

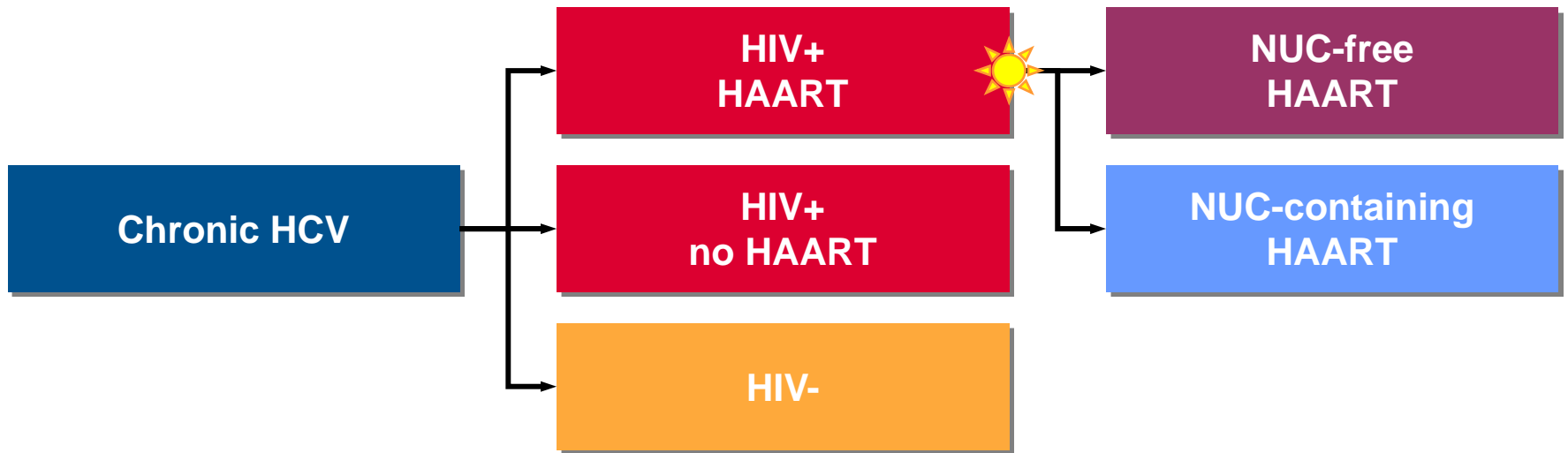
# The influence of nucleoside free HAART on the treatment of chronic hepatitis C with pegylated interferon / ribavirin combination treatment

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# Methods - Study design

- **Chronic HCV infection, 150 HIV+ , 50 HIV- patients**
  - 1:1 randomization NUC-free vs. NUC containing

