5 Year efficacy of a bivalent killed whole-cell oral cholera vaccine in Kolkata, India: A cluster-randomised, double-blind, placebo-controlled trial


**BACKGROUND:**

Efficacy and safety of a two-dose regimen of bivalent killed whole-cell oral cholera vaccine (Shantha Biotechnics, Hyderabad, India) to 3 years is established, but long-term efficacy is not. We aimed to assess protective efficacy up to 5 years in a slum area of Kolkata, India.

**METHODS:**

In our double-blind, cluster-randomised, placebo-controlled trial, we assessed incidence of cholera in non-pregnant individuals older than 1 year residing in 3933 dwellings (clusters) in Kolkata, India. We randomly allocated participants, by dwelling, to receive two oral doses of modified killed bivalent whole-cell cholera vaccine or heat-killed Escherichia coli K12 placebo, 14 days apart. Randomisation was done by use of a computer-generated sequence in blocks of four. The primary endpoint was prevention of episodes of culture-confirmed Vibrio cholerae O1 diarrhoea severe enough for patients to seek treatment in a health-care facility. We identified culture-confirmed cholera cases among participants seeking treatment for diarrhoea at a study clinic or government hospital between 14 days and 1825 days after receipt of the second dose. We assessed vaccine protection in a per-protocol population of participants who had completely ingested two doses of assigned study treatment.

**FINDINGS:**

69 of 31 932 recipients of vaccine and 219 of 34 968 recipients of placebo developed cholera during 5 year follow-up (incidence 2.2 per 1000 in the vaccine group and 6.3 per 1000 in the placebo group). Cumulative protective efficacy of the vaccine at 5 years was 65% (95% CI 52-74; p<0.0001),
and point estimates by year of follow-up suggested no evidence of decline in protective efficacy.

**INTERPRETATION:**

Sustained protection for 5 years at the level we reported has not been noted previously with other oral cholera vaccines. Established long-term efficacy of this vaccine could assist policy makers formulate rational vaccination strategies to reduce overall cholera burden in endemic settings.

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