SUMMARY OF THESIS*

OLIVEIRA, Consuelo Silva de - Eficácia clínica da vacina tetravalente (RRV-TV) contra rotavírus em Belém, Pará. Belém, 1999. (Dissertação de Mestrado – Universidade Federal do Pará).

CLINICAL EFFICACY OF A TETRAVALENT VACCINE (RRV-TV) AGAINST ROTAVIRUS IN BELÉM, PARÁ, BRAZIL

There is currently growing evidence that infantile rotavirus gastroenteritis will be controlled only through the development of an effective vaccine targeted for use in early childhood. This study was conducted with the aim of assessing the protective efficacy of the lower-titer rhesus-human reassortant rotavirus tetravalent vaccine (RRV-TV, 4 x 10^4) against the major clinical indicators of severity cases of rotavirus diarrhoea; for this, were re-examined 91 rotavirus-associated diarrhoeal episodes that were recorded during an efficacy trial carried out previously in Belém, Pará, Brazil. The source of information for study were the data recorded in field forms used to perform the routine surveillance for diarrhoeal episodes, as well as those forms in which daily clinical records were made while diarrhoea persisted. Relative efficacy was specifically against the following clinical parameters: a) duration of diarrhoea; b) maximum number of liquid/semiliquid stools per day; c) duration of vomiting episodes/24h; d) maximum number of vomiting episodes/24h; e) fever (rectal temperature); f) dehydration; and g) need for treatment. The overall clinical severity of rotavirus gastroenteritis has been graded using a numerical twenty-point scoring system (i.e., maximum of 20 points) which allowed the classification of diarrhoeal cases in mild (0-6 scoring interval), moderate/severe (9-14) and very severe (>14). A significant (p<0.05) protection conferred by RRV-TV was observed in five of the seven clinical parameters under analysis, as follows: a) duration of diarrhoea (52%, pure rotavirus diarrhoea); b) maximum number of liquid/semi-liquid stools per day (42% and 53% against all- and- pure diarrhoeal episodes, respectively); c) maximum number of vomiting (56% and 62% for all-and-pure diarrhoeal cases, respectively); d) dehydration (42% and 48% against all-and-pure cases of diarrhoea, respectively); and e) the need for rehydration (42% and 46% for all-and-pure cases, respectively). High protective efficacy levels were achieved against rotavirus type G2-related diarrhoea during the second year of follow-up, if considered both the number-and-the maximum number vomiting episodes: 90% and 100%, respectively. Also for G2 type, the overall cumulative protection of 100% against those episodes scored greater than 14. Similar rates of protection against mixed – (35%) and – pure (37%) rotavirus gastroenteritis were yielded after two years of follow-up. While no efficacy was achieved against mild (0-8 scored) diarrhoea, RRV-TV was 75% (p = 0.02) efficacious against the very severe cases of rotavirus gastroenteritis; there was a tendency for protection against all-and-pure diarrhoeal episodes with clinical scores ranging from 9 to 14: 44% (p = 0.06) and 45% (p = 0.08), respectively. The results of study support the view that RRV-TV appears to selectively protect against the most severe rotavirus disease.