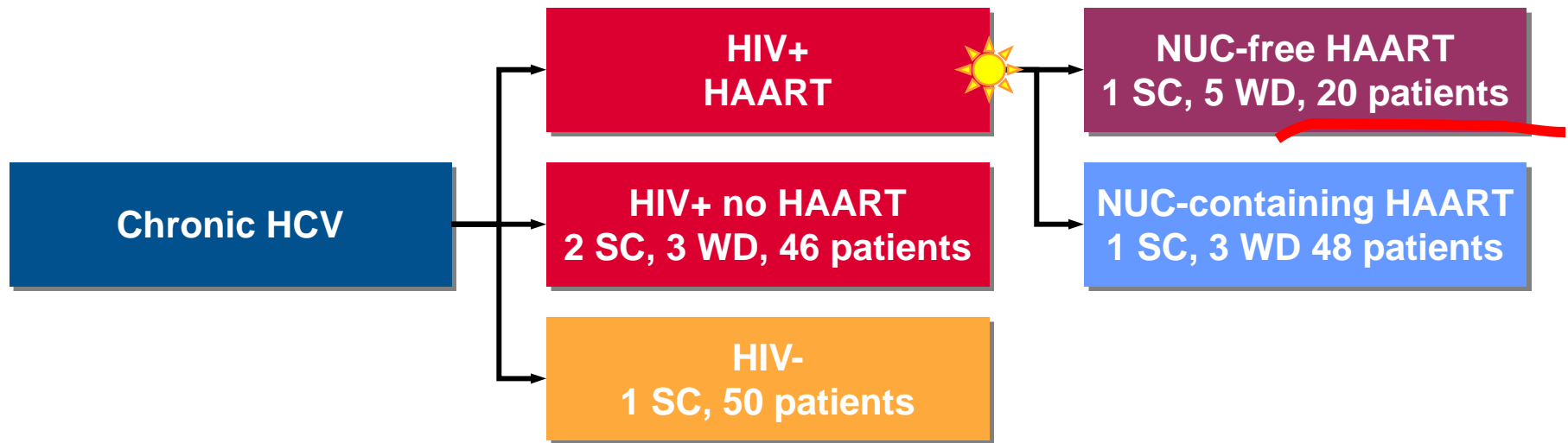


# Methods - Treatment modalities

- **Pegylated interferon alfa-2a 180 µg / week**
- **Duration 24 weeks GT 2/3, 48 weeks GT 1/4**
  - amendment I: HIV+ patients 48 weeks for all GT
- **Ribavirin 800 mg**
  - amendment II: GT 1/4 infections 1000 / 1200 mg

# Patient disposition

- **189 patients screened +/- randomized**
  - 9 patients screen failure
  - 12 patients consent withdrawal
  - 4 patients incomplete data
  - ***164 patients available for analysis***



# Baseline demographics

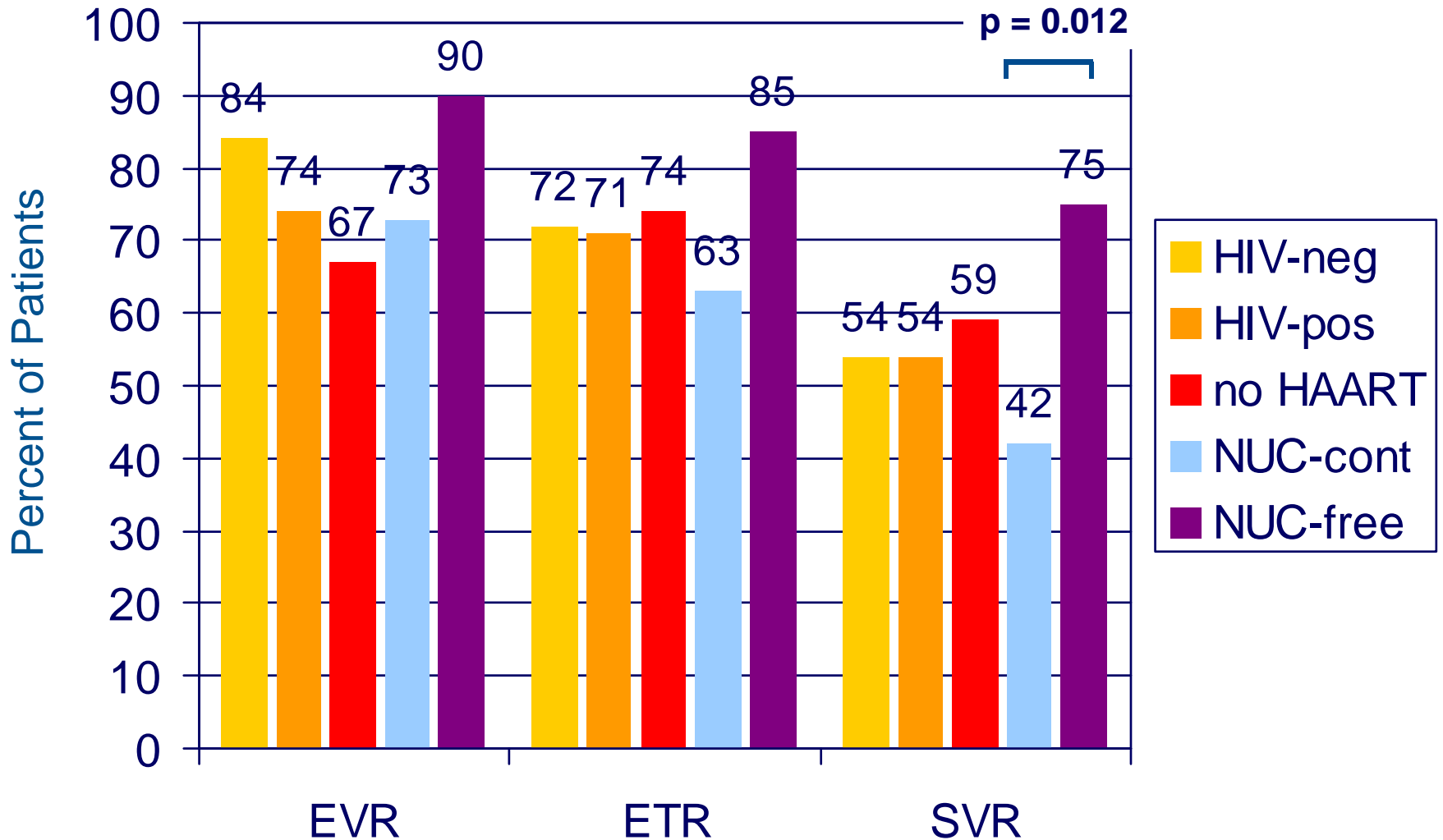
% patients or median (IQR)

