Repurposing BCG Vaccine to Protect against COVID-19: A Real-life Family Report

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The author declares that there are no competing interests.

Consents

All the described adults were fully previously informed about the risk benefit ratio and the consent to participate and to publish the report were granted. As parents, we also approved given BCG vaccine booster to our children.

Dear Editor,

Non-spike targets for T cell-mediated protection in the absence of neutralizing antibodies have been shown to play a significant role in protection against SARS CoV-2 infection and non-spike antigens were suggested to be included in second-generation vaccines¹. In this correspondence, I would like to suggest that the one century old and very safe BCG vaccine is inducing a tailored immunity against SARS CoV-2 infection that abolishes the necessity to develop new vaccines amid this evolving pandemic while I am presenting my real-life family experience repurposing it to protect my family and I against COVID-19.

One year ago, in May 2021, I've been acting as a reviewer to an interesting article that showed highly promising effectiveness of booster BCG jabs to protect against COVID-19 infection, that was later published². I suggest that I've been chosen as a reviewer for this article basing on my previous published analysis, published at the same journal, of a potential role for BCG vaccination/boosters to be used to provide protection against COVID-19³. Meanwhile, I've been still struggling to publish a critical analysis that reclassified COVID-19 to be considered as an immunological disorder, that was later published⁴. Notably, BCG vaccine is known to provide immunity against respiratory tract infections in different age groups including the geriatric population and was suggested to generate trained immunity against SARS-CoV2⁵ and its induced trained immunity as well as generating cross reactive T cells were among other potential factors by which BCG could protect against COVID-19^{6,7}

Since my wife and I (both in the 4th decade of life at that month) are blessed with two young daughters (4 and 2 year-old plus few months in May 2021) and we had our human anxiety; I am working in my private clinic and some private hospitals dealing almost exclusively with COVID-19 patients and similarly my wife is working as a pharmacist in a tertiary hospital quarantining deteriorating COVID-19 patients and thus, I've decided that all of us should consider receiving booster BCG vaccination shots (our first BCG jab was at birth as mandatory in Egypt). Moreover, I recommended these boosters to my parents (in their 8th decade) and to my first-degree relatives: my sister and her husband (both in the

4th decade of life), and their 3 young children, one male and two females; all of them in their first decade. Informative verbal consent was granted, and we all received booster BCG vaccination and authorized their administration to our kids.

Notably, even before we receive BCG vaccination, all of us, including kids, were not wearing masks most of time, as this mandate was and is not strictly applied in Egypt. Surprisingly, my father routine laboratory investigation done at a hospital, he attended for a urological procedure, showed positive SARS CoV-2 IgG though he has never complained of COVID-19, and I suggest all of us could have been likewise; silent carriers for some while, as over 80% of people all over the world do. Interestingly, my father is not complaining of any notable chronic diseases and all the described adults have not suffered from any COVID-19 like manifestations for seven months post BCG vaccination and when later three kids and one female adult suffered from cough (first dry and later productive), fever and sore throat, they were managed promptly and effectively using Kelleni's protocol that is being used as an immunomodulatory early management COVID-19 protocol abolishing the need for laboratory or radiological investigations with absolute safety and efficacy in children, adults and pregnant patients^{8,9}. Notably, after ten months post vaccination and during SARS CoV-2 B.1.1.529 (Omicron) variant infection another adult male, two adult females and two other kids suffered from COVID-19 like manifestations and were also properly and promptly managed using Kelleni's protocol.

I wish to report full safety of BCG boosters in all the administered children and adults described in this letter. Tenderness at the site of administration that lasted for one week was reported for my kids whom I've administered the boosters intradermally in the abdomen (the same route of administration was used with my parents, my sister, my wife and I and they followed me after I've given it first to myself in an area that I can see and control using my other hand as well, and they chose to receive it likewise, but my brother-in-law chose to receive it, as usual, intradermally at the upper arm with his three children and a new characteristic BCG scar has later developed for only those who received it in the shoulder and is more evident than the old scar for the shot given at birth (Figure 1). Local erythema at the site of administration developed for all participants, and it lasted

for several months in the abdominal skin without tenderness until eventually faded leaving a mild scar in the adults. My father and I experienced mild-moderate headache that was self-limited in two days without analgesics for my father. However, I was the only one to feel some neck pain in the following day and it was relieved after a single dose of diclofenac 50 mg administer at night. My brother-in-law has experienced mild bacterial infection at the site of administration with pus formation and no systemic manifestations a week after vaccination and it was self-limited with only local administration of topical gentamicin cream twice daily for two days.

Noteworthy, during the Omicron variant wave uprise, one female adult was forced to receive the inactivated SARS CoV-2 vaccines in order not to lose her job and she couldn't escape this mandate and when her children suffered COVID-19 potential manifestations, they recovered promptly using Kelleni's Protocol as well their mother, but she reported the worst "flu like" manifestations in her life and some mild manifestations e.g., nasal stuffiness and mild hoarseness of voice persisted for almost a month, and I suggest that this could be an example of antibody dependent enhancement that unless promptly managed with Kelleni's Protocol could have led to severe complications. She described an unusual inefficient immune response since she received the inactivated SARS CoV-2 vaccines that needed six months to regain the earlier homeostasis and in my clinical practice I encountered several similar complaints from different patients, and it wasn't exclusive to the inactivated SARS CoV-2 vaccines.

Importantly, this clinical report has obvious limitations including the paucity of numbers, and the interaction of natural immunity as an important confounder¹⁰; for instance, my father has refused to wear a mask throughout the pandemic with free movement and no COVID-19 symptoms were ever encountered. However, I suggest this is the first global report about repurposing booster BCG vaccine to protect children against COVID-19 and considering its well-known safety record, low cost manufacturing⁵ and its potential to prevent at least severe COVID-19, further trials should be considered in the pediatric and geriatric populations.

Taken together, I wish to suggest that BCG vaccine/booster should be considered as of choice to be administered to immunocompetent children to yield enhanced protection against COVID-19 and this should be also considered for immunocompetent geriatric adults, and I suggest that its induced immunity could protect safely and effectively against severe COVID-19 induced by SARS-CoV-2 current and evolving variants and if combined with early treatment using Kelleni's protocol this could abort the evolution of this pandemic while relieving all its associated mandates and the need for PCR tests.

Finally, I confirm my suggestion that most healthy young adults do not need any vaccine against COVID-19 as natural immunity will always use memory T cells generated from silent infections or even prior common cold infections to provide basal immunological protection that would be very solid when combined with Kelleni's early management immunomodulatory protocol that provides a full protection against severe COVID-19 and its complications, yet for immunocompetent pediatric and geriatric populations and though Kelleni's protocol perfectly works, one might consider the safe and economic BCG vaccine or boosters as an adjuvant, after a personalized informed risk benefit ratio is provided.

Figure 1:

A characteristic prominent scar developed in the shoulder of one child who received a booster BCG vaccine (photo captured on May 05, 2022).

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