Rotavirus vaccine trials successful in Asia and Africa

August 5 2010

Studies in Asia and Africa have shown that a rotavirus vaccine is safe and effective in preventing severe rotavirus gastroenteritis (severe RVG), which is responsible for more than half a million child deaths worldwide. The authors of these two studies, published Online First in The *Lancet*, have now added their voices to those of WHO and other international experts, calling for the roll-out of the vaccine across both continents.

In the first study, Dr K Zaman, International Centre for Diarrhoeal Disease Research, Dhaka, Bangladesh, and Dr John C Victor, PATH, Seattle, WA, USA, and colleagues carried out a randomised controlled trial at two locations: rural Matlab, Bangladesh; and an urban and semi-urban part of Vietnam. The study is the first clinical efficacy trial of an already licensed rotavirus vaccine in developing countries in Asia. A total of 2036 infants aged 4-12 weeks without symptoms of gastrointestinal disorders were randomly assigned (1:1) to receive three oral doses of Merck's pentavalent rotavirus vaccine or placebo at around 6 weeks, 10 weeks, and 14 weeks of age, in conjunction with routine infant vaccines including oral poliovirus vaccine.

Over nearly 2 years of follow-up, the researchers recorded 38 cases of severe RVG in the vaccine group, compared with 71 in the placebo group, giving a calculated vaccine efficacy of 48%. Rates of serious adverse events were low in both the vaccine (2.5%) and placebo (2.0%) groups, with no serious adverse event considered linked to receipt of the intervention. Despite this efficacy being lower than demonstrated in

trials in high-income countries, the authors of both studies believe use of the vaccine could save many thousands of lives across both continents.

Dr Victor says: "Our main goal is to prevent the most severe disease that might lead to death in areas where treatment is inaccessible. Because we saw indications that the vaccine is even more efficacious in preventing the most severe disease children experience, I am very optimistic about the impact that rotavirus vaccines will have on mortality in these settings."

The authors conclude: "With a WHO recommendation for rotavirus vaccines now in place, governments of developing countries in Africa and Asia are deciding how to prioritise introduction of rotavirus vaccine in their public health agendas. Our trial shows that a live oral rotavirus vaccine has the potential to halve the incidence of severe rotavirus gastroenteritis in developing populations in Asia. Alongside efficacy results for this vaccine in Africa, our study supports WHO's strong recommendation for expansion of rotavirus vaccine use to the poorest nations in Africa and Asia. Rotavirus vaccines have the potential to protect the lives of nearly 2 million children in the next decade alone."

In the second paper, Dr George E Armah, University of Ghana, Accra, Ghana, and Dr Kathleen M Neuzil, PATH, Seattle, WA, USA, and colleagues analysed the effects of the same vaccine in Africa, where some 240 000 rotavirus-related deaths occur annually. The researchers carried out a randomised controlled trial of the vaccine in Ghana, Kenya, and Mali. In this study, 5468 children aged 4□□ weeks without symptoms of gastrointestinal disorders were randomly assigned in a 1:1 ratio to receive three oral doses of the same vaccine as above or placebo at around 6 weeks, 10 weeks, and 14 weeks of age. Infants with HIV infection were not excluded.

The researchers recorded 79 cases of severe RVG in the vaccine group,

compared with 129 in the placebo group, giving a vaccine efficacy of 39%. Rates of serious adverse events were again low in both the vaccine (1.5%) and placebo (1.7%) groups, with the most common reported event being gastroenteritis.

The authors say: "The vaccine provided significant protection against severe rotavirus gastroenteritis in infants for nearly 2 years of follow-up. This protection was especially high through the first year of life (64.2% vaccine efficacy), when the disease burden, including mortality, is highest."

They conclude: "In Africa, where young children are dying from diarrhoeal disease and prompt medical care is often out of reach, the need to prevent rotavirus is especially urgent. Introduction of rotavirus vaccines for African children, along with imminent introduction of pneumococcal and meningococcal conjugate vaccines in parts of Africa, could instigate a new era of reduction of childhood disease and mortality."

In a linked Comment, Dr E Anthony S Nelson, Chinese University of Hong Kong, Hong Kong Special Administrative Region, China, and Dr Roger I Glass, Director of the Fogarty International Center, National Institutes of Health, Bethesda, MD, USA, say: "We will not be able to assess the true effectiveness of the vaccines in low-income settings and the possible benefit of herd protection until these products are more widely used and their effects are properly evaluated. Reassuring governments in low-income countries that they will be able to purchase vaccine at a reasonable price, when support from the GAVI Alliance ends, will be the quickest way to encourage their introduction and to establish whether these vaccines will stand alongside smallpox, measles, and poliomyelitis vaccines in their public health benefits."

They conclude: "Beyond this, there is a clear need for further research to

understand why the efficacy of both live oral rotavirus vaccines is lower among children in low-income countries than high-income countries. Could simple interventions, such as slightly delaying immunisation, adding an additional dose of vaccine, or withholding breast milk around the time of vaccine administration, improve the efficacy of the vaccine in these challenging settings? Finding an answer to these questions could add value to these new vaccines while doing much to improve the health and survival of children."

Provided by Lancet

Citation: Rotavirus vaccine trials successful in Asia and Africa (2010, August 5) retrieved 18 April 2024 from https://medicalxpress.com/news/2010-08-rotavirus-vaccine-trials-successful-asia.html

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.