	HIV-	HIV+ no HAART	HIV+ NUC-cont	HIV+ NUC-free
Sex (male)	60*	72	77	85
Age (years)	41 (33 - 49)	39 (33 - 43) *	41 (39 - 45) *	43 (39 - 46) *
Transmission risk				
IVDU	40	35	25	5
sexual	8	2	10	10
blood products	10	2	6	-
unknown	26	59	58	85
PI / NNRTI / 3xNUC	-	-	58/31/13	100/5/-
AZT	-	-	33	-
d4T	-	-	17	-
ABC	-	-	31	-
TDF	-	-	46	-
CD4 count (/μl)	-	580 (436 - 755) *	490 (361 - 573) *	390 (297 - 601) *
HIV-RNA (log10)	-	3.9 (3.3 - 4.3)	1.7	1.7
ALT (IU/ml)	61 (40 - 92)	64 (31 - 121)	75 (51 - 120)	75 (54 - 124)
HCV-Genotype 1/4	56	63	63	55
HCV-RNA (log10)	5.7 (5.2 - 6.2)	5.7 (5.2 - 6.0)	5.4 (5.1 - 6.0)	5.8 (5.4 - 6.6)

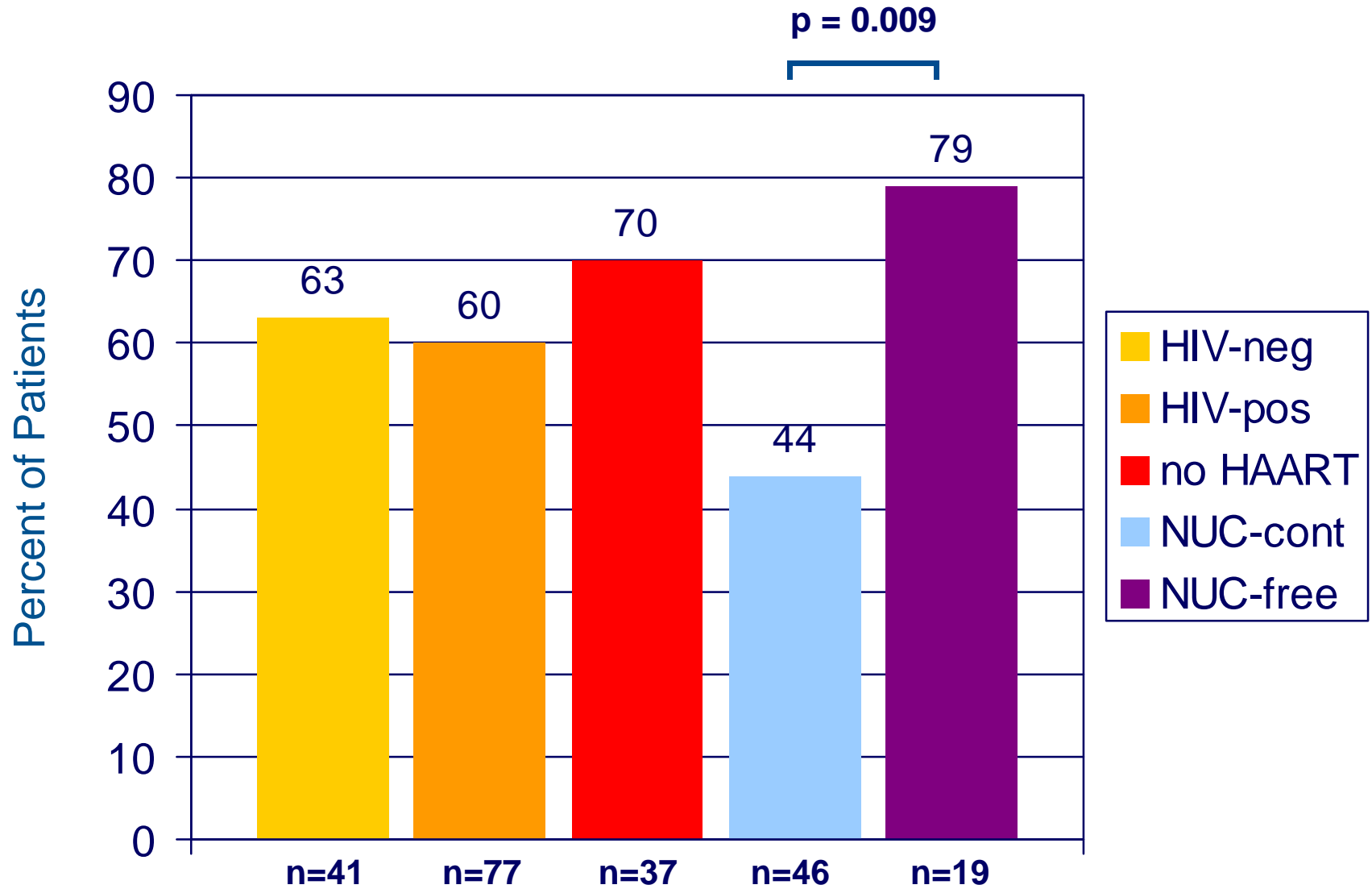
\*p< 0.05 HIV- vs HIV+; \*p<0.05 no HAART vs. NUC-cont. vs. NUC free

