



Anal histologic HSIL in HIV positive women – Prevalence and risk factors: AMC 084

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Disclosures

• No financial relationships or conflict of interest to disclose





Background

Accurate estimates of prevalent histologic anal high-grade squamous intraepithelial lesions (hHSIL) are not available for HIV+ women.

By performing concurrent anal cytology and high resolution anoscopy (HRA)-directed biopsy, we determined the prevalence and risk factors for anal hHSIL in HIV+ women.





Methods

Prospective cohort study of 265 HIV+ women age 24-69, without a known prior history of (h/o) anal cytologic or histologic HSIL

Conducted at 11 US sites through the AIDS Malignancy Consortium (AMC).

- Boston Medical Center, Boston, MA
- UCSF, San Francisco, CA
- Thomas Street Clinic, Baylor College of Medicine, Houston, TX
- Cornell Clinical Trials, New York, NY
- Montefiore Medical Center, New York, NY
- University of Pittsburgh, Pittsburgh, PA
- Wake Forest University Health Sciences, Winston-Salem, NC
- University of Puerto Rico, San Juan, PR
- John. Stroger Hospital of Cook County, Chicago, IL
- Beth Israel Deaconness Medical Center, Boston, MA
- Laser Surgery Center, New York, NY



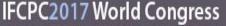


Administered detailed questionnaire

Collected cervical and anal specimens for cytology and detection of HR-HPV DNA with Hybrid-Capture-2 (HC2) assay (Qiagen Corp, Valencia, CA).

Performed HRA with at least 2 biopsies (directed or random)







Analysis

Analyses of risk factors of anal histologic HSIL (hHSIL) at study entry

- Univariate: Chi-square tests
- Multivariate: Logistic regression





Prevalent anal histologic HSIL

75/265 HIV+ women







Demographics

Characteristics		n (%) of Total N=265	n (%) of HSIL N=75	p-value
Age	Mean (SD)	50 (9)	50 (8)	0.40
	Non-hisp Black	167 (63%)	39 (52%)	
Race/ethnicity	Non-hisp White	45 (17%)	16 (21%)	0.06
	Hispanic	53 (20%)	20 (27%)	
Smoking status	Former/current smoker	173 (67%)	54 (75%)	0.09
U	Never smoked	85 (33%)	18 (25%)	
Education	High school diploma or less	144 (57%)	43 (61%)	0.44
Education	Some college or higher	110 (43%)	28 (39%)	0.44
	<\$20,000	180 (84%)	57 (90%)	
Annual income	≥\$20,000	34 (16%)	6 (10%)	0.10



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Clinical history

History of		n (%) of Total N=265	n (%) of HSIL N=75	p-value	
Anal cay with a man	No/declined	115 (44%)	26 (36%)	0.00	
Anal sex with a man	Yes	145 (56%)	47 (64%)	0.08	
Anal sex partners entire life	0-1	185 (73%)	45 (67%)	0.18	
	≥2	67 (27%)	22 (33%)		
Anogenital warts	No	200 (75%)	53 (71%)	0.25	
	Yes	65 (25%)	22 (29%)	0.25	
Abnormal cervical	Yes	75 (33%)	23 (35%)	0.61	
cytology	No/unsure	153 (67%)	42 (65%)	0.01	
Sexual assault	No	138 (53%)	36 (49%)	0.47	
	Yes	123 (47%)	37 (51%)	0.47	





HIV Characteristics

Character	istics	n (%) of Total N=265	n (%) of HSIL N=75	p-value	
CD4 count	≤200	20 (8%)	<mark>12 (16%)</mark>	-0.01	
at visit 1	>200	<mark>243 (92%)</mark>	<mark>63 (84%)</mark>	<0.01	
Viral load at visit 1	Detectable	71 (27%)	23 (31%)	0.36	
	Undetectable	192 (73%)	51 (69%)		
Nadir CD4 cell	≤200	128 (51%)	<mark>46 (65%)</mark>	.0.04	
count	>200	125 (49%)	<mark>25 (35%)</mark>	<0.01	
cART	Yes	250 (96%)	72 (99%)	0.40	
	No/unsure	10 (4%)	1 (1%)	0.19	





