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Letter to the Editor

"Versatile Use of Mycobacterium indicus pranii (MIP) Vaccine" – Comment and a Case Report

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Dear Editor,

Kindly refer to the article "Versatile use of Mycobacterium indicus pranii (MIP) vaccine," by Thangaraju et al (2023). The authors have described the role of MIP in various infectious diseases including HIV, Covid 19 as vaccine and adjuvant therapy. I want to highlight a case of side effects of this Mycobacterium vaccine (Sehgal et al 2020 & 2021, Jaiswal et al 2022). Sepsivac, which is heat killed Mycobacterium W, a non-pathogenic strain of Mycobacterium was developed by Prof. GP Talwar of National Institute of Immunology (NII) & Cadilla Pharmaceuticals Limited (CPL) as immunomodulator. This has been developed by CPL and CSIR, used for treatment of Covid-19.

A sixty-three-year-old, diabetic gentlemen, father of a doctor, suffered from Covid -19, confirmed by RT-PCR and admitted in a hospital on October 10, 2020. In the hospital, he was treated with routine protocol prevalent at that time that is Hydroxychloroquine, Ivermectin, paracetamol, oxygen and other supportive measures. During the hospital stay, he was also given Injection Sepsivac (M.W, heat killed vaccine) for 3 consecutive days, in deltoid region; 0.1 ml (intradermal) at 3 sites in a day by doctor son himself and thus eliminating the chance of wrong administration. The patient was discharged from the hospital on October17, 2020, after a week of hospitalization in a stable condition. In January 2021, after about two months of discharge from the hospital, he developed necrotic nodules on his arms at 8 sites of Injection Mw (Sepsivac)-5 on right arm and three on left arm. He was given steroid orally and locally for 25 days for this but to no relief. In January 2021, the patient reported to the author. A biopsy was advised to the patient, which he refused. The recovery of these lesions then occurred after a course of Roxithromycin 150 mg b.i.d for ten days along with local steroids (Clobetasone propionate) slowly with local antibiotics in a span of six months. The lesions, however, healed with scarring, which are visible even after one and a half years (June 2023).

An immunomodulator may be of potential benefit in managing COVID patients, as they have high cytokine levels. The Global Research Collaboration for Infectious Disease Preparedness (GLOPID-R) and the World Health Organization have identified adjuvant therapy as one of the key areas of research to save lives of patients infected with COVID-19 (Global Research Forum 2020).

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Fig. 1 : Showing the lesions on forearm eight weeks after the vaccine on injection site on left; vaccine in the middle and the lesions after ten days of treatment on right side.

A heat-killed *Mycobacterium* w (Mw), originally developed as an immunomodulator for leprosy has been reported to act through the toll-like receptors (TLRs) pathway and enhances the host-T cell responses (Sharma et al 2017). Sehgal et al (2021) showed the benefit of Mw in patients with severe Covid-19 disease. Use of Mw in COVID-19 patients was observed to be safe and well tolerated, without any major safety concern (Sehgal et al 2020).

Injections site immunological reaction to Mw, however, is a known phenomenon. Sharma et al (2017) reported injection site reaction in 82.4% of the patients. 68% of the patients experienced mild intensity of the reaction whereas 12.91% had moderate to severe reaction at local site.

In our case, interesting observations are - local site reaction despite intradermal injection, the reaction occurring after two months, delayed healing of reaction and healing with scarring (Fig.1). Mw (MIP) as an immunomodulator continues to be of wide interest in immunotherapy and immunoprohylaxis of leprosy, tuberculosis, Covid-19, warts, cancer, and several other applications (Thangaraju et al 2023). Because of its wider use, this undesirable side effect is being reported as an experience.

References

1. Global Research Forum (2020). COVID 19 public health emergency of international concern global research and innovation forum: towards a research roadmap. 2020. https://wwwwhoint/blueprint/priority-diseases/keyaction/Global_Research_Forum_FINAL_VERSION_for_web_14_feb_2020pdfua=1 [Last accessed on 2020 Mar 23]. Available from: [Google Scholar]
2. Jaiswal SR, Arunachalam J, Saifullah A et al (2022). Impact of immune modulator Mycobacterium-w on adaptive natural killer cells and protection against Covid-19. *Front Immunol*. **13**: 887230. http://doi.10.3389/fimmun.2022.887230.
3. Sehgal IS, Bhalla A, Puri GD et al (2020). Safety of an immunomodulator Mycobacterium w in Covid -19. *Lung India*. **37**: 279-281.

4. Sehgal IS, Guleria L, Singh S et al for the ARMY trial study group (2021). A randomised trial of Mycobacterium w in critically ill patients with Covid-19: Army-1. *ERJ Open Res*. **7**: 00059-02021.
5. Sharma SK, Katoch K, Sarin R et al (2017). Efficacy and Safety of Mycobacterium indicus pranii as an adjunct therapy in Category II pulmonary tuberculosis in a randomized trial. *Sci Rep*. **7**: 3354. doi: 10.1038/s41598-017-03514-1. PMID: 28611374; PMCID: PMC5469738.
6. Thangaraju P, Sajitha V, Sree Sudha TY et al (2023). Versatile use of Mycobacterium indicus pranii (MIP) vaccine. *Indian J Lepr*. **95**: 51-64.

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