

Higher rate of virological failure in women compared to men when starting dual antiretroviral treatment - Sexspecific analysis from the Frankfurt HIV Cohort

B. Koenigs¹, M. Bickel², S. Goepel¹, P. Gute², E. Herrmann³, P. de Leuw¹, G. Schuetfort¹, C. Stephan¹, T. Wolf¹, A. Haberl¹

¹University Hospital Frankfurt, HIVCENTER, Frankfurt, Germany, ²Infektiologikum Frankfurt, Frankfurt am Main, Germany,

³University Frankfurt, Institute of Biostatistics and Mathematical Modelling, Frankfurt, Germany

Conclusions: In this retrospective analysis of 341 pretreated patients starting a dual ART regimen there was a higher rate of virologic failure at baseline in women (72.3%) than in men (55.9%). The highest rate of virologic failure however occurred in African women (89.7%). Our findings contradict the prevalent opinion that women switch ART predominantly due to tolerability reasons and less often due to virologic failure compared to men. - After one year on dual ART virologic response rates - defined as a viral load <50 copies/mL - were similar in men (72.9%) and women (63.9%) but there still was a lower rate of viral suppression in African patients (men 54.5% and women 44.8%). The results of our study underline the need to consider possible sex differences in virologic response to ART.

Background: Even though dual antiretroviral treatment (ART) is not recommended for naive patients yet there is a clinical need for dual nuke-sparing regimen in pretreated patients. The total number of dual ART regimen will more probably increase in the near future since the first fixed dosed INSTI/NNRTI dual combination has been licensed in November 2017. Nevertheless, the typical characteristics of patients on dual ART in clinical everyday life remain unclear. Our study aims to create a profile of patients on dual ART under special consideration of possible sex specific differences.

Method: All patients of the Frankfurt HIV Cohort who started a dual ART between January 2008 and January 2015 were included in this retrospective study. In a sub-analysis we analyzed the ART outcome in patients who stayed on the dual regimen for at least one year. The primary study objective was the virologic response rate defined as a viral load <50 copies/mL after 12 months of treatment. Secondary objectives: sex specific differences in baseline characteristics, antiretroviral regimen, virologic and immunologic response.

Results: During the observational period 547 patients, 415 men (75.9%) and 132 women (24.1%), received a dual ART regimen. Complete sets with baseline and follow up data at week 52 were available for 341 patients, 258 men (75.7%) and 83 women (24.3%). Baseline characteristics are shown in table 1.

Women were more likely to be of African origin ($p < 0.0001$), and a higher rate of female than male patients had a detectable viral load at baseline ($p = 0.0113$). African women had the highest rate of virologic failure at baseline (89.7%) and there was a significant difference compared to the failure rate of non-African women (63.0%); p -value < 0.01.

After one year on dual ART 53 women (63.9%) and 188 men (72.9%) had an undetectable viral load (n.s.). There were significant lower response rates in African patients compared to non-African patients: African women 55.2% and African men 45.5%; p -value < 0.001. - The most common dual combinations in men were INSTI+PI (50.8%), PI+PI (27.2%) and CCR5 antagonist+PI (15.5%); in women the most frequently used dual combinations were INSTI+PI (43.4%), PI+PI (33.7%) and CCR5 antagonist+PI (18.1%). The virologic response rate in patients treated with PI+PI (45.9%) was lower compared to all other combinations (70.7%).

