Naunyn-Schmiedeberg's Archives of Pharmacology
https://doi.org/10.1007/s00210-024-03557-y

RESEARCH

Sarecycline for moderate to severe acne: a promising narrow-spectrum antibacterial drug

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Received: 18 September 2024 / Accepted: 19 October 2024

Abstract

Sarecycline, a narrow-spectrum antibacterial drug approved by the FDA in 2018, targets *Cutibacterium acnes* while potentially minimizing disruption to the gut microbiota. The aim of this study is to assess the efficacy and safety of sarecycline compared to placebo in treating moderate to severe facial acne. A comprehensive search of PubMed, MEDLINE, and Cochrane databases was performed, with data extraction and screening conducted independently by two authors. Statistical analysis used RevMan, and the risk of bias was evaluated using RoB 2. Three RCTs ($n = 2287$ patients, mean age 19.6–20.8 years) met the inclusion criteria. Sarecycline (1.5 mg/kg) administered daily for 12 weeks significantly reduced inflammatory and non-inflammatory lesion counts compared to placebo ($p < 0.00001$). Other outcomes were not statistically significant. Sarecycline 1.5 mg/kg daily is an effective and well-tolerated treatment for moderate to severe acne with minimal side effects.

Keywords Sarecycline · Acne vulgaris · Inflammatory lesions · Papules · Pustules

Introduction

Acne vulgaris is a common chronic inflammatory condition that affects 80% of adolescents, 54% of adult women, and 40% of adult men)Moore et al. 2023, 2019; Pariser et al. 2019). In the evolving view of acne pathogenesis, inflammation has emerged as a key driving factor for the entire acne pathway, from the development of microcomedoes to comedo, papules, pustules, cysts, and acne scars. Acne

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Published online: 04 November 2024

vulgaris involves many inflammatory pathways, including toll-like receptor 2 and 4 upregulation, downstream upregulation of matrix metalloproteinases, collagen breakdown, increased pro-collagen, and increased T-helper cells. *Cutibacterium acnes* has been found to trigger innate immunological and inflammatory processes in epidermal keratinocytes via TOLR and to promote IL-1 production in human monocytes via the NLRP3 inflammasome (Leyden et al. 2018; Harper et al. 2023; Moura et al. 2022).

For over a half-century, the tetracycline antibacterial drug class has been a cornerstone of oral therapy for acne vulgaris treatment. Tetracycline-class antibacterial drugs are regarded as first-line treatment for inflammatory lesions in moderate-to-severe acne when used in conjunction with topical therapy. These antibacterial drugs inhibit bacteria by blocking protein synthesis. They have antibacterial activity against Gram-positive organisms such as *Cutibacterium acnes* (previously known as *Propionibacterium acnes*) as well as several Gram-negative germs that are not implicated in acne. Furthermore, tetracycline-class antibacterial drugs have anti-inflammatory characteristics, which may increase their effectiveness in treating acne (Pariser et al. 2019; Zhanel et al. 2019; 2019).

However, currently available oral tetracycline-class antibacterial drugs for acne, such as doxycycline and minocycline, have significant limitations. Side effects with minocycline might include dizziness, lightheadedness, tinnitus, and vertigo; with doxycycline, photosensitivity; and gastrointestinal (GI) problems include anorexia, nausea, vomiting, and diarrhea. Furthermore, the broad spectrum of antimicrobial activity of doxycycline and minocycline, as well as the potential risks of disrupting the microbial flora and causing the development of antimicrobial resistance, have prompted medical community directives to encourage a more responsible use of systemic antibacterial drugs for acne (Haidari et al. 2020; Kaul et al. 2019).

Sarecycline is a narrow-spectrum tetracycline-class antibacterial drug that was authorized by the Food and Drug Administration (FDA) in October 2018 for the treatment of moderate-to-severe acne vulgaris in patients aged 9 years and above (Moore et al. 2023).

