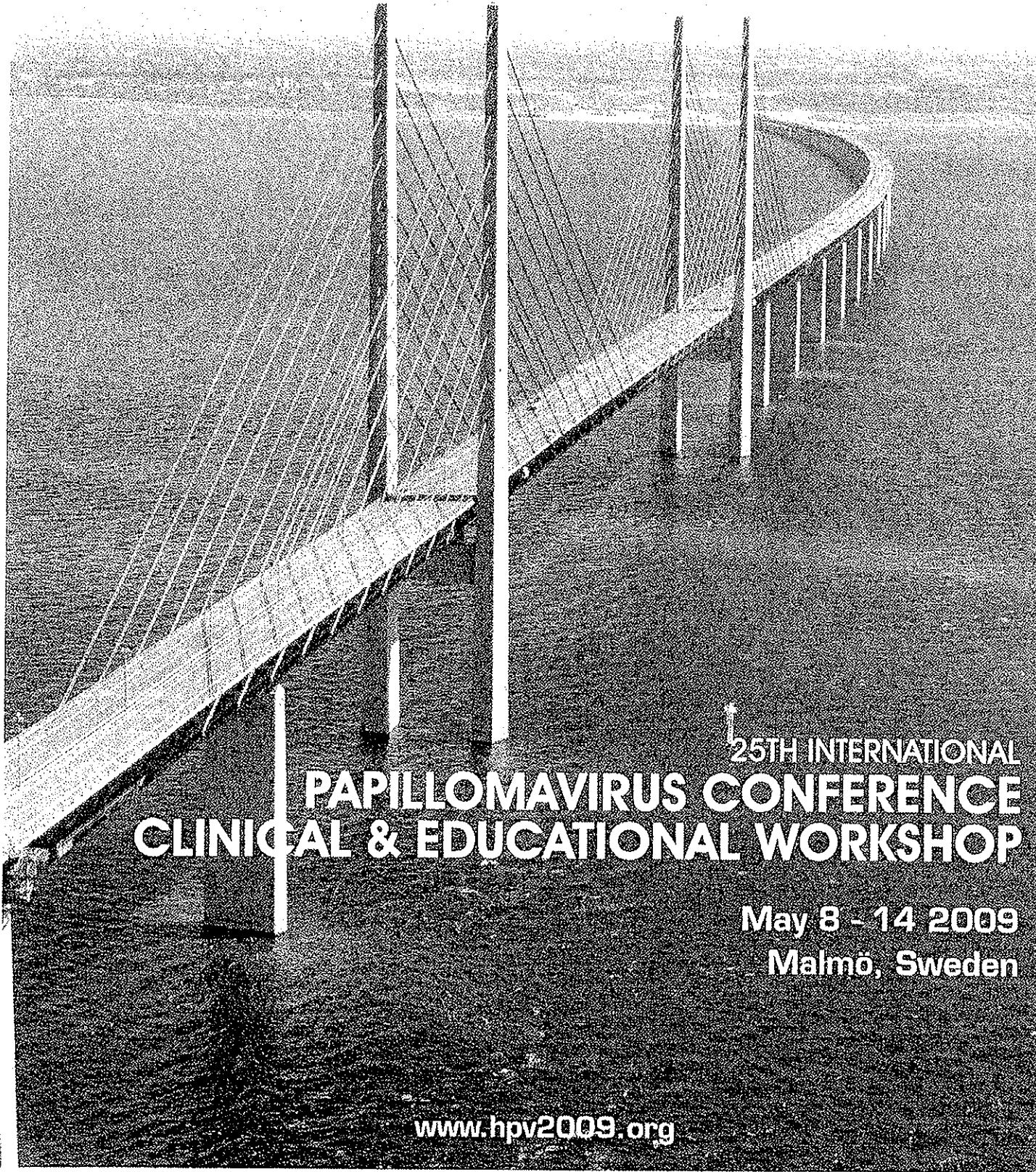


ABSTRACT BOOK



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LONG-TERM EFFICACY OF A PROPHYLACTIC HUMAN PAPILLOMAVIRUS TYPE 16 VACCINE

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BACKGROUND: Prophylactic human papillomavirus (HPV) L1 virus-like particle (VLP) vaccines have demonstrated high levels of protection against HPV infection and cervical intraepithelial neoplasia (CIN) in randomized controlled trials (RCTs) through limited follow-up. **OBJECTIVE:** To provide efficacy data after administration of a prophylactic HPV-16 L1 VLP vaccine at a mean of 8.5 years (range: 7.2-9.5 years), the longest duration of follow-up reported to date. **METHODS:** Between March 2006 and May 2008, 290 women who had participated in a phase IIb RCT of this vaccine in Seattle (November 1998-January 2004) were enrolled in an extended follow-up study. **RESULTS:** During the RCT period, one woman exhibited HPV-16 infection by HPV DNA detection at a single visit (month 12) in the vaccine group; 15 women exhibited HPV-16 infection and 5 women developed HPV-16-associated CIN in the placebo group. During the extended follow-up period, no woman exhibited HPV-16 infection or developed HPV-16-associated CIN in the vaccine group; 6 women exhibited HPV-16 infection (vaccine efficacy [VE] = 100%; 95% confidence interval [CI]: 25%-100%) and 3 women developed HPV-16-associated CIN (VE = 100%; 95% CI: <0%-100%) in the placebo group. Approximately 86.3% of vaccine recipients remained HPV-16 competitive Luminex[®] immunoassay seropositive at 8.5 years. Overall, throughout the combined RCT and extended follow-up periods, 1 woman exhibited HPV-16 infection and no woman developed HPV-16-associated CIN in the vaccine group; 21 women exhibited HPV-16 infection (VE = 96%; 95% CI: 73%-100%) and 8 women developed HPV-16-associated CIN (VE = 100%; 95% CI: 47%-100%) in the placebo group. **CONCLUSIONS:** The prophylactic HPV-16 L1 VLP vaccine remains highly efficacious against HPV-16 infection 8.5 years after its administration. While there was limited power to definitely address the efficacy against cervical lesions during the extended follow-up period, it was reassuring that no vaccine-recipient developed HPV-16-associated CIN.