

## TWELVE-MONTH INCIDENCE OF ANAL HIGH-GRADE SQUAMOUS INTRAEPITHELIAL LESIONS (HSIL) IN A COHORT OF GAY AND BISEXUAL MEN (GBM): RESULTS FROM THE STUDY OF THE PREVENTION OF ANAL CANCER (SPANC)

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**Background:** GBM are at greatly increased risk of anal cancer and anal HSIL is the presumed cancer precursor. We report the 12-month incidence of HSIL in a cohort of GBM and its association with human papillomavirus (HPV) biomarkers.

**Methods:** SPANC participants underwent cytological and histological assessments and HPV genotyping at baseline, 6-month and 12-month visits. Composite HSIL was defined as detection of cytological and/or histological HSIL. Biomarkers were tested at baseline only, and included HPV viral load, E6/E7 mRNA, and dual cytological staining for p16/Ki67.

**Results:** Of 617 men recruited, 439 (71.2%) men attended all three visits. Among 233 men (median age: 50, 30.9% HIV-positive) who did not have composite HSIL at baseline, 53 developed HSIL by 12 months, an incidence of 20.9 per 100 person-years (95%CI: 16.0-27.4). Neither age, HIV status, nor lifetime or recent sexual behaviour was associated with HSIL development. Testing positive to high-risk HPV (HRHPV) at baseline, including HPV16 (HR=2.85, 95%CI 1.60-5.08) and HPV18 (HR=2.41, 95%CI 1.13-5.16), and testing positive to HPV biomarkers including HPV16 E6/E7 mRNA (HR=2.36, 95%CI 1.29-4.32) and dual p16/Ki67 staining (HR=5.40, 95%CI 2.05-14.1) were highly associated with incident HSIL. HSIL incidence was lowest in those who tested negative to HRHPV consistently at baseline and 6-month visits (5.7 per 100 person-years), compared with those who had persistent HPV16 infection (55.3 per 100 person-years, HR=9.97, 95%CI 3.82-26.0) and persistent infection of other HRHPV types (35.4 per 100 person-years, HR=6.00, 95%CI 2.39-15.0).

**Conclusion:** Incident anal HSIL was extremely common in sexually active GBM and was highly associated with HRHPV infection. Repeated testing for HRHPV should be considered as a screening strategy for anal cancer prevention in high-risk populations.

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