

THE USE OF DUAL THERAPY (DT) WITHOUT PRIOR RESISTANCE TESTING MAY BE AN ALTERNATIVE IN SETTINGS WHERE ACCESS IS DIFFICULT. MORE INFORMATION WITH THE DESIGN OF CONTROLLED CLINICAL TRIALS SHOULD BE CARRIED OUT IN OUR SETTING

AUTHORS

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PARTNERSHIPS

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BACKGROUND

Dual therapy with DTG + 3TC is an option for switching ART in PLWH with undetectable viral load (uVL) and without known mutations associated with resistance to 3TC or DTG. However, access to resistance testing is limited or unavailable in low-resource settings

OBJECTIVE

To analyze the time to virologic failure using Dual Therapy (DT) without prior genotypic resistance testing

MATERIALS AND METHODS

An open prospective cohort study of People living with HIV (PLWHIV) with undetectable Viral Load (uVL) and DT prescription without prior resistance test was performed between **5/2021** and **12/ 2023** from Muñiz Hospital (Argentina).

Demographic and clinical characteristics:

- sex,
- age at diagnosis,
- type of previous ART,
- CD4 previous and post DT,
- VL during follow-up and time between diagnosis and DT prescription

Statistical analysis:

- Categorical data resumed by percentage
- Numeric data by mean and SD or median and IQR, and Spearman rho; $p=0.05$.
- Mc Nemar test, were compared Pre- and post-DT VL.
- Survival analysis was performed with detectable VL (dVL) as failure and compared with log rank test according to previous ARVs.

RESULTS/ANALYSIS

- Patients Number=98 PLWH uVL, 100% with previous exposure to 3TC or FTC. Females 41 (42,3%), males 56 (57,7%).

Table 1 shows baseline characteristics of the cohort.

Figure 1 shows the survival analyses. 92 PLWHIV were follow-up 2415 months. Incidence Density: 0.00083 detectable dVL/month

Graph 1: Survival analysis. Model Failure: Detectable Viral Load; follow up in months.

Overall (1.A) and previous ART: integrase inhibitors (INSTI) (1.B), non-nucleoside inhibitors (NNRTI) (1.C) and protease inhibitors (PI) (1.D).