Sarecycline is suggested for the treatment of moderate-to-severe inflammatory lesions of non-nodular acne (Pariser et al. 2019). In addition to anti-inflammatory properties in vitro, sarecycline is effective against Gram-positive bacteria such as *Cutibacterium acnes*. Minimal inhibitory doses that prevent 50% growth of *P. acnes* have been demonstrated in preclinical research, which are equivalent to other tetracyclines used to treat acne. However, unlike doxycycline and minocycline, sarecycline has poor efficacy against enteric Gram-negative bacteria such as *Escherichia coli*, *Klebsiella pneumoniae*, and *Enterobacter cloacae* (Rupert and Hughes 2020; Duarte and Sousa 2021).

If proven in clinical trials, sarecycline's more selective narrow-spectrum antibacterial activity may help to ensure less disruption of the GI microbiota. So, this study aims to measure the safety and efficacy of oral sarecycline compared to placebo in patients with moderate to severe facial acne.

Methods

This systematic review and meta-analysis followed Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA). All steps were taken in accordance with the Cochrane Handbook of Systematic Reviews of Interventions. The study protocol was registered on OSF (registration doi is https://doi.org/https://doi.org/10.17605/OSF.IO/4SRU3) (Page et al. 2021; Higgins et al. 2019).

Eligibility criteria

Randomized control trials that studied sarecycline 1.5 mg/kg/day versus placebo in patients with acne vulgaris were included and their outcome measures were analyzed. Case reports, case series, animal studies, laboratory, editorials, non-English literature, unpublished literature, reviews, thesis, conference abstracts, and studies that did not mention sarecycline as a treatment for patients with acne vulgaris were excluded.

Search strategy

The PubMed Central, Web of Science, Scopus and Embase databases were used to search potentially interesting articles published from the database from till February 6th 2024, using the following search strategy (Sarecycline OR "Minocycline sulfone" OR "Sarecyclinum" OR "WC3035") AND (Acne OR "Acne vulgaris" OR "Acneiform eruptions" OR "Pimples" OR "Zits" OR "Comedones" OR "Blackheads" OR "Whiteheads" OR "Pustules" OR "Cystic acne" OR "Inflammatory acne" OR "Non-inflammatory acne" OR "Acne lesions"), after removing the duplicate studies using EndNote, title/abstract screening was done using Rayyan software package (Ouzzani et al. 2016); then, a full-text screening of included abstracts was done to finalize the included studies.

Statistical analysis

RevMan Cochrane was used for the statistical analysis. The categorical variables (TEAEs, headache, nausea, vomiting, and nasopharyngitis) were represented using event and

total, whereas the continuous variables (percent change from baseline in the inflammatory lesion and change in absolute noninflammatory lesion count from baseline to the end of follow-up) were described using mean and standard deviation (SD). Patient outcomes were assessed by 12 weeks.

Data extraction

Two independent authors retrieved information from the eligible articles following the inclusion and exclusion criteria, and information was collected on a standardized data sheet that included the summary sheet for (author's name, study design, country, number of centers, total participants, follow up period, main inclusion criteria, primary outcome, and conclusion), baseline characteristics include (age, sex, race, inflammatory lesions, non-inflammatory lesions, and IGA) and outcome ascertainment.

Quality assessment

We used a Cochrane risk-of-bias tool for randomized control trials (RoB 2) (Sterne et al. 2019), which has five domains: the randomization process (bias in selection) of all reported results, deviation from the intended intervention (bias in performance), missing outcome data (bias in attrition), outcome measurement (bias in detection), and selection of reported results (bias in reporting). The domains' judgments are "low risk," "some concerns," and "high risk." Furthermore, all risk biases have three judgment possibilities.

Results

Literature search results

Our systematic search identified 143 potential studies. After eliminating 13 duplicates, a further exclusion of 102 studies occurred during title/abstract screening. Subsequent full-text screening resulted in the exclusion of an additional 25 studies. Ultimately, three studies (Leyden et al. 2018; Moore et al. 2018) met the eligibility criteria for inclusion in both the quantitative and qualitative synthesis of this systematic review (Fig. 1; PRISMA).

Characteristics of included studies

All the studies incorporated into our analysis were multicenter randomized controlled trials (RCTs), comprising a total of 2287 patients. The mean age of participants ranged from 19.6 to 20.8 years. Two trials were conducted in the USA (Moore et al. 2018), while one study took place in Ireland (Leyden et al. 2018). Sarecycline was administered orally once a day at a dosage of 1.5 mg/kg, with a follow-up period of 12 weeks.

