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Current rotavirus vaccines: effective and safe

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Question

Are current rotavirus vaccines safe and effective in preventing diarrhoea in infants and children?

Context

Rotavirus infections were a common cause of diarrhoea-related hospital admissions before the rota-virus vaccine was introduced in Belgium. Infections with rotavirus can still induce severe diarrhoea in children which could lead to complications including death. However, in low childhood mortality countries such as Belgium deaths due to rotavirus are rare.

Two rotavirus vaccines are globally available and prequalified by the World Health Organisation (WHO). Both the monovalent vaccine Rotarix (RV1, GlaxoSmithKline) and the pentavalent vaccine RotaTeq (RV 5, Merck) are currently approved for use in Belgium. Several other vaccines are available but are only licensed in single countries in Asia. The first ever licensed rotavirus vaccine, RotaShield (RR-TV, Wyeth Laboratories) was withdrawn from use following reports of intussusceptions. Later observations suggested that this risk was age-related and more common in infants who were over 90 days old when receiving the first dose.

Criteria for study selection

This Cochrane review included trials in children comparing rotavirus vaccines which were prequalified by the WHO versus placebo or no vaccine. The main outcomes reported by the review are severe cases of rotavirus diarrhoea, severe all-cause diarrhoea, all-cause death, serious adverse events and intussusception specifically.

Summary of the results

The authors identified fifty-five trials with a total of 216,480 participants. Thirty six trials assessed Rotarix and 15 trials assessed RotaTeq. The remaining four trials investigated Rotavaq, a vaccine not available in Belgium. The review authors performed separate analyses for high- and low-mortality countries as determined by the WHO. This Cochrane Corner, aimed at Belgian paediatricians, will therefore only discuss the results for low-mortality countries on the two vaccines available in Belgium.

Rotarix

At one year follow up, vaccination with Rotarix reduced the number of severe cases of rotavirus diarrhoea by 84% compared to placebo with the risk decreasing from 13 cases per 1000 participants to 2 per 1000 (95% CI[^]: 1-3 per 1000; 43,799 participants, 7 studies, high-certainty evidence). The number of severe cases of all cause diarrhoea was lowered by 41% (24 per 1000 vs 4 per 1000 (95% CI: 3-5); 36,002 participants, 9 studies, moderate-certainty evidence). At two years follow-up, Rotarix vaccination resulted in a 82% reduction of severe rotavirus diarrhoea cases (41 per 1000 vs 24 per 1000 (95% CI: 19-30); 28,051 participants, 3 studies, high-certainty evidence) and a 37% reduction of all-cause diarrhoea cases (moderate-certainty evidence). There was no increased risk of serious adverse events (high-certainty evidence) or intussusception (low-certainty evidence).

RotaTeq

At one year follow up, RotaTeq vaccination decreased the number of severe rotavirus diarrhoea cases from 17 cases per 1000 to 1 per 1000 (95% CI: 1-5 per 1000), a 92% reduction (4132 participants, 5 studies, moderate-certainty evidence). In children followed for up to two years after vaccination, severe cases of rotavirus diarrhoea were reduced by 82% (25 per 1000 vs 4 per 1000 (95%

CI: 2-10); 7318 participants, 4 studies, moderate-certainty evidence). The review authors did not identify any studies reporting on severe all-cause diarrhoea after RotaTeq vaccination. No increased risk for serious adverse events (high certainty evidence) or intussusception (low-certainty evidence) was detected.

Conclusion

In the first two years, Rotarix prevents more than 80% of severe rotavirus diarrhoea cases. The evidence concerning the efficacy of RotaTeq for severe rotavirus diarrhoea is slightly less certain, but it probably also prevents 82 to 92% of cases. Rotarix probably prevents 37 to 41% of severe cases of all-cause diarrhoea. No studies were identified that reported this outcome for RotaTeq. Rotavirus vaccination with either Rotarix or RotaTeq does not increase the number of serious adverse events and may have little or no effect on the number of intussusception cases.

Implications for practice

The review supports the WHO recommendations for the use of these rotavirus vaccines and Rotarix and RotaTeq are shown to have similar efficacy and safety profiles. Although the safety data exclude a risk of intussusception of the magnitude seen with RotaShield, the review underlines the importance of continued surveillance for intussusception or other serious adverse events in countries where rotavirus vaccination has been introduced systematically.

REFERENCE:

Soares-Weiser K, Bergman H, Henschke N, Pitan F, Cunliffe N. Vaccines for preventing rotavirus diarrhoea: vaccines in use. Cochrane Database of Systematic Reviews 2019, Issue 3. Art. No.: CD008521. DOI: 10.1002/14651858.CD008521.pub4.

Access the full text of these reviews via the Cebam Digital Library for Health (www.cebam.be/nl/cdlh or www.cebam.be/fr/cdlh)

[^] CI: confidence interval