Safety of HPV vaccination in adolescent girls

Population : Adolescent girls
Intervention: HPV vaccination
Comparison: Placebo/ no vaccination
Outcome : Severe adverse events following immunization

In immunocompetent adolescent girls who are naïve to vaccine-related HPV types, what is the (attributable) incidence of serious adverse events for any dose of HPV vaccination?				
			Rating	Adjustment to rating
Quality Assessment	No. of studies/starting rating		3/ RCT[1] 2/ observational	4
	Factors decreasing confidence	Limitation in study design	None serious	0
		Inconsistency	None serious	0
		Indirectness	None serious	0
		Imprecision	Serious[2]	-1
		Publication bias	None serious	0
	Factors increasing confidence	Large effect	Not applicable	0
		Dose-response	Not applicable	0
		Antagonistic bias and confounding	Not applicable	0
	Final numerical rating of quality of evidence			**3**
Summary of Findings	**Statement on quality of evidence**			**We are moderately confident in the estimate of effect on health outcome. The true effect is likely to be close to the estimate of the effect.**
	Conclusion			**We are moderately confident that the risk of severe adverse events following vaccination with any dose of HPV is low.**

[1] Three RCTs investigated safety and reactogenicity of HPV vaccines in young adolescent females: Block SL et al and Reisinger KS et al (quadrivalent vaccine), and Pedersen C et al (bivalent vaccine). Compared with recipients of placebo (in quadrivalent vaccine studies) or control Hepatitis A vaccine (in bivalent vaccine studies), HPV vaccine recipient were more likely to have local injection-site reactions, but were not significantly more likely to experience serious or systemic adverse events. These findings are consistent with large safety studies in older adolescent females and women (See WHO Background Paper for references). One observational study (Grimaldi-Bensouda L et al) investigated whether the quadrivalent human papillomavirus (HPV) vaccine was associated with risk of autoimmune disorders (ADs) in young females. No evidence of an increase in the risk of ADs was observable following vaccination. One further large cohort study (Arnheim-Dahlström L et al.) found no evidence supporting associations between exposure to qHPV vaccine and autoimmune, neurological, and venous thromboembolic adverse events.

[2] Limited post marketing surveillance periods of these vaccines do not permit final assessments of possible rare or long-term adverse effects.

References

Arnheim-Dahlström L, Pasternak B, Svanström H, Sparén P, Hviid A. Autoimmune, neurological, and venous thromboembolic adverse events after immunisation of adolescent girls with quadrivalent human papillomavirus vaccine in Denmark and Sweden: cohort study. BMJ 2013;347:f5906.

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