Demographic distribution revealed that 53.9% of the study participants were females. Ethnic breakdown indicated 338 individuals (14.77%) identified as African Americans, and 1652 participants (72.23%) identified as Caucasians. The mean count of inflammatory lesions ranged from 29.7 to 33.5, while the mean count of non-inflammatory lesions ranged from 42.3 to 53.2. Investigator's Global Assessment (IGA) revealed that the majority of participants (79.97%) had a moderate score of "3," whereas 315 participants (13.77%) were assessed with severe acne, indicated by a score of "4" (Tables 1 and 2).

Quality assessment

According to the Cochrane Risk of Bias Assessment Tool for Randomized Clinical Trials II (ROB-II), the quality of all included studies was low risk of bias. All domains in the three trials showed a low risk of bias except the missing outcome data domain showed some concerned risk of bias in two trials (Fig. 2).

Outcomes

Efficacy outcomes

Percent change in inflammatory lesion count at week 12 This outcome, involving 2144 patients across three trials, revealed a significant difference between sarecycline and placebo groups in favor of sarecycline ([MD] = −15.37, 95% [CI]: [−19.17, −11.57], $p < 0.00001$). The combined results exhibited homogeneity ($p = 0.85$, $I2 = 0\%$) (Fig. 3).

Change in absolute noninflammatory lesion count at week 12 Examining 2144 patients in three trials, the overall effect estimates demonstrated a significant difference favoring sarecycline over placebo (MD = −2.83, 95% CI: [−4.54, −1.12], $p < 0.00001$). The pooled results displayed homogeneity ($p = 0.7$, $I2 = 0\%$) (Fig. 4).

Safety outcomes Regarding safety outcomes for the intervention, this study analyzed five different adverse events: treatment-emergent adverse events (TEAE), headache, nausea, vomiting, and nasopharyngitis.

Treatment-emergent adverse events (TEAE) Pooling data of 2133 patients across three trials, the overall effect estimates indicated a non-significant difference between sarecycline and placebo groups (relative risk [RR] = 0.95, 95% CI: [0.83, 1.09], $p = 0.46$). The combined results showed homogeneity ($p = 0.86$, $I2 = 0\%$) (Fig. 5).

