

Comparison of healthcare utilization of colposcopy, repeat conventional cytology and hrHPV triage for the management of women with ASC-US cytology in routine healthcare services of Medellin, Colombia: The ASCUS-COL Trial

Armando Baena¹, Maria C Agudelo¹, Marcela Riveros², Carolina Lopez³, Guadalupe Posada⁴, Carlos A Buitrago⁵, David Suescun⁶, Luis J Gomez⁴, Juan C Ochoa⁷, Mark Stoler⁸, Philip E Castle⁹, Peter Sasieni¹⁰, Maribel Almonte¹¹, Rolando Herrero¹¹, Gloria I Sanchez¹

¹Group Infection and Cancer, School of Medicine, Universidad de Antioquia, Medellin, Colombia. ²Pablo Tobon Uribe Hospital, Medellin, Colombia ³Department of Pathology, School of Medicine, Universidad de Antioquia, Medellin, Colombia. ⁴Dinamica IPS, Medellin, Colombia. ⁵Clinica SOMA, Medellin, Colombia. ⁶Laboratory of Pathology and Cytology Suescun, Medellin, Colombia. ⁷Unidad Videodiagnóstica de la Mujer, Medellin, Colombia. ⁸Department of Pathology and Laboratory Medicine, University of Virginia, Charlottesville, VA, USA. ⁹Department of Epidemiology and Population Health, Albert Einstein College of Medicine, Bronx, New York. ¹⁰Centre for Cancer Prevention, Wolfson Institute of Preventive Medicine, Barts and The London School of Medicine and Dentistry, Queen Mary University of London, London, UK. ¹¹Prevention and Implementation Group, International Agency for Research on Cancer, Lyon, France.

Evaluation of healthcare utilization under routine conditions is useful to determine the real efficiency of services delivery. We compared under routine conditions of opportunistic screening settings the efficiency of immediate colposcopy (IC-arm), conventional cytology at 6/12 months (RC-arm) and triage with hrHPV test (HPV-arm) to reduce untreated CIN2+ and healthcare utilization during 2 years of follow-up of 2,661, 20-69 years old women with ASC-US cytology. Between January, 2011 and January, 2014, women from 3 Health Management Organizations (HMOs) of Medellin, Colombia were randomized to the 3 strategies. All services but HC2-hrHPV test were routinely delivered by HMOs-contracted Healthcare Provider Institutions (HPIs). Healthcare utilization (number of cervical cytologies, colposcopies and biopsies) was ascertained from databases and/or manually from medical records. Participants were invited to an exit visit 24 months after enrollment to receive cytology/hrHPV and those \geq ASC-US/hrHPV+ were referred to a certified re-trained gynaecologist/colposcopist who obtained at least one biopsy in all women. Histologic diagnoses were blindly confirmed by two well-trained pathologists. The primary endpoint was confirmed CIN2+ detected at exit visit. Women that attended exit visit (n=2,117) or did not attend but were diagnosed with CIN2+ during follow-up (n=18 disease free at exit visit) or upgraded to CIN2+ by expert pathologists (n=15 with disease at exit visit) were included in per-protocol analysis. Compared to RC-arm, only women in HPV-arm showed lower CIN2+ relative risk (RR=0.60, 95% CI: 0.38-0.93) and lower relative healthcare utilization (RU=0.88, 95% CI: 0.82-0.94). Women \geq 30 years of HPV-arm presented lower CIN2+ risk (RR=0.44, 95% CI 0.22-0.82) but similar healthcare utilization (RU=1.1, 95% CI 0.91-1.23). Risk of CIN2+ of \leq 29 years old women was similar among arms and RU was 45% and 36% significantly lower in RC-arm only. HPV testing was more efficient to manage women \geq 30 years old with ASCUS cytology in routinely delivered services of HMOs of Medellin, Colombia.

Key words: cervical cancer screening, triaging, pragmatic trial, health services research, comparative effectiveness research, Colombia