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RATIONALE OF USING SINGLE DOSE RIFAMPICIN AS A CHEMOPROPHYLAXIS AGAINST LEPROSY IN CURRENT INDIAN SCENARIO

Dermatology

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KEYWORDS

Mycobacterium leprae (M. Leprae) predominantly affects peripheral nerves and immunologically mediated lepra reactions that can cause nerve damage in the face, arms, and legs, often resulting in disability, stigma and social exclusion. Over the past decade, the annual number of new leprosy cases reported to World Health Organisation (WHO) from nearly 150 countries has plateaued at slightly more than 2,00,000 patients.[1] In India, 128/682 (18.7%) districts are still reporting more than one new case per 10,000 population. [2] Despite of this burden, Leprosy has been a neglected disease with poor awareness among both the public as well as the medical practitioners.

Chemoprophylaxis is an important cornerstone of a leprosy elimination and the most effective approach towards reducing the risk of leprosy amongst close contacts of newly diagnosed leprosy patients within the past 3 months.[1]Chemoprophylaxis provides a temporary protection by reducing the bacterial load with the use of antimicrobial agents and does not induce lasting immunological protection therefore it cannot replace vaccines. Initially, dapsone was used as a chemoprophylaxis but The main problem with this mode of prophylaxis was that dapsone/acedapsone had to be given for long periods and, hence, the possibility of being irregular, especially in case of dapsone, on account of selfadministration. Another cause of concern had been the risk of increasing dapsone resistance on account of irregularities and low drug concentrations, as with acedapsone, which had already been observed to be a worldwide phenomenon. [3]Childhood vaccination with Bacillus Calmette-Guérin (BCG) also had a protective effect of nearly 60%, and previously immunised contacts appeared to benefit from an 80% protective effect. [1]Later, Following the demonstration of its potent bactericidal action against M. leprae, and thus the efficacy of rifampicin in treatment of leprosy, its utility in prophylaxis of the disease was considered. As the drug had been shown to kill over 99% M. leprae following a single dose, it had been considered that a limited administration of rifampicin may be useful for prophylaxis of the disease.Urine discolouration is a common side-effect of rifampicin and this factor was mentioned actively when seeking informed consent from participants But, post-exposure prophylaxis through single-dose rifampicin (SDR-PEP) needs a scale-up to demonstrate its impact. This is challenging, as countries need information on the cost-effectiveness, duration of implementation, expected outcomes, and uncertainties.[2]

In 1988, a chemoprophylaxis study with single-dose rifampicin (SDR) was implemented in the Southern Marquesas Islands; this trial was not controlled. After 10 years, findings suggested an effectiveness of SDR of 35–40%. Due to the high leprosy incidence in the Pacific islands, chemoprophylaxis programmes were also done in the Federated States of Micronesia, Kiribati, and Marshall Islands in the mid-1990s. Rifampicin–ofloxacin–minocycline was given to adults (aged ≥15 years) and rifampicin only to children younger than 15 years. By 1999, a substantial reduction in case detection rates was observed, but the latest figures from 2016 indicate that this reduction was not sustained.[1] A more rigorous trial was the COLEP study in Bangladesh, a single-centre, double-blind, cluster randomised, placebo-controlled trial. SDR given to contacts of individuals with newly diagnosed leprosy resulted in an overall reduction in incidence of leprosy of 57%. [1]Although, the efficacy of SDR depended on contact level. Some subgroups appeared to respond well to SDR, such as people who were not blood relatives and neighbours of neighbours, demonstrated protection of up to around 70%. At 4 years and 6 years of follow-up, there were no longer differences between treatment and placebo groups.[1]There was a high level of acceptance by patients and health-care staff of home-based or community-based contact screening and SDR administration across different sociocultural, epidemiological, and health system settings.

Chemoprophylaxis with SDR in India, was shown to be cost-effective in both the short (5 years) and long term (25 years), with benefits depending on the extent to which disability can be prevented and its cost-effectiveness should also be considered carefully from this perspective. [2]Although, in some populations, there is a marked reluctance of index patients to disclose their disease status to neighbors and sometimes even to household members. In such situations, alternative approaches to contact tracing are needed, for which disclosure of the disease status of the index patient is not required.

Since 2018, WHO has included post-exposure prophylaxis with SDR in their guidelines for leprosy control. [1]The WHO Guidelines for the Diagnosis, Treatment and Prevention of leprosy suggested that to prevent leprosy in healthy close contacts of patients with leprosy, SDR should be administered if the contacts were aged 2 years or older, both leprosy and tuberculosis have been ruled out, and in the absence of other contraindications, for young children and contacts who were underweight, scales were required to establish bodyweight for calculating the correct rifampicin dose. SDR should be given to contacts no earlier than 1 month after initiation of MDT of the individual newly diagnosed with leprosy to avoid immediate re-infection, as patients are assumed to become non-infectious within 4 weeks of treatment start. Also, alternative and possibly more effective prophylactic regimens should be investigated. Finally, the development of suitable field-friendly diagnostic tests for subclinical infection can help establish those contacts who would benefit most from post-exposure prophylaxis.[1]

Newer trials like Post Exposure Prophylaxis for Leprosy (PEOPLE) in the Comoros and Madagascar uses double dose of rifampicin (20 mg/kg) to the contacts [14], and PEP ++ combines rifampicin with either clarithromycin or moxifloxacin (a fluoroquinolone with potential side effects) for 3 once monthly doses. [4]There is no doubt that we need better intervention to further reduce the transmission of leprosy and progress toward zero leprosy.

Having considered all the above recommendations, the author believe that SDR has potential utility in the prevention of leprosy and disability among the contacts of the patient. The incidence and prevalence of leprosy has sustained in India in the last decade contrary to the expectations. The authors also believe that leprosy research in the last few years due to more inclination of fraternity towards cosmetology. Inspite of adequate role of SDR in leprosy prevention, general awareness about its use is very low amongst treating physicians. Through this letter, the authors want to initiate the discussion about implementation of SDR in routine management/ prevention of leprosy.

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