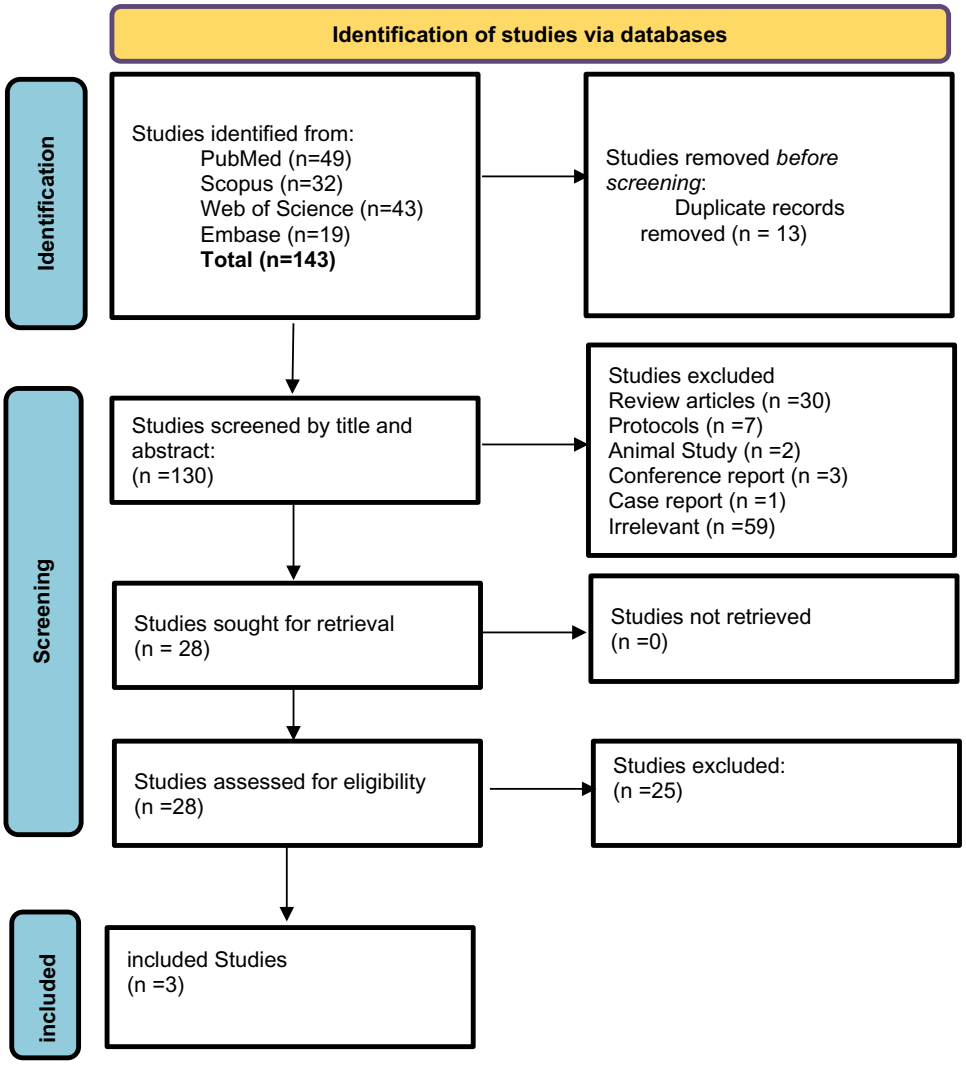

Fig. 1 PRISMA flow diagram

Headache Across three trials with 2133 patients, the overall effect estimates revealed no significant difference between sarecycline and placebo groups (RR = 0.71, 95% CI: [0.46, 1.09], $p = 0.12$). The pooled results displayed homogeneity ($p = 0.67$, $I2 = 0\%$) (Fig. 6).

Nausea Three trials were included in this outcome with 2133 patients. The overall effect estimates showed a non-significant difference between the sarecycline and placebo groups (RR = 1.58, 95% CI: [0.92, 2.72], $p = 0.10$). The pooled results were homogenous ($p = 0.22$, $I2 = 34\%$) (Fig. 7).

Vomiting The analysis of two trials with 1990 patients showed a non-significant difference in overall effect estimates between sarecycline and placebo groups (RR = 1.45, 95% CI: [0.62, 3.37], $p = 0.39$). The pooled results were homogeneous ($p = 0.97$, $I2 = 0\%$) (Fig. 8).

Nasopharyngitis Analyzing 2133 patients in three trials, the overall effect estimates demonstrated a non-significant difference between sarecycline and placebo groups (RR = 1.08, 95% CI: [0.65, 1.79], $p = 0.77$). The pooled results maintained homogeneity ($p = 0.19$, $I2 = 40\%$) (Fig. 9).

Discussion

The systematic review of three clinical trials involving a large cohort of patients demonstrated that sarecycline was significantly more effective than placebo in reducing both inflammatory and noninflammatory lesions by week 12. The analysis showed consistent results across the trials, with no observed heterogeneity, indicating that sarecycline consistently outperformed placebo in improving these key clinical outcomes. Additionally, the safety analysis of over 2100 patients revealed no significant differences between

