

Awareness in Sexual Health: U=U and prevention

OC 44 Loss of "U=U status" in Women with HIV: insights into possible reasons for a higher risk compared to Men

Authors

R. Fontana Del Vecchio¹, C. Marelli², A. Tavelli³, C. Costa⁴, V. Barocci⁵, S. Gambino⁶, J. Testa⁷, M. Merelli⁸, E. Zappulo⁹, L. Taramasso², G. Madeddu¹⁰, C. Pinnetti¹¹, A. Cingolani¹², A. d'Arminio Monforte³, A. Cozzi-Lepri¹³ on behalf of Icona Foundation Study Group

Affiliation

¹Department of Infectious Diseases, Umberto I Public Hospital, Siracusa, Italy, ²Department of Specialist Medicine, Infectious Disease Clinic, IRCCS Ospedale Policlinico San Martino, Genoa, Italy, ³ICONA Foundation, Milan, Italy, ⁴Infectious Diseases Department, SOC 1, USL Centro Firenze, Santa Maria Annunziata Hospital, Florence, Italy, ⁵Department of Biomedical Sciences & Public Health, Polytechnic University of Marche, Ancona, Italy, ⁶Infectious Diseases Unit, Bolzano Hospital, Bolzano, Italy, ⁷Infectious Diseases Unit, Busto Arsizio Hospital, ASST Valle Olona, Busto Arsizio (VA), Italy, ⁸Azienda Sanitaria Universitaria del Friuli Centrale, Udine, ⁹Department of Clinical Medicine and Surgery, Section of Infectious Diseases, University of Naples "Federico II", Naples, Italy, ¹⁰Unit of Infectious Disease, Department of Medicine, Surgery and Pharmacy, University of Sassari, Sassari, Italy, ¹¹Clinical Department of Infectious Diseases, National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS, Rome, Italy, ¹²Clinic of Infectious Diseases, Catholic University, Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Rome, Italy, ¹³Centre for Clinical Research, Epidemiology, Modelling and Evaluation (CREME), Institute for Global Health, University College London, London, UK

ABSTRACT

There is solid evidence that there is zero risk of HIV transmission from an HIV positive partner with VL \leq 200 copies/ml (the Undetectable=Untransmittable, U=U status). Previous data reported that female sex at birth (FSAB) vs. MSAB is associated with higher risk of not maintaining the U=U status. Mechanisms leading to this observed difference have not been elucidated. ART management of women during pregnancy is complicated as treatment guidelines have changed over time regarding the use of specific drugs (i.e. DTG) which could lead to reduced adherence or ART interruptions. Also, women may have less time to focus on their own health before a certain age.

We included person with HIV (PWH) enrolled in the ICONA cohort who achieved a VL \leq 200 copies/mL for the first time after January 1 2012, and kept the U=U status for \geq 6 months. The main outcome was the proportion of participants who spent >10% of the total PYFU with a VL > 200 copies/mL. Person-years of follow-up (PYFU) above or below threshold of 200 copies/ml were also calculated using consecutive VL pairs, the trapezoid rule and linear interpolation. Participants' characteristics at baseline were compared according to FSAB using chi-square and non-parametric tests. A logistic regression model was used to model the proportion of participants with VL > 200 copies/mL. We hypothesized at the outset that pregnancy and fertility age might be effect measure modifiers in the association between FSAB and risk of losing the U=U status. We formally tested the interaction with age in the logistic model. We calculated the total and direct effect of FSAB by means of unadjusted and adjusted odds ratio overall and stratified by age. After restricting the analysis to only FSAB, we estimated the total effect of pregnancy on risk of losing U=U status after controlling for confounding factors.

We included 8,172 PWH enrolled in the Icona cohort of whom 1,409 (17.2%) FSAB. FSAB were less likely to have Italian nationality, with lower level of education, more likely to be with lower level of education, unemployed or have occasional jobs, more likely to have acquired HIV through sexual contacts and less likely to have a CVD comorbidity (Table 1). FSAB were under follow-up for a total of 6,591 PYFU of which 96.3% were with a VL \leq 200 copies/mL vs. 98.1% in MSAB. In terms of proportion of PWH with >10% PYFU with VL > 200 copies/mL this was 9.4% in FSAB vs 4.8% in MSAB (adjusted OR=1.57, 95% CI: 1.25-1.97, p-value < 0.0001). There was some evidence for an interaction between sex and age (p= 0.10, Table 2) but in the subset of FSAB there was inconclusive evidence for an association between no. of pregnancies and risk of losing the U=U status (Table 3).