Risk Factors for HSIL

Characteristics	5	n (%) of Total N=265	n (%) of HSIL N=75	p-value	
Cervical	ASCUS+	77 (30%)	24 (32%)	0.65	
cytology	Normal	180 (70%)	51 (68%)	0.05	
Cervix HPV	HPV + 76 (29%) 27 (38%)		27 (38%)	0.06	
HC2	HPV -	184 (71%)	44 (62%)	0.06	
Anal	ASCUS+	155 (61%)	<mark>56 (78%)</mark>	<0.001	
cytology Normal		101 (39%)	16 (22%)	20.001	
Anal HPV HC2	HPV+	124 (48%)	51 (71%)	-0.001	
	HPV -	133 (52%)	21 (29%)	<0.001	

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Anal Cytology and Histology

	Anal Histology			
Anal Cytology	n (%) of Total N=256	n (%) of HSIL N=72		
Normal	101 (39%)	16 (22%)		
ASCUS/LSIL	130 (51%)	38 (53%)		
ASC-H/HSIL	25 (10%)	18 (25%)		

Note: 9 were unevaluable for anal cytology, including 3 of hHSIL





Multivariate model of risk factors for hHSIL:

Parameter (n=227)		p-value	OR (95% CI)
Race	Black non-hispanic vs white/other	0.006	0.39 (0.20, 0.76)
Nadir CD4	<=200 vs >200	0.032	<mark>2.05 (1.06, 3.95)</mark>
Anal Cytology	Abnormal vs normal	0.076	1.94 (0.93. 4.02)
Anal HPV	Detected vs. not detected	0.002	3.08 (1.53,6.20)





Multivariate model of risk factors for hHSIL: (omitting Anal Cytology & HPV results)

Parameter (n=227)		p-value	OR (95% CI)
Race	Black non-hispanic vs white/other	0.040	0.53 (0.28, 0.97)
Nadir CD4	<=200 vs >200	0.004	2.53 (1.36, 4.71)

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Summary

Highest reported rate of prevalent hHSIL in HIV+ women \rightarrow 28% Abnormal anal cytology \rightarrow 60% Anal HPV+ \rightarrow 50%

22% of hHSIL were associated with normal anal cytology





Discussion

Despite univariate analyses showing significance (at p<.1) for

- Race, Smoking status, History of Anal sex
- Nadir CD4 and Baseline CD4
- Anal HPV and Cervical HPV

Only race (Black, non-Hispanic), nadir CD4 and anal HPV were significant in the final model





Special thanks to the women who participated in our study

Enrolling AMC sites PIs and research staff

Baylor College of Medicine, Thomas Street Clinic UCSF Montefiore Medical Center Weill Medical College of Cornell University Boston University School of Medicine Laser Surgery Care, New York University of Pittsburgh

University of Puerto Rico

Wake Forest University Health Sciences

John H. Stroger Hospital of Cook County

AMC Statistical Center, University of Arkansas

EMMES

AMC leadership

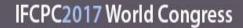
Qiagen

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Extra slides (full model results)





Multivariate model of risk factors for hHSIL: with all significant variables from univariate analysis

Parameter (n=227)		p-value	OR (95% CI)
Race	Black vs White/other	0.011	0.41 (0.21, 0.82)
Smoking	Former or current smoker vs Never smoker	0.398	1.37 (0.66, 2.84)
Baseline CD4	<=200 vs >200	0.390	1.63 (0.54, 4.94)
Nadir CD4	<=200 vs >200	0.06	1.93 (0.97, 3.83)
h/o anal sex	Yes vs No/Declined	0.424	1.31 (0.67, 2.56)
Anal cytology at baseline	All others vs NILM	0.122	1.81 (0.85. 3.83)
Qiagen Anal HPV	Detected vs. not detected	0.003	3.01 (1.44,6.31)
Qiagen Cervical HPV	Detected vs. not detected	0.673	0.85 (0.41, 1.79)





Multivariate model of risk factors for hHSIL: with all significant variables from univariate analysis (without Anal Cytology & Qiagen HPV results)

Parameter (n=227)		p-value	OR (95% CI)
Race	Black vs White/other	0.056	0.53 (0.28, 1.02)
Smoking	Former or current smoker vs Never smoker	0.154	1.66 (0.83, 3.32)
Baseline CD4	<=200 vs >200	0.142	2.24 (0.76, 6.58)
Nadir CD4	<=200 vs >200	0.016	2.24 (1.16, 4.31)
h/o anal sex	Yes vs No/Declined	0.306	1.40 (0.74, 2.66)