Table 1 Summary of included studies

Study ID	Study design, country	Total patients	Follow-up duration	Main inclusion criteria	Primary outcomes	Conclusion
Moore 2018 (SC1401)	Phase 3, Randomized, Double-Blind Clinical Trials, USA	968	12-week	Eligible patients were aged 9 to 45 years, weighed 33 to 136 kg, and had 20 to 50 inflammatory lesions, ≤ 100 noninflammatory lesions, ≤ 2 nodules, and a score of 3 (moderate) or 4 (severe) on the Investigator's Global Assessment (IGA) scale for inflammatory lesions of acne	The Skindex-16, a 16-item questionnaire measuring the effects of skin disease on patients' quality of life using 3 scales (symptoms, emotions, and functioning), with scores standardized from 0 (never bothered) to 100 (always bothered), was administered to patients at baseline and week 12	Oral sarecycline 1.5 mg/kg per day was effective in improving acne severity and inflammatory and noninflammatory lesion counts, with the onset of efficacy for inflammatory lesions observed as early as week 3, and the onset of efficacy for absolute reduction in noninflammatory lesion count observed at week 6 for the study SC1401 and at week 9 for study SC1402. A benefit was also seen for non-facial acne at week 12. Sarecycline was well tolerated and associated with low rates of vestibular side effects, phototoxicity, and GI side effects, all of which are commonly observed with the use of currently available first-line oral tetracycline-class antibiotics for moderate to severe acne
Moore 2018 (SC1402)	Phase 3, Randomized, Double-Blind Clinical Trials, USA	1034	12-week	Eligible patients were aged 9 to 45 years, weighed 33 to 136 kg, and had 20 to 50 inflammatory lesions, ≤ 100 noninflammatory lesions, ≤ 2 nodules, and a score of 3 (moderate) or 4 (severe) on the Investigator's Global Assessment (IGA) scale for inflammatory lesions of acne	The Skindex-16, a 16-item questionnaire measuring the effects of skin disease on patients' quality of life using 3 scales (symptoms, emotions, and functioning), with scores standardized from 0 (never bothered) to 100 (always bothered), was administered to patients at baseline and week 12	
Leyden 2018	Double-blind, placebo-controlled RCT, Ireland	285	12-week	Eligible patients were aged 12 to 45 years, weighted between 52 and 88 kg, with facial acne vulgaris characterized by 20 to 50 inflammatory lesions, 30 to 100 noninflammatory lesions, and no more than two facial nodules and a score of 3 (moderate) or 4 (severe) on the Investigator's Global Assessment (IGA) scale for inflammatory lesions of acne Females of childbearing potential had to have a negative pregnancy test and use an effective method of contraception	Efficacy endpoints included absolute and percent changes from baseline in inflammatory and noninflammatory (open and closed comedones) lesion counts	Oral sarecycline 1.5 mg/kg per day was effective, safe, and well-tolerated by patients aged 12 to 45 years with moderate to severe acne These results supported the phase 3 development of sarecycline 1.5 mg/kg/day for the treatment of moderate to severe acne

Table 2 Baseline characteristics of enrolled patients in the included studies

Study ID	Age (years), mean (SD)		Sex (female), *N* (%)		Race, *N* (%)						Inflammatory lesions count, mean (SD)		Non-inflammatory lesions count, mean (SD)		IGA score, *N* (%)			
					Black (African Americans)		White (Caucasian)		Others						3 (moderate)		4 (severe)	
	Sarecycline	Placebo	Sarecycline	Placebo	Sarecycline	Placebo	Sarecycline	Placebo	Sarecycline	Placebo	Sarecycline	Placebo	Sarecycline	Placebo	Sarecycline	Placebo	Sarecycline	Placebo
Moore 2018 (SC1401)	19.6 (8.75)	19.8 (8.75)	268 (55.5)	271 (55.9)	80 (16.6)	79 (16.3)	377 (78.1)	377 (77.7)	26 (5.4)	29 (6.0)	29.7	30.2	42.4	43.7	413 (85.5)	410 (84.5)	3.1 (0.4)	3.2 (0.4)
Moore 2018 (SC1402)	20.4 (8.75)	19.7 (8.5)	315 (60.7)	292 (56.7)	66 (12.7)	76 (14.8)	407 (78.4)	391 (75.9)	45 (8.7)	48 (9.3)	30.3	30.2	42.3	43.9	440 (84.8)	439 (85.2)	79 (15.2)	76 (14.8)
Leyden 2018	19.9 (7.0)	20.8 (7.0)	40 (57.1)	47 (65.3)	21 (30.0)	16 (22.2)	46 (65.7)	54 (75.0)	0	1 (1.4)	33.5 (20.0)	32.6 (7.8)	52.9 (18.0)	53.2 (18.4)	65 (92.9)	62 (86.1)	5 (7.1)	10 (13.9)

sarecycline and placebo in the occurrence of treatment-emergent adverse events, headache, nausea, vomiting, and nasopharyngitis. The relative risks across these outcomes were close to unity, and none reached statistical significance, suggesting that sarecycline's safety profile is comparable to that of placebo. The pooled results across all safety outcomes consistently demonstrated homogeneity, further supporting the reliability of these findings.