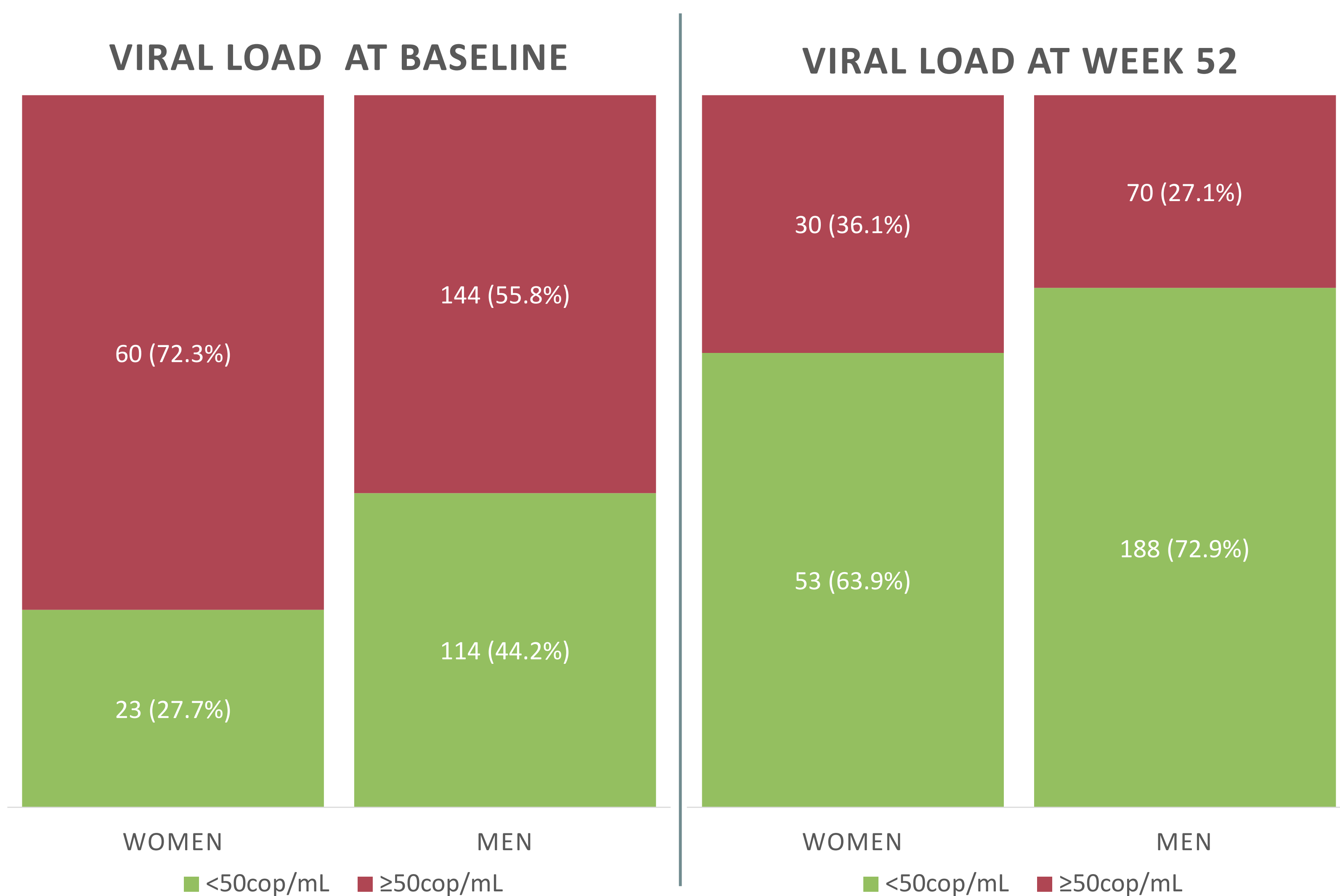


Figure 1: Viral load at baseline and after one year on dual ART

	All patients N = 341	Female patients N = 83	Male patients N = 258	p-value ¹
Median Age (years)	47.8	44.1	48.9	0.5390
African origin n (%)	51 (15.0%)	29 (34.9%)	22 (8.5%)	<0.0001
Median Time on ART (years)	11.9	11.3	12.2	0.5992
Median CD4 count (n/μL)	404	367	414	0.1228
Viral load <50 copies/mL n (%)	137 (40.2%)	23 (27.7%)	114 (44.2%)	0.0113

Table 1: Baseline characteristics of patients starting dual ART, ¹p-values for differences between women and men χ^2 -test and Wilcoxon rank-sum test where used