# Virological Response Rates

*ITT, missing = failure*



# SVR Rates *per protocol*



# Comparison NUC-cont. vs. NUC-free

## *Treatment modalities and AEs*

	HIV+ NUC-cont	HIV+ NUC-free	p-value
HCV-RNA (log10)	5.4 (5.1 - 6.0)	5.8 (5.4 - 6.6)	0.048
HCV-Genotype 1/4	30 (63%)	11 (55%)	0.497
Weight adapted RBV	25 (52%)	11 (55%)	0.826
Treatment duration	37 (24 - 48)	47 (31 - 47)	0.753
80 / 80 / 80 rule	32 (67%)	17 (85%)	0.188
All adverse events			
grade 1/2	12 (5 - 18)	11 (7 - 19)	0.628
grade 3/4	0 (0 - 1)	0 (0 - 1)	0.591
Haematological events			
grade 1/2	4 (1 - 6)	3 (0 - 11)	0.989
grade 3/4	0 (0 - 0)	0 (0 - 0)	0.548
Tx-Discontinuation AE	5 (10%)	3 (15%)	0.593

# Comparison SVR vs. Non-SVR

## *NUC containing HAART*

	No SVR n=28	SVR n=20	p-value
Sex (male)	20 (71%)	16 (80%)	0.635
Age (years)	42 (39 - 45)	41 (37 - 45)	0.966
Transmission risk			
IVDU	8 (29%)	4 (20%)	0.964
sexual	3 (11%)	2 (10%)	
blood products	2 (7%)	1 (5%)	
unknown	15 (54%)	13 (65%)	
<i>HCV-Genotype 1/4</i>	<i>22 (79%)</i>	<i>8 (40%)</i>	<i>0.003</i>
<i>HCV-RNA (log10)</i>	<i>5.7 (5.3 - 6.5)</i>	<i>5.1 (4.6 - 5.4)</i>	<i>&lt; 0.001</i>
Weight based RBV	17 (61%)	8 (40%)	0.157
HAART			
3x / 4x NUC	4 (14%)	2 (10%)	0.658
AZT	11 (39%)	5 (25%)	0.301
d4T	5 (18%)	3 (15%)	0.793
ABC	11 (39%)	4 (20%)	0.155
TDF	12 (43%)	11 (55%)	0.406
CD4 (/μl)	524 (361 - 655)	459 (364 - 566)	0.341

# Conclusions

- **High sustained virological response rates were achieved**
  - comparable to HIV-negative patients
- **NUC-free HAART was associated with higher SVR-rates compared to NUC-containing regimen**
  - selection bias cannot be ruled out
- **Lower HCV-RNA and HCV genotypes 2 and 3 were associated with higher SVR rates**

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