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Perspective

BPaLM regimen in India: A remarkable step towards tuberculosis elimination

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ABSTRACT

India is having a high burden of drug-resistant tuberculosis. In a country with overwhelmed health facilities, it is a challenging task to address issues related to tuberculosis elimination. Further, India aims to achieve the global target of tuberculosis elimination by 2025, which is five years earlier than the global target. To achieve this uphill target, there is a constant need to improve the management of tuberculosis. One such latest development is the introduction of bedaquiline, pretomanid, linezolid, and moxifloxacin (BPaLM)-based regimens to fight against multidrug-resistant tuberculosis. The present article sheds light on this new treatment rolled out by the Government of India.

1. Perspective

Tuberculosis (TB) is an outcome of the infection due to *Mycobacterium tuberculosis*. The disease is highly prevalent in densely populated countries of Asia and Africa.[1] As per an estimate, about 1/4th of the population of the world is having latent tuberculosis.[2] And this scenario, when added on with malnutrition, smoking, alcoholism, and other diseases like diabetes, leads to a grave situation resulting in a high number of cases. Further, overcrowding, poor hygiene, and a lack of proper cough etiquette result in clinical deterioration of the health of the individuals and ultimately TB.[3]

Additionally, India is a high-burden country for drug-resistant TB (DR-TB).[4] There are various types of drug-resistant tuberculosis, i.e., isoniazid mono-resistant (H-Mono), extensively drug-resistant (XDR-TB), rifampicin-resistant TB (RR-TB), pre-extensively drug-resistant (pre-XDR-TB), and multidrug-resistant (MDR-TB). MDR-TB is caused by strains of the *M. tuberculosis* complex that are resistant to at least isoniazid and rifampicin. India has the second-highest global incidence of MDR-TB, with 1.3 million cases of DR-TB in 2018. MDR-TB affected 12% of patients who have already undergone treatment as well as 2.8% of new cases. In India, there are 135,000 cases of MDR-TB/RR-TB.[5]

Numerous problems are linked to the handling of these cases. High pill burden, numerous adverse drug responses, and extended treatment duration were the causes of these problems, which in turn impacted treatment results, the emergence of serious drug resistance, and morbidity in a considerable proportion of cases.[5] In December 2022, the World Health Organization updated its treatment guidelines, and in order to address these concerns, it proposed a six-month treatment schedule for people with DR-TB, replacing

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the nine-month or longer 18-month regimens. Pretomanid, a novel drug created by the nonprofit TB Alliance, is meant to be used either with or without moxifloxacin (BPaL and BPaLM, respectively), in conjunction with bedaquiline and linezolid.[5,6]

TB elimination is a difficult task, meaning less than 1 case per 1000000 population. India aims to eliminate TB by 2025, which is five years earlier than the global targets. This goal can only be achieved with a sincere political will and uninterrupted supply of drugs, backed by the introduction of newer treatment guidelines.[7] Acting towards its goal of TB elimination and following the World Health Organization's updated management guidelines, the Government of India announced on August 9, 2024, to roll out a new shorter, i.e., 26-week-long, BPaLM regimen consisting of four drugs: bedaquiline, pretomanid, linezolid, and moxifloxacin.[8] This regimen is proven to be more effective, relatively cheaper, and patient-friendly with less pill burden and adverse drug reactions. Further, it is proven in preventing transmission.[5]

The National Institute of Research in Tuberculosis, Chennai, and the Indian Council of Medical Research conducted a study that yielded outcomes that led to over 90% of patients achieving success. This new regimen is based on those findings. Furthermore, the typically 14–17% fatality rate decreased to roughly 3-4%.[8] International trials and studies have reported similar outcomes. A 90% positive result was reported in a study conducted in South Africa. 93% of the participants in another multi-country ZeNIX research claim success.[5]

In summary, the Indian government's rollout of the BPaLM regimen is a positive step, particularly for a country that accounts for nearly 27% of global TB cases. This initiative could significantly aid India's goal of eliminating TB by 2025. However, care must be taken during the transition from traditional regimens, as some side effects of the BPaL drugs have been reported. Therefore, regular monitoring and follow-ups for potential adverse reactions will be essential.

2. Source of Funding

None.

3. Conflicts of Interest

None declared.

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