Oral sarecycline at a dose of 1.5 mg/kg per day for 12 weeks was effective in treating moderate to severe acne vulgaris. This effectiveness may be attributed to sarecycline's anti-inflammatory properties that target the early inflammatory processes believed to occur during the development of comedones (Moore et al. 2018).

Both studies implemented a rigorous 12-week treatment period, which increased the reliability and comparability of the findings on sarecycline's effectiveness. Both studies confirmed that sarecycline significantly outperforms placebo in reducing inflammatory lesion counts. This outcome is consistent with previous findings that highlight sarecycline's efficacy in decreasing both inflammatory and non-inflammatory lesions, thereby supporting its therapeutic potential (Haidari et al. 2020; Duarte and Sousa 2021).

We concluded that sarecycline is well-tolerated across treatment groups, with no serious adverse events reported. The safety profile is comparable between sarecycline and placebo groups, reinforcing the general safety of sarecycline in treating acne. Nausea is identified as the most common treatment-related side effect. However, the incidence of nausea is similar in both the sarecycline and placebo groups in the current study, aligning with the previous study's findings of a modest increase in nausea (Haidari et al. 2020; Duarte and Sousa 2021).

No adverse events related to urticaria or vulvovaginal candidiasis were reported in our study, while the others did note a slight increase in vulvovaginal candidiasis and mycotic infections in the sarecycline group. This difference might reflect variations in patient populations, study design, or reporting practices between the studies (Haidari et al. 2020; Duarte and Sousa 2021).

Unlike other tetracyclines, sarecycline features a distinctive modification in its chemical structure: a 7-[(methoxy-(methyl)-amino)-methyl] methyl] group at the C7 position on the hydrocarbon ring. This C7 moiety is the longest and largest found in any tetracycline-class drug. It extends into the mRNA channel of the ribosome, where it interacts directly with the A site codon. This interaction likely interferes with the movement of mRNA through the channel and/or disrupts the codon-anticodon pairing, leading to increased stabilization on the bacterial 70S ribosome. This stabilization blocks tRNA accommodation and strongly inhibits mRNA translation (Bunick et al. 2021).

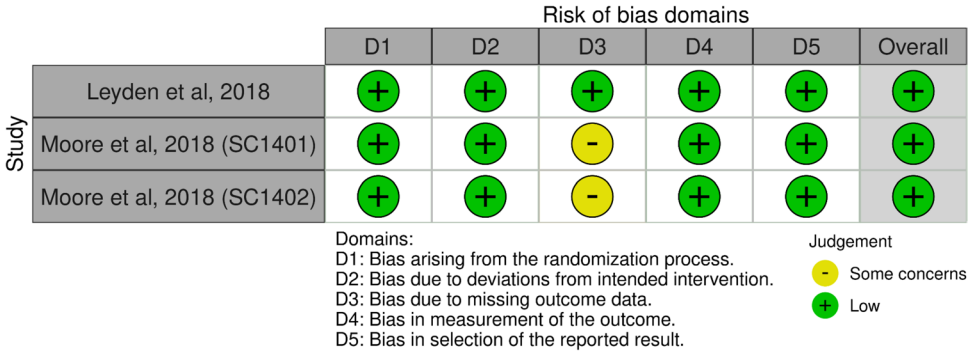

Fig. 2 Risk of bias assessment

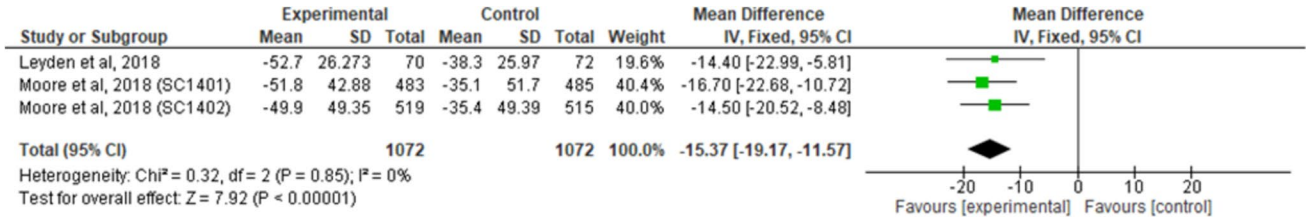

Fig. 3 Forest plot showing percent change from baseline in inflammatory lesion count at week 12

