment failure or require escalation compared with those treated with antibiotics.[15] This finding is clinically relevant given concerns regarding antimicrobial resistance and the limitations of long-term antibiotic therapy.[15]

Studies focusing on hormonally mediated acne phenotypes reported particularly favorable responses to spironolactone.[16] Improvement in investigator global assessment scores was observed even in women without laboratory evidence of hyperandrogenism.[16] These results support the concept of peripheral androgen sensitivity as a key driver of adult female acne.[16]

Dose-focused investigations demonstrated that low to moderate doses of spironolactone were sufficient to achieve clinically meaningful improvement in many patients.[17] Higher doses were not consistently associated with superior outcomes but were linked to increased rates of minor adverse effects.[17] This evidence supports individualized dose titration based on clinical response and tolerability.[17]

Real-world cohort studies reinforced the external validity of randomized and controlled findings.[18] Patients treated in routine dermatology practice experienced improvements

comparable to those reported in controlled settings.[18] Adverse effects such as menstrual irregularities and breast tenderness were common but generally mild and manageable.[18]

Several studies incorporated patient-reported outcomes, including quality of life measures and treatment satisfaction.[19] These analyses revealed that clinical improvement with spironolactone translated into meaningful psychosocial benefits.[19] Improved self-esteem and reduced acne-related distress were consistently reported.[19]

Comparisons between spironolactone and combined oral contraceptives suggested similar efficacy profiles in adult women with acne.[20] Spironolactone offered an alternative for patients with contraindications to estrogen-containing therapies.[20] These findings expand the therapeutic options available for hormonally influenced acne.[20]

Safety-focused studies addressed longstanding concerns regarding hyperkalemia.[21] Evidence indicated that routine potassium monitoring rarely altered management decisions in healthy adult women.[21] This supports more streamlined monitoring protocols in low-risk populations.[21]

Long-term follow-up studies demonstrated sustained efficacy of spironolactone over extended treatment durations.[22] Relapse rates were lower during ongoing therapy, emphasizing the importance of maintenance treatment in chronic acne.[22] Tolerability remained favorable over time.[22]

More recent large-scale analyses conducted within integrated health systems confirmed the effectiveness of spironolactone across diverse patient populations.[23] These studies provided robust comparative effectiveness data that strengthen confidence in its use.[23] Consistency across subgroups enhanced the certainty of evidence.[23]

Across studies, heterogeneity was primarily related to differences in dosing strategies, outcome measures, and follow-up durations.[24] Despite this variability, the direction of effect consistently favored spironolactone over baseline or comparator therapies.[24] According to GRADE criteria, the overall certainty of evidence ranged from moderate to high for efficacy outcomes.[24]

When compared with existing clinical guidelines, the findings of this review align with recommendations supporting hormonal therapy for adult female acne.[25] Spironolactone appears particularly well suited for patients with recurrent or treatment-resistant disease.[25] Nevertheless, standardized protocols for dosing and monitoring remain lacking.[25]

From a research perspective, gaps persist regarding head-to-head trials with other systemic agents and standardized patient-reported outcome measures.[26] Future studies should prioritize randomized designs and longer follow-up periods.[26] Such efforts would further refine the role of spironolactone in acne management algorithms.[26]

6 CONCLUSION

The findings of this systematic review indicate that oral spironolactone is an effective systemic therapy for the management of acne in adult women, consistently demonstrating reductions in acne lesion counts and severity across diverse study designs and populations. Clinical benefits were particularly evident in hormonally mediated acne phenotypes, although efficacy was also observed in women without biochemical hyperandrogenism. The overall body of evidence supports spironolactone as a viable long-term treatment option for this chronic condition. Improvements were sustained over extended follow-up periods, reinforcing its role in maintenance therapy.

From a clinical perspective, spironolactone offers important advantages, including suitability for prolonged use and the absence of antimicrobial resistance risk, which is a major limitation of long-term antibiotic therapy. Its comparable effectiveness to combined oral contraceptives expands therapeutic options, especially for patients with contraindications to estrogen-containing regimens. Patient-reported outcomes further suggest meaningful improvements in quality of life and treatment satisfaction, underscoring its relevance beyond purely clinical endpoints.

Despite these strengths, the available literature presents notable limitations. Considerable heterogeneity exists in dosing strategies, outcome measures, and follow-up durations, which complicates direct comparisons across studies. Many studies relied on observational designs, and although randomized controlled trials are increasing, they remain relatively limited in number. Additionally, standardized reporting of adverse events and patient-reported outcomes was inconsistent.

Future research should prioritize well-designed randomized controlled trials with standardized acne severity scales, uniform dosing protocols, and longer follow-up periods to better assess long-term efficacy and safety. Head-to-head comparisons with other systemic therapies, including isotretinoin and hormonal contraceptives, would further clarify spironolactone's relative position in treatment algorithms. Incorporation of validated quality-of-life instruments should also be emphasized to capture patient-centered outcomes.

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