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Progress of Phage Therapy for Acne Vulgaris

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Abstract: *Acne is a chronic recurrent skin disorder associated with abnormal sebum secretion, hyperkeratosis of hair follicles, microbial imbalance, and inflammatory responses. The microbiome disruption mediated by Cutibacterium acnes is the core pathogenic factor. Traditional treatment regimens (e.g., antibiotics, combination therapies, phototherapy) can alleviate symptoms but may lead to antibiotic resistance and adverse reactions with prolonged use, leaving clinical needs unmet. Bacteriophages, as viruses that specifically infect bacteria, offer advantages such as host-targeting specificity, environmental friendliness, high safety, and low risk of inducing resistance, providing a novel alternative pathway for acne treatment. This article systematically reviews the pathogenesis of acne and the limitations of traditional therapies, with a focus on the biological characteristics of bacteriophages, therapeutic classifications (e.g., bacteriophage cocktail therapy, bacteriophage-antibiotic combination therapy), and preclinical and clinical research progress in acne treatment. It also analyzes core challenges in bacteriophage therapy, including incomplete regulatory frameworks, unclear pharmacokinetic/pharmacodynamic mechanisms, and insufficient toxicity evaluation. Studies demonstrate that bacteriophages exert therapeutic effects through mechanisms such as specific lysis of Cutibacterium acnes and inhibition of biofilm formation. Preclinical experiments and Phase I clinical trials have confirmed their safety and preliminary efficacy, but large-scale randomized controlled trials and mechanistic studies are still required to advance their clinical translation. Future efforts should focus on microbiome-based therapeutic strategies, improve regulatory and quality control systems, accelerate the translation of phage therapy from basic research to clinical application, and provide safer and more effective treatment options for acne patients.*

Keywords: *Acne, Phage Therapy, Propionibacterium Acnes Bacteriophages, Dermatological Diseases*

1. Introduction

1.1. Acne and Bacteriophages

Acne is a multifactorial disorder associated with abnormal sebum secretion, hyperkeratosis of the pilosebaceous unit, microbial colonization, and inflammatory responses [1]. The incidence is associated with multiple factors including social, environmental, genetic, gender, age, hormonal, dietary, sleep, and psychological factors. Studies have shown that the microbiome imbalance of *Propionibacterium* acnes (*P. acnes*) (formerly known as *Dermatobacter* acnes) is a key pathogenic factor in acne[2]. The Gram-positive bacterium, *Cutibacterium* acnes, constitutes approximately 90% of the skin microbiome in healthy adults and directly participates in the pathophysiological process of acne by colonizing hair follicles and inducing inflammatory responses [2].

The pathological characteristics of acne are the formation of comedones (which are commonly classified as whiteheads or blackheads) in the pilosebaceous follicles due to the obstruction by sebum and dead skin cells[3]. They can easily induce anxiety, depression, and anger in patients, which may intensify when treatment fails to produce satisfactory results[4].

Bacteriophages are specialized viruses that parasitize and infect bacteria. They attach to bacterial surfaces by recognizing specific receptors, transfer their genetic material, and reside within the host bacteria, thereby disrupting their life process [5]. Based on their interaction mechanisms, bacteriophages are classified into two types: virulent and temperate. Virulent bacteriophages inject their genetic material

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into the host bacteria, then replicate continuously to produce lysins and lysozyme, directly causing bacterial lysis and death. Temperate bacteriophages integrate their genetic fragments into the host bacterial genome, regulating gene expression to influence the host's physiological functions[5][6].

1.2. Traditional Treatment Modalities for Acne

1.2.1. Antibiotic

Vitamin A derivatives have been used for treating mild and moderate acne, effectively reducing the number of comedones and inflammatory lesions. Benzoyl peroxide exhibits significant inhibitory effects against *P. acne*, with a better antibacterial activity than topical antibiotics. Aspartic acid and salicylic acid are also commonly used as comedolytic agents in adjunctive acne therapy. Additionally, the combined use of antibiotics such as clindamycin, erythromycin, and minocycline enhances therapeutic efficacy. However, potential adverse effects such as photosensitivity and hyperpigmentation warrant close attention when oral antibiotics are prescribed for acne treatment[7].

1.2.2. Combined Treatment

Combination therapy represents a novel strategy for acne management, with the triad therapy comprising clindamycin phosphate, benzoyl peroxide, and adapalene demonstrating significant efficacy in moderate to severe acne. The addition of benzoyl peroxide effectively reduces the risk of antibiotic resistance[6]. In 2023, the U.S. Food and Drug Administration (FDA) approved Cabtreo™, the first topical triad therapy for acne (containing 1.2% clindamycin phosphate, 0.15% adapalene, and 3.1% benzoyl peroxide). However, as a chronic recurrent disease, acne is prone to developing antibiotic resistance with prolonged treatment, which remains a major limitation of traditional therapies.

