

EDITORIAL

**BCG VACCINE - AN INNOVATION FOR DIABETES TREATMENT IN PAKISTAN?**

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Pakistan is a third world country with very small health budget and a diabetes prevalence of about 6.9% among adults, accounting for over 86,000 deaths. If phase 2 trials testing the ability of BCG to reverse type 1 Diabetes become successful in remission of insulin from pancreas this would be very useful to treat diabetes in Pakistan as BCG is readily available, less expensive, has less storage problems, less side effects and doesn't require skilful person to administer.

**Keywords:** Diabetes; BCG; Pakistan

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According to International Diabetes Federation's published statistics about diabetes in Pakistan in 2015, Pakistan has a diabetes prevalence of about 6.9% among adults, accounting for over 86,000 deaths.<sup>1</sup> IDDM (also known as diabetes type 1) is an autoimmune disorder in which body's own T cells react with beta cells of pancreas resulting in depletion of insulin which is responsible for glucose uptake in the cells.<sup>2</sup> Diabetes also forms a major risk factor of MI and increases mortality due to masking of alarming symptoms. It also leads to serious irreversible complications like neuropathy, retinopathy etc.

According to Phase 1 randomized control trials, which was published in the August 8 2012<sup>3</sup>, the BCG (Bacillus Calmette-Guérin) vaccine induces the production of TNF which eliminates auto reactive "bad" T cells resulting in remission of insulin production from the pancreas. Another study in July 1 2001<sup>4</sup>, also demonstrated reversal of type 1 diabetes by restoration of endogenous beta cell function by inducing TNF alpha through BCG vaccine.

On the other hand, some studies demonstrated that there was no effect of BCG vaccine in the prognosis of patients with type 1 Diabetes Mellitus.<sup>5,6</sup> Nevertheless, a phase 2 clinical trial testing the ability of BCG to reverse type 1 Diabetes has been approved by FDA and is currently underway.

If phase 2 trials become successful in remission of insulin from pancreas this would be very useful to treat diabetes in Pakistan which is a third world country with very small health budget. Being a developing country lacks tertiary care centres all over and BCG, being a part of EPI, is available in PHC which means it would be accessible to rural areas

also. BCG vaccine is provided free by the government of Pakistan and therefore will lack expenses caused by other treatment methods. Ease of BCG administration allows its widespread use and doesn't require skilful person for its administration. Also, there is no storage problem as it can easily be stored in a refrigerator. Its administration causes a very few side effects such as mild inflammation at the site of injection which are tolerable. Thus, it would be of great use in reducing morbidity and mortality in a poor country with a heavy burden of diabetes.

The latest development in phase 2 clinical trial is the enrolment of over 130 of the 150 candidates that are needed for the trial and have been given at least one dose of the BCG vaccine or placebo to over 100 participants. The participants will be followed over a five-year period and the latest updates are soon to be expected. Estimated primary completion date for phase 2 trial is July 2020. Also, patients who participated in the Phase 1 BCG study are being followed up.

All patients who were randomized to receive placebo during the blinded portion of the Phase 1 study have now received two doses of the BCG vaccine, just as the patients randomized to BCG did. All the data on the long term follow up of Phase 1 patients is expected to be published in 2017.

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