

Review

Next-Generation TB Vaccines: Progress, Challenges, and Prospects

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Abstract: Tuberculosis (TB), caused by *Mycobacterium tuberculosis* (MTB), is a prevalent global infectious disease and a leading cause of mortality worldwide. Currently, the only available vaccine for TB prevention is Bacillus Calmette–Guérin (BCG). However, BCG demonstrates limited efficacy, particularly in adults. Efforts to develop effective TB vaccines have been ongoing for nearly a century. In this review, we have examined the current obstacles in TB vaccine research and emphasized the significance of understanding the interaction mechanism between MTB and hosts in order to provide new avenues for research and establish a solid foundation for the development of novel vaccines. We have also assessed various TB vaccine candidates, including inactivated vaccines, attenuated live vaccines, subunit vaccines, viral vector vaccines, DNA vaccines, and the emerging mRNA vaccines as well as virus-like particle (VLP)-based vaccines, which are currently in preclinical stages or clinical trials. Furthermore, we have discussed the challenges and opportunities associated with developing different types of TB vaccines and outlined future directions for TB vaccine research, aiming to expedite the development of effective vaccines. This comprehensive review offers a summary of the progress made in the field of novel TB vaccines.

Keywords: tuberculosis (TB); *Mycobacterium tuberculosis* (MTB); vaccines; clinical trials; deep learning



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1. Introduction

Tuberculosis (TB) is an ancient disease widely distributed across the world and is the leading cause of death from bacterial infections [1]. In 17–18th century Europe, TB was known as the “white plague”, with almost 100% of Europeans infected and 25% of them dying from the disease [2]. In 1882, Robert Koch, a German microbiologist, deciphered *Mycobacterium tuberculosis* (MTB) as the etiological factor responsible for TB, thereby opening a new chapter in the prevention, diagnosis, and treatment of TB [3]. With the continuous development of anti-TB drugs and improvements in sanitation and living conditions, the incidence and mortality of TB decreased significantly. However, since the 1990s, the global TB epidemic has worsened due to factors such as the emergence of drug-resistant strains of MTB, the use of immunosuppressive agents, drug addiction, poverty, and population movements [4]. TB has become a leading re-emerging infectious disease and a serious global health problem, especially in developing countries.

Despite the effectiveness of anti-TB drugs, eradicating TB still faces many challenges. On 27 October 2022, the World Health Organization (WHO) Global TB Report showed that approximately one-quarter of the world’s population is infected with MTB [4]. In 2021, the estimated global number of new TB cases was 10.6 million, a 4.5% increase from 2020, and the number of deaths from TB was 1.6 million, a 6.7% increase from 2020 [5]. China is one of the countries with a high burden of TB, with an estimated number of TB cases only second to India and Indonesia, accounting for 7.4% of the global TB incidence [5]. In 2015, the WHO introduced the “End TB Strategy”, a comprehensive plan that outlines ambitious targets for the period of 2020–2035. These objectives include a significant reduction of 90% in the

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