1.2.3. Light Intracavitary

Phototherapy encompasses laser therapy, photodynamic therapy (PDT). Photodynamic reactions generate reactive oxygen species (ROS) and singlet oxygen, which disrupt bacterial cell wall lipids to achieve bactericidal effects and clear inflammatory lesions. It may still induce adverse effects such as burns, swelling, pain, and scar formation in the treated area even though it effectively addresses antibiotic resistance. Consequently, there is an urgent need to explore novel alternative therapies to tackle antibiotic resistance in acne treatment [7].

1.2.4. Novel Therapeutic Approaches of Bacteriophages

Phages can specifically target and reduce *P. acne* without disrupting the skin's normal microbiota, which prevents antibiotic resistance and addresses the growing challenge of drug resistance in traditional acne treatments[8]. *Podwojniak A* et al. highlight that significant limitation is continuing to exist, while current acne therapies show some efficacy [9]. Microbiome-based strategies should bring to the forefront for a priority for future development. Furthermore, long-term antibiotic use can readily promote the formation of bacterial biofilms, which protect bacteria from host defense systems. Therefore, combination therapy is a more appropriate option for both antibiotics and bacteriophages with narrow antimicrobial spectra [10] .

2. Research Status of Bacteriophage Therapy

2.1. Advantages and Limitations

The advantages of phage therapy lie in the following aspects: Firstly, it is more environmentally friendly compared to chemical antibiotics [11]. Secondly, it causes minimal interference with the skin and organs, acting only locally due to its host specificity[12]. Thirdly, it has broad accessibility, as systemic administration allows it to distribute throughout the patient's body, including the central nervous system [13] . Fourthly, it can inhibit the formation of bacterial biofilms, overcoming the issue of resistance to most antibiotics [14]. Finally, it demonstrates good safety and tolerability[14].

However, it also has limitations. Firstly, bacteriophage may develop resistance by resisting phage DNA integration through the CRISPR-Cas system [15]. Secondly, the specificity may be lower than expected, potentially weakening therapeutic efficacy and even posing risks such as facilitating bacterial infections in humans[16].

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2.2. Classification of Phage Therapy

Bacteriophage cocktail refers to a mixed formulation of two or more bacteriophages, which can compensate for the narrow antibacterial spectrum of a single bacteriophage [17]. Bacteriophage-antibiotic combination therapy utilizes the selective pressure of bacteriophages and bacterial competitiveness to restore bacterial sensitivity to antibiotics, thereby overcoming drug resistance [18][19]. Bacteriophage composite formulations are combination treatment regimens based on modified delivery systems, which enhance the bacteriophage's ability to lyse biofilms, improve stability, and increase skin permeability by combining bacteriophages with different dosage form carriers [20]. Genetically engineered bacteriophages are created by artificially modifying the bacteriophage genome to avoid safety concerns associated with unknown functional open reading frames (ORFs) .The specific enzymes encoded by these bacteriophages can form evolutionary clusters according to host bacterial types, almost never inducing drug-resistant strains, and are considered potential alternatives to antibiotics[19].

2.3. Preclinical Study

Current research on phage therapy for acne is relatively limited, with most studies focusing on the isolation and characterization of phages. The core phage types under investigation include *Cutibacterium* bacteriophages, formerly *Propionibacterium acnes* bacteriophages *(P. acnes* bacteriophages*)* [21][22][23][24][25], was first identified by Brzin [26] in 1964, followed by Zierdt C's discovery that 88% of acne-associated strains were sensitive to this bacteria. These phages exhibit low genetic diversity and broad host range, making them ideal candidates for acne phage therapy, with significant antibacterial activity demonstrated in both in vitro and in vivo experiments[27].

Relevant studies have confirmed that Propionibacterium bacteriophages were isolated from patients with varying degrees of acne, which demonstrated high lysis rates and therapeutic potential for skin lesions in both in vitro experiments and mouse models[28]. Nguyen D P et al. isolated and identified a novel *P. acnes* bacteriophage, KIT08, which exhibits moderate lysis capacity and rapid infection characteristics[21]. The proteins encoded by its ORFs 23 and 34, may play a role in acne treatment. Frantar A. et al. isolated two lytic bacteriophages, Ristretto and Corretto, from opportunistic oral pathogens, which can completely eliminate mature biofilms formed by multiple P. acnes strains[22]. Chen B. et al. isolated nine bacteriophages with lytic activity from human skin, which significantly disrupt biofilm structures and reduce biofilm biomass, confirming the therapeutic potential of bacteriophages in biofilm-associated infections[24]. Esquivel F C J et al. demonstrated in cell experiments that bacteriophages exhibit high clearance efficiency against P. acnes IA1 while having minimal impact on non-target strains [23]. Mayank G et al. showed in rat studies that high-dose, long-term oral administration of bacteriophage suspensions did not induce adverse reactions or significant immune responses [29].

2.4. Clinical Research

Bacteriophage therapy has been applied in multiple countries [30], but clinical trials in human diseases remain relatively scarce, with most studies focusing on retrospective research and Phase I/II clinical trials. Only a few related drugs have progressed to Phase II and are expected to advance to Phase III, while clinical trials of bacteriophages for acne remain at the Phase I stage [31][32][33][34] . A PubMed database search using the keywords "bacteriophage" and "clinical research" yielded 360 relevant articles, of which only 23 were clinical research articles, with the highest study stage being Phase II. Among these, only one Phase I clinical trial was conducted for bacteriophage therapy targeting acne[31][32][33][34].