Our analysis confirms a substantial higher risk of VL > 200 copies/mL in FSAB vs. MSABs after achieving the U=U status. Some of this risk was mediated by sociodemographic factors and data also carried evidence that it may vary by age but not strictly to issues related to pregnancy.

Table 1: Main characteristics of study population according to sex at birth.

	Total (N=8172)	FSAB (N=1409)	MSAB (N=6367)	p-value
Age, median (IQR)	36 (28-45)	37 (28-46)	36 (28-44)	0.09
Age class, n (%)				0.21
≤26 years	1541 (18.9%)	254 (18.0%)	1287 (19.0%)	
26-50 years	5603 (68.6%)	959 (68.1%)	4644 (68.7%)	
>50 years	1028 (12.6%)	196 (13.9%)	832 (12.3%)	
Italian nationality, n (%)	6488 (79.4%)	813 (57.7%)	5675 (83.9%)	<0.0001
Education level, n (%)				<0.0001
Primary school	265 (3.2%)	107 (7.6%)	158 (2.3%)	
Secondary school	1189 (14.6%)	235 (16.7%)	954 (14.1%)	
High school	2437 (29.8%)	341 (24.2%)	2096 (31.0%)	
University	1151 (14.1%)	88 (6.3%)	1063 (15.7%)	
Unknown	3130 (38.3%)	638 (45.3%)	2492 (36.9%)	
Occupation, n (%)				<0.0001
Self-employed	1165 (14.3%)	87 (6.2%)	1078 (15.9%)	
Employed	3221 (39.4%)	423 (30.0%)	2798 (41.4%)	
Unemployed	863 (10.6%)	240 (17.0%)	623 (9.2%)	
Occasional worker	165 (2.0%)	58 (4.1%)	107 (1.6%)	
Student	322 (3.9%)	28 (2.0%)	294 (4.4%)	
Retired	211 (2.6%)	39 (2.8%)	172 (2.5%)	
Disabled person	16 (0.2%)	3 (0.2%)	13 (0.2%)	
Housewife	100 (1.2%)	99 (7.0%)	1 (0.01%)	
Other/Unknown	2109 (25.8%)	432 (30.7%)	1677 (24.8%)	
Mode of HIV transmission, n (%)				<0.0001
Heterosexual contacts	3033 (37.1%)	1224 (86.9%)	1809 (26.8%)	
PWID	416 (5.1%)	85 (6.0%)	331 (4.9%)	
Other/Unknown	4723 (57.8%)	100 (7.1%)	4623 (68.4%)	
Diabetes, n (%)	269 (3.3%)	36 (2.6%)	233 (3.5%)	0.08
Hepatitis diagnosis, n (%)	17 (0.2%)	1 (0.1%)	16 (0.2%)	0.34*
Cancer diagnosis, n (%)	244 (3.0%)	51 (3.6%)	193 (2.9%)	0.12
CVD diagnosis, n (%)	119 (1.5%)	12 (0.9%)	107 (1.6%)	0.04
Other comorbidity, n (%)	136 (1.7%)	27 (1.9%)	109 (1.6%)	0.42

*Fisher's exact test.

Table 2: OR from fitting a logistic regression model to estimate the probability of losing the U=U-status, stratified by age (≤50, >50 years).

Age		Unadjusted (total effect)	Adjustment for Italian nationality	Adjustment for Italian nationality and education	Adjustment for Italian nationality education and employment	
		OR (95% CI)	aOR	aOR	aOR	Interaction p-value
≤50 years	FSAB vs. MSAB	2.24 (1.80-2.79)	1.69 (1.34-2.13)	1.67 (1.32-2.10)	1.69 (1.33-2.13)	0.10
>50 years	FSAB vs. MSAB	0.93 (0.4-2.13)	0.75 (0.31-1.80)	0.74 (0.31-1.79)	0.75 (0.31-1.83)	

Table 3: OR from fitting a logistic regression model to estimate the probability of losing the U=U-status within FSAB

	OR (95% CI)	Type 3 p-value	aOR* (95% CI)	Type 3 p-value
Number of pregnancies		0.72		0.91
1 vs. 0	1.18 (0.65-2.17)		0.87 (0.47-1.63)	
2+ vs. 0	1.42 (0.49-4.11)		0.96 (0.33-2.86)	

*Adjusted for age class, Italian nationality, education level, occupation, and mode of HIV transmission. OR: odds ratio; aOR: adjusted odds ratio; CI: confidence interval.