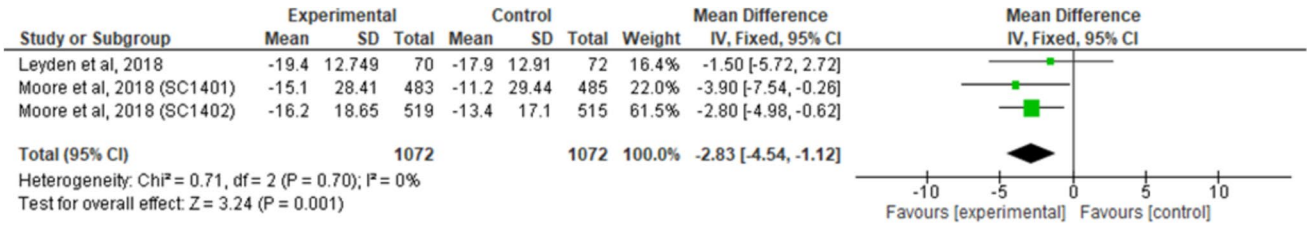

Fig. 4 Forest plot showing a change in absolute noninflammatory lesion count from baseline to the end of follow-up at week 12

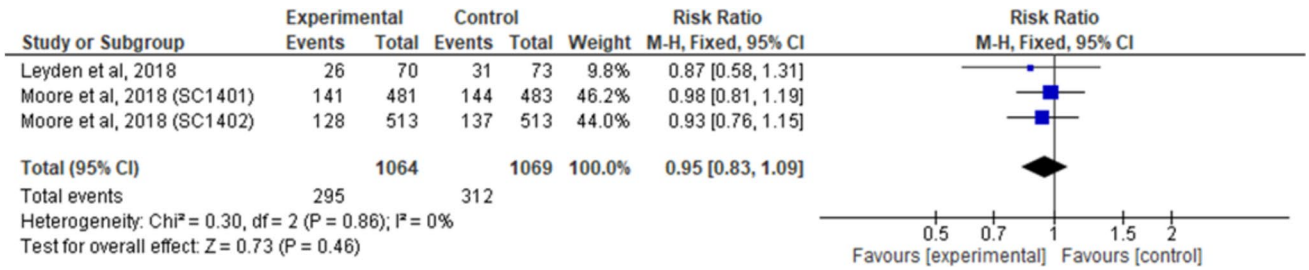

Fig. 5 Forest plot showing the incidence of TEAEs

Strengths

This systematic review represents the first meta-analysis specifically focused on sarecycline as a treatment for acne, offering valuable insights into its effectiveness and safety. Conducted in adherence to rigorous PRISMA guidelines, the review upholds high standards of methodological transparency and reproducibility. It benefits from the absence of heterogeneity in dosing regimens and follow-up periods among the included studies, as well as consistency in outcome measures, which enhances the reliability and comparability of the findings. The application of meta-analytic techniques facilitates precise estimation of treatment effects and identification of potential patterns, providing a more nuanced understanding of sarecycline's impact than individual studies alone.

