

Poliovirus Vaccine Immunity among Chronically Malnourished Pakistani Infants: A Randomized Controlled Trial from Developing Country

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Abstract : Purpose: Pakistan is the final frontier for a polio-free world. Chronic malnutrition is associated with lack of effective gut immunity, and possibly associated with poliomyelitis in children received multiple OPV. We evaluate IPV dose administered together with OPV results in higher immunogenicity and mucosal immunity compared to OPV alone in chronically malnourished infants. Methods AND Materials: A community-based, unblinded-randomized-trial, conducted in 5 peri-urban, low-middle-income households of Karachi, in infants 9-12 months. Two study groups were non-malnourished (HAZ= -2 or more) and chronic malnourished (HAZ <-2SD), with 2-arms each i) OPV and ii) OPV and IPV. Two blood specimens (2ml) at baseline and at day 28 and two stool specimens (6 gm.) at day 29 and after 7 days. All infants received a bOPV challenge dose after first stool specimen. Calculated sample size was 210 in each arm. Serological (baseline compared to 28 days post-vaccine) and mucosal immunity after one week of bOPV challenge dose were study outcomes. Results: Baseline seroprevalence in malnourished infants were low compared to non-malnourished (P1, P2 and P3 ($p < 0.001$)). There is significant rise in antibody titer and P1 seroprevalence in Mal A and B after receiving study vaccine; much higher in Mal B. Infants randomized to bOPV + IPV study vaccine showed incremental immune response against P1 (Mal B, 92.2%; Nor B, 98.4%), P2 (Mal B, 90.4%; Nor B, 94.7%), and P3 (Mal B, 85.6% and Nor B, 93.5%) was observed. A significant proportion of infants in malnourished (P1, 13%; P2, 24%; P3, 26%) and normally nourished group (P1, 5%; P2, 11%; P3, 14%) were found to be seronegative at baseline. Infants who received BOPV + IPV as their study vaccine showed a very high seroconversion response after vaccine ($p < 0.001$ for P1, P2 and P3). Majority of the specimens were negative at baseline (Mal A, 2%, Mal B, 1%; Nor A, 2%; Nor B, 1%), and remains negative after bOPV challenge dose (Mal A, 8%, Mal B, 6%; Nor A, 11%; Nor B, 10%). Conclusion: Malnourished-infants have low poliovirus-seroprevalence that increased remarkably after IPV. There is less viral shedding after IPV in infants.

Keywords : chronic malnutrition, infants, IPV, OPV

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