

Novel Cholera Vaccine Consisting of Outer Membrane Vesicles

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Technology description

Cholera remains a persistent threat in the developing world, where clean drinking water is scarce. Due to lack of access to adequate medical facilities and the epidemic nature of the disease, a cholera vaccine is the most viable option for dealing with the disease in endemic areas. However, current vaccine formulations are ineffective as they are too expensive and complicated to reach those most affected by the disease. Researchers at Tufts University School of Medicine have developed a novel cholera vaccine comprised of outer membrane vesicles from the causative agent, *Vibrio cholerae*. This new vaccine is stable at ambient temperatures and thus has the potential to be less expensive and more effective than current cholera vaccines, which would allow increased distribution to those in need.

Background

Cholera is a potentially fatal diarrheal disease endemic to many areas, including some of the most impoverished in the world. The disease is acquired by ingestion of food or water contaminated with the Gram-negative bacterium *Vibrio cholerae*. Although cholera is often preventable and treatable, it is responsible for many deaths worldwide and prone to severe outbreaks due to lack of access to adequate medical facilities/treatments. It is for this reason that the World Health Organization recommends that cholera vaccines be used in endemic areas to prevent/control outbreaks. However, existing cholera vaccines are too expensive for many endemic countries and also require temperature-controlled distribution systems, which both complicate and increase the cost of distribution. Thus, cholera vaccines often do not reach those who would benefit most from such protection.

Invention

Recent work at Tufts University School of Medicine by Dr. Andrew Camilli has led to the development of a novel cholera vaccine comprised of outer membrane vesicles (OMVs) from *V. cholerae*. OMVs are spherical blebs naturally shed by Gram-negative bacteria and are composed of a lipid bilayer containing outer membrane proteins and other periplasmic components. Some proteins found in OMVs from pathogenic bacteria include toxins, adhesins, and immunomodulatory compounds. OMVs provide a means by which bacteria can interact with other cells in their environment. Because OMVs are naturally produced during growth in broth culture, they can be easily collected in standard laboratory conditions. Additionally, OMVs are stable at ambient temperatures and therefore do not require special

storage conditions. Experiments have shown that immunization of adult mice with OMVs leads to the production of antibodies specific to *V. cholerae* proteins. Additionally, immunization of pregnant dams confers protective immunity to their offspring even when challenged with infectious doses 100-fold higher than the ID₅₀. This protection can extend long term as pups born 84 days post-immunization were still protected from infection. OMV vaccines can be delivered via multiple methods including the intranasal, intragastric, or intraperitoneal routes, with similar efficacy. Also, it is possible to create a multivalent vaccine using *V. cholerae* OMVs, as heterologous antigens expressed in *V. cholerae* can be naturally loaded into OMVs.

Advantages

This technology provides the following significant improvements over previous cholera vaccines:

- OMVs are stable at ambient temperatures, thus temperature-controlled storage is not necessary.
- An OMV-based vaccine can be administered by many methods, including the intranasal route, which may obviate potential side effects and allow for easier distribution.
- V. cholerae* OMVs can be loaded with heterologous antigens, thus using the same technology to produce vaccines against additional pathogens.
- Vaccination of a pregnant female confers protective immunity to the offspring of that individual.
- A *V. cholerae* OMV vaccine has the potential to be less expensive and more effective than current cholera vaccine formulations, which would allow increased distribution to those in need.

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