In other areas of drug-resistant diseases, phage therapy has demonstrated promising efficacy: Cammuso T M first employed phage therapy in Canada to treat life-threatening periprosthetic joint infections. Through twice-daily intra-articular and intravenous administration (dose of 7×10^9 PFU per session), the patient's wound achieved complete healing within one month post-treatment [35][36]. In the clinical treatment of acne, M. G, S successfully screened three bacteriophages and developed a triple bacteriophage cocktail formulation, BX001. After in vitro skin and ocular tissue irritation tests confirmed its inability to penetrate the human epidermis, a double-blind, randomized Phase I clinical trial was conducted involving 75 patients with mild to moderate acne vulgaris. Patients were divided into a high-dose group, a low-dose group (2 log units lower than the control group), and a carrier gel control group. The treatment involved daily topical application to the face for 4 weeks, followed by a 1-week follow-up. The results demonstrated that the BX001 topical gel exhibited good safety and excellent tolerability, effectively reducing the P. acnes load on the face. All adverse events were mild to moderate, with no severe adverse events or treatment discontinuation [31]. The bacteriophage cocktail prepared by Emad H

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H et al. and the lysozyme-HEC gel formulation, after demonstrating efficacy in vitro, were administered to volunteers aged 25 years or older with moderate to severe facial acne caused by multidrug-resistant acne[20]. The treatment involved three applications per day, each lasting 30 minutes, for 1 week. After treatment, inflammatory symptoms, lesion size, and comedone count at acne lesions in the treatment group were significantly reduced. Multidrug-resistant Propionibacterium acne was completely eradicated, with no adverse reactions observed.

Currently, phage therapy has been listed as a routine treatment in Georgia, Poland, and Russia, while Western countries such as the United States, the United Kingdom, Belgium, France, and Germany primarily utilize it as a personalized therapeutic agent or compassionate use for infections refractory to other antibiotics [37].

3. Challenges in Phage Therapy

3.1. Inadequate Regulatory System

Currently, there are no approved phage therapeutics for marketing, and phage therapy is only used for a small number of patients with no other treatment options or in compassionate use scenarios [38]. Data on efficacy and safety based on randomized controlled clinical trials are the key breakthrough for the approval of phage therapeutics. the European Pharmacopoeia (EPA) implemented unified quality standards for phage therapeutics and active substances for the first time[39] in 2024 and the UK Medicines and Healthcare products Regulatory Agency (MHRA) issued the "Regulatory Considerations for Phage Therapeutic Use in the UK" in 2025 [40], which provide a new regulatory pathway for special characteristic exemptions in phage therapy.

3.2. Insufficient Research in Pharmacokinetics and Pharmacodynamics

The application of phage therapy must adhere to a strict pharmacokinetic (PK) and pharmacodynamic (PD) research protocols as other drugs. However, the current understanding of the in vivo PK/PD mechanisms of phages remains insufficient, due to the PK/PD characteristics of phages involve dynamic interactions among phage, host bacteria, and the human immune system, which fundamentally differ from those of traditional antimicrobial agents[37]. Additionally determining the phage dosage is the first step in establishing a PK/PD system, as the required phage varies among different bacterial specie, which make dynamic changes in bacterial and phage populations difficult to quantify precisely. Additionally, breakthroughs are needed in key issues such as the absorption, distribution, metabolism, and excretion (ADME) processes of phage therapeutics (PTMPs)[41].

3.3. Toxicity and Safety Evaluation Requires Further Investigation

With regard to the safety evaluation of phage therapy, factors such as pH, temperature, and ionic strength during storage, formulation stability, purity, effects on the skin microbiota, interactions with the immune system, and potential toxicity to eukaryotic cells are required to be focused on [45]. Western regulatory authorities have explicitly stipulated that phages for human administration must possess core characteristics such as a strictly lytic life cycle, absence of sequences encoding harmful genes, and no universal transduction potential.

4. Discussion

As a chronic recurrent dermatological disorder mediated by multiple factors, acne can be alleviated by conventional treatment regimens, but long-term use may lead to issues such as antibiotic resistance. Bacteriophage therapy, with its strong host specificity, minimal environmental impact, and favorable safety profile, has demonstrated unique advantages in addressing antibiotic resistance and has shown initial efficacy in clinical acne treatment, indicating great prospects. However, it faces multiple challenges such as imperfect regulatory system, unclear PK/PD mechanism, and insufficient toxicity assessment, and the research on it in the treatment of acne is still in the early stage. In the future, improving the regulatory standards and quality control system, deepening the research on the biological characteristics and mechanism of phage, and carrying out large-scale and high-quality randomized controlled clinical trials are the challenges to promote the transformation of phage therapy from basic research to clinical application.

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