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Safety, tolerability and side effects of human papillomavirus vaccines: A systematic quantitative review

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Recently, many studies have evaluated HPV vaccine safety and adverse effects. Two vaccines have been recently evaluated in randomized controlled trials: The bivalent vaccine for HPV 16 and 18 (Cervarix, GlaxoSmithKline Biologicals, Rixensart, Belgium) and the quadrivalent vaccine for HPV 6, 11, 16, and 18 (Gardasil, Merck and Co., Inc., Whitehouse Station, NJ). We have performed a systematic review of all randomized controlled trials in which HPV vaccines were compared with placebo regarding safety, tolerability and adverse effects. Studies were searched up to March 2013 in the databases: Pubmed, Embase, Scielo and Cancerlit. Odds Ratios (OR) of most incident adverse effects were obtained. Twelve reports, involving 29,540 subjects, were included. In the HPV 16/18 group, the most frequently reported events related to the vaccine were pain (OR 3.29; 95% CI: 3.00-3.60), swelling (OR 3.14; 95% CI: 2.79-3.53) and redness (OR 2.41; 95% CI: 2.17-2.68). For the HPV 6/11/16/18 group the events were pain (OR 2.88; 95% CI: 2.42-3.43) and swelling (OR 2.65; 95% CI: 2.0-3.44). Concerning the HPV 16/18 vaccine, pain was the most common outcome detected. These effects can be due to a possible VLP-related inflammation process. Fatigue was the most relevant general effect observed followed by fever, gastrointestinal symptoms, and headache. In the HPV 6/11/16/18 group, only general symptoms, pain and swelling were observed. Pain and swelling were the most frequent. Comparing HPV 16/18 to HPV 6/11/16/18 vaccines, the former presented more adverse effects, perhaps because there are many more trials evaluating the bivalent vaccine. Other studies are needed to clarify this issue.

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