



Live attenuated polio vaccine: characteristics

Polio: the threat and the success of vaccines

Polio is a disease that causes paralysis. Before the age of polio vaccines, thousands of paralysis cases occurred every year around the world. For example, in the USA in 1952, there were 21,000 cases of paralysis. Most cases of paralysis affect the lower extremities, but respiratory paralysis also exists. During the early 20th century, "iron lung" wards were populated with children suffering from polio induced respiratory paralysis. Since the introduction of the polio vaccines in the 50s and 60s of the 20th century, the rates of paralysis resulting from this disease dropped dramatically. In 1988, the year when the World Health Organization declared the initiative for the global extermination of polio, approximately 1000 children a day suffered from paralysis (350,000 thousand a year). Following years of concentrated effort and dozens of billions of polio vaccines, in 2012, a total of 262 cases of polio paralysis occurred around the world.

The types of polio vaccines and the differences between them

There are two types of polio vaccines: inactivated vaccine and live attenuated vaccine. These two vaccine types had and still have a vital role in the extermination of polio. The inactivated vaccine provides a high level of protection for the individual against polio symptoms. On the other hand, the inactivated vaccine does not immunize the intestines, due to the fact that it does not produce IgA antibodies that protect the intestines (below – analysis dated 2012 (Hird & Grassly)¹. Meaning, a person immunized with the inactivated vaccine can carry the violent virus in his intestines and spread it to its surroundings. The live attenuated virus provides protection of the intestines against infection by the virus, and prevents its spread in the surroundings. This vaccine is the corner stone in the global effort to exterminate polio. Currently, this is the most efficient tool for exterminating polio in Israel and worldwide. As long as a wild polio strain was not detected in Israel, the inactivated vaccine was sufficient, as practiced in countries where a wild polio virus has not been detected over recent years. When a wild polio virus was detected in certain regions of Israel, and children were found to secrete it in their stool, individual protection can longer be relied

on, and it is necessary to protect the general population of Israel by exterminating the virus from the country. The live attenuated vaccine is the effective, and actually the only tool that can stop the intestinal secretion and proliferation of the wild virus, and stop its continued secretion in the stool by children carrying the virus.

The live attenuated vaccine (OPV) has been used in various vaccines for the past 60 years. The strains in use were generated from master-strains stored in the laboratories of the World Health Organization and are derivatives of the original Sabin strains. To date, 11 billion doses of the manufacturer's OPV vaccines that are currently being used in the Israeli vaccination campaign, have already been administered. The OPV's efficacy in its different compositions has been proven through vast experience in thousands of immunized individuals as early as the 20th century 60s. The vaccine that contained three strains has already been given to billions of people and it stopped polio outbreaks in many countries over the past decades.

The vaccine currently being administered in Israel (Sabin type bOPV)

The vaccine currently being administered in Israel contains two strains (polio strains 1 and 3), and is identical to the vaccine that was administered in Israel in three million doses during the polio outbreak of 1988, and to the one administered during the routine vaccinations in Israel from 1990 through 2005, both in terms of the method of preparation and in its composition, except for the absence of strain 2 from the vaccine. This can be seen, inter alia, by comparing the manufacturer's leaflets of the two vaccines:

The POLIO SABIN™ (oral) type trivalent vaccine (tOPV):

http://www.old.health.gov.il/units/pharmacy/Trufot/ShowAlon.asp?tmpPath=/units/pharmacy/trufot/alonim/Polio_Sabin_DR_1335775598373.pdf

The POLIO SABIN™ (oral) type bivalent vaccine (bOPV):

http://www.who.int/immunization_standards/vaccine_quality/OPV_bivalent_GSK_WHO_package_insert_text_english.pdf

Strain 2 was removed from the vaccine for two reasons: a) Strain 2 has not been spread in the world since 1999 b) Its presence lowered the immunized person's reaction against the two remaining strains. The vaccine containing two strains was tested in a controlled double blind randomized trial to prove its immune efficacy (immunogenicity), in which 900 infants in India participated, and it was found to be more effective than the vaccine containing three strains, that was used in Israel between 1961 and 2005². In the efforts to exterminate the virus over recent years, 2.5 billion doses of the vaccine currently being used in Israel were given worldwide, without change in the safety profile compared to the older vaccines. The efficacy and safety of the vaccine containing two strains is not inferior to that of any existing vaccine, and is even superior to them.

Success of the combined approach (inactivated + attenuated vaccine) in preventing the risk of the attenuated vaccine

In the framework of the campaign, the live-attenuated vaccine will be given only to individuals who have previously received at least one dose of the inactivated vaccine. In Israel, there were no cases of paralysis as a result of vaccination (VAPP) throughout all the years during which the combined program was administered, where a live attenuated vaccine containing three strains of the virus was given together with the inactivated vaccine (trivalent OPV + enhanced IPV). This combination was included in the routine immunization program for the 15 years between 1990-2004, during which about 7 million vaccine doses were given, and there was not a single case of VAPP. Therefore, Israeli experience also proves that the combination of an inactivated vaccine with a live attenuated one is safe.

The World Health Organization knows of only one case of VAPP³ among the individuals receiving the live attenuated vaccine (OPV) who have previously received at least one dose of inactivated vaccine (IPV) in countries worldwide. In the USA, throughout all the years where the combined program of the live attenuated vaccine plus the inactivated vaccine (eIPV + OPV) was in use, not a single case of VAPP occurred in toddlers who received at least one past dose of IPV.

Conclusion:

- 1. The polio virus has penetrated Israel and it is spreading in the south. If the Ministry of Health does not intervene, there is a high risk for the occurrence of paralytic polio in Israel.**
- 2. The inactivated vaccine (IPV) cannot prevent the virus from spreading, and therefore it is necessary to also add the attenuated vaccine (OPV).**
- 3. The live attenuated vaccine developed by Sabin and is still being used for preventing polio, has been in use for over 40 years.**
- 4. This vaccine can cause paralysis in approximately 1 to a million vaccine doses, only among the population of individuals who were not immunized with an inactivated vaccine beforehand.**
- 5. In an immunized population as in Israel, this risk is next to zero.**
- 6. The factual base for the efficacy and safety of the live attenuated vaccine is as follows:**
 - a. Experience of using the trivalent attenuated vaccine given in Israel only to those who received the inactivated vaccine in the years 1990-2004: approximately 7 million vaccine doses were administered in this method during this period, and not a single case of paralysis resulting from the attenuated vaccine occurred. These data are better than any clinical trial.**
 - b. The vaccine being administered in the present campaign is not new, but rather improved, due to the removal of strain 2 of the virus, and it is manufactured under the same conditions and by the same methods as the trivalent vaccine. Even its name has not changed and it is still named after Sabin.**
 - c. In a controlled clinical study that was conducted, this vaccine was found to have an advantage over the trivalent vaccine, and no disadvantage was found compared to it.**

Sources:

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