

Usefulness of E7 mRNA in HPV16-positive women to predict the risk of progression to HSIL/CIN2+

Cristina Marti¹, Lorena Marimon², Ariel Glickman¹, Carla Henere¹, Adela Saco², Natalia Rakislova², Aureli Torné³, Jaume Ordi², and Marta del Pino⁴

¹Institute Clinic of Gynaecology, Obstetrics, and Neonatology, Hospital Clinic

²Hospital Clínic de Barcelona

³Hospital Clinic de Barcelona Institut Clinic de Ginecologia Obstetricia i Neonatologia

⁴Institute Clinic of Gynaecology, Obstetrics, and Neonatology, Hospital Clinic - Institut d'Investigacions Biomediques August Pi i Sunyer (IDIBAPS), University of Barcelona, Barcelona,

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Abstract

Objective: To evaluate whether E7 mRNA can predict the risk of progression in women with HPV16 infection. **Design:** prospective observational study **Setting:** Tertiary university hospital **Population:** A cohort of 139 women referred to colposcopy for an abnormal screening result fulfilling the following inclusion criteria: 1) a positive test result confirming HPV16 infection; 2) a biopsy sample with a histological diagnosis of absence of lesion or low-grade SIL/CIN grade1 (LSIL/CIN1); 3) no previous HPV vaccination; 4) no pregnancy; and 5) no previous cervical treatments; and 6) no immunosuppression. **Methods:** At the first visit all women underwent a cervical sample for liquid-based cytology, HPV testing and genotyping, and HPV16 E7 mRNA analysis and a colposcopy with at least one colposcopy-guided biopsy. Follow-up visits were scheduled every six months. In each control a liquid-based Pap smear, HPV testing, as well as a colposcopy examination with biopsy if necessary were performed. **Main outcome measures:** Histological diagnosis of HSIL/CIN2+ at any time during follow-up **Results:** E7 mRNA expression was positive in 55/127 (43.3%) women included in the study and seven (12.7%) progressed to HSIL/CIN2+. In contrast, only 1/72 (1.4%) women with no HPV16 E7 mRNA expression progressed ($p=0.027$). HPV16 E7 mRNA expression was associated with a 10-fold increased risk of progression (HR 10.0; 95%CI 1.2-81.4). **Conclusions:** HPV16 E7 mRNA could be useful for risk stratification of women with HPV16 infection in whom a HSIL/CIN2+ has been ruled out.

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