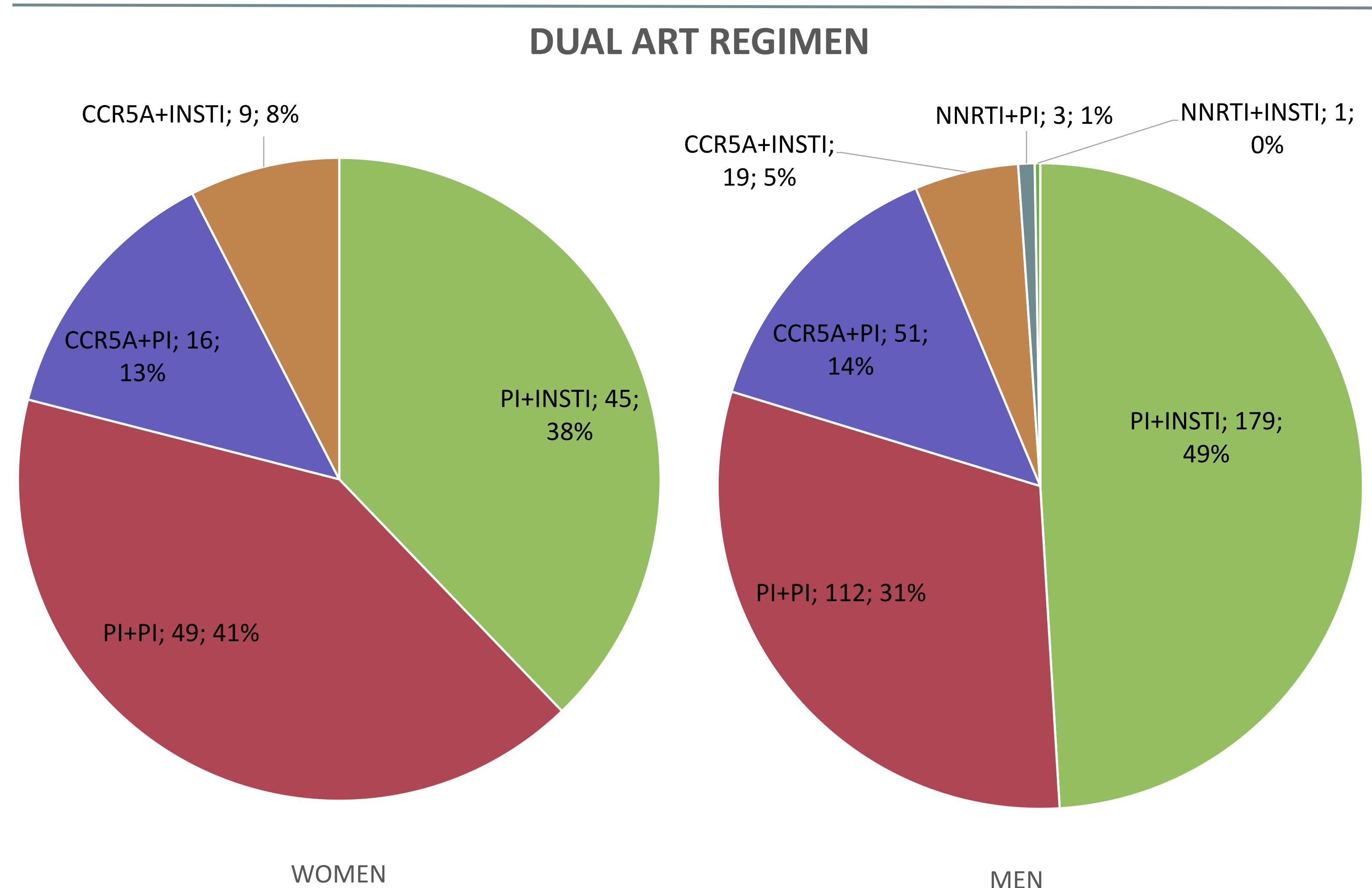


Figure 2: Dual regimens in men and women