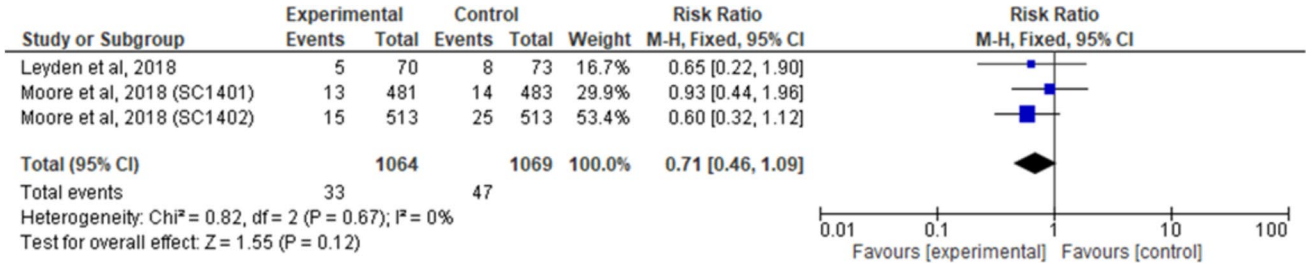

Fig. 6 Forest plot showing the incidence of headache

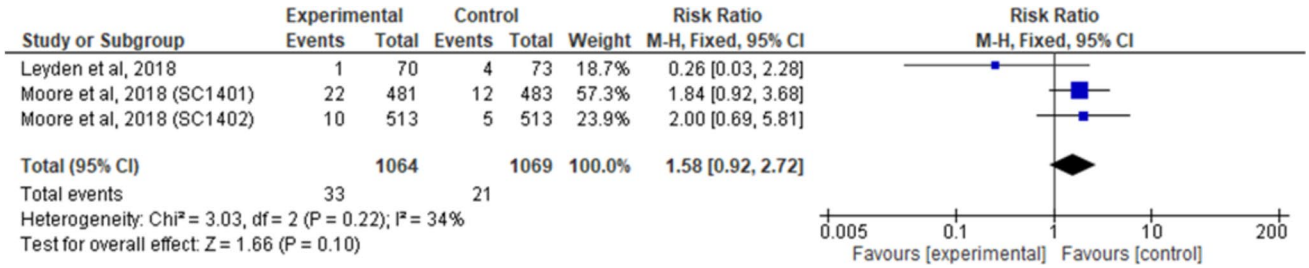

Fig. 7 Forest plot showing the incidence of nausea

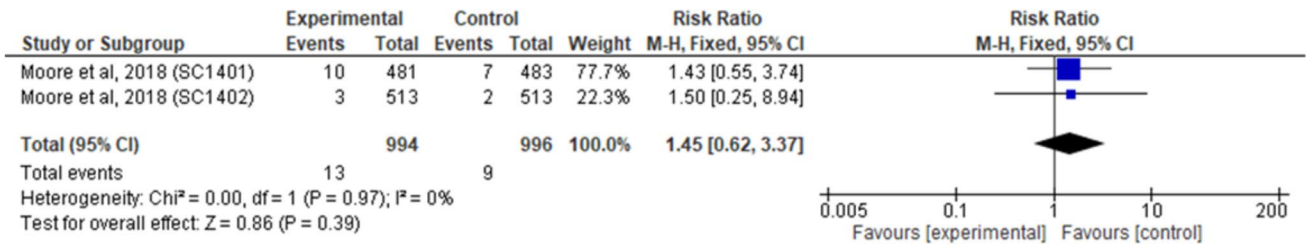

Fig. 8 Forest plot showing the incidence of vomiting

Fig. 9 Forest plot showing the incidence of nasopharyngitis

Limitations

Despite its strengths, this review has several limitations. The relatively low number of included studies may affect the generalizability and robustness of the findings. Additionally, the study populations were not sufficiently large or diverse in terms of age groups and ethnicities, which limits the applicability of the results to broader patient demographics. Furthermore, the 12 weeks of follow-up durations in the included studies restrict the ability to evaluate the long-term efficacy and safety of

sarecycline, indicating that future research with extended follow-up periods would offer more reliable and comprehensive outcomes.

Recommendations for future studies

We strongly recommend conducting additional randomized controlled trials (RCTs) on this topic. Future studies should include longer follow-up periods to better assess sarecycline's long-term efficacy and safety, with more representative populations.

Conclusions

Oral sarecycline 1.5 mg/kg daily is superior to placebo in treating moderate to severe acne vulgaris as it reduces both inflammatory and non-inflammatory lesions more effectively. The safety profile of sarecycline was comparable to placebo with no major difference in the incidence of the adverse events.

Acknowledgements We would like to acknowledge the Princess Nourah bint Abdulrahman University Researchers, Supporting Project number (PNURSP2024R227), Princess Nourah bint Abdulrahman University, Riyadh, Saudi Arabia.

Author contribution All the authors contributed according to the ICMJE criteria. All authors declare that all data were generated in-house and that no paper mill was used.

Data availability All data relevant to this study are included in this article or upon request from the corresponding author.

Declarations

Ethics approval and consent to participate This article does not contain any studies with human participants or animals performed by any of the authors.

Consent for publication Not applicable.

Competing interests The authors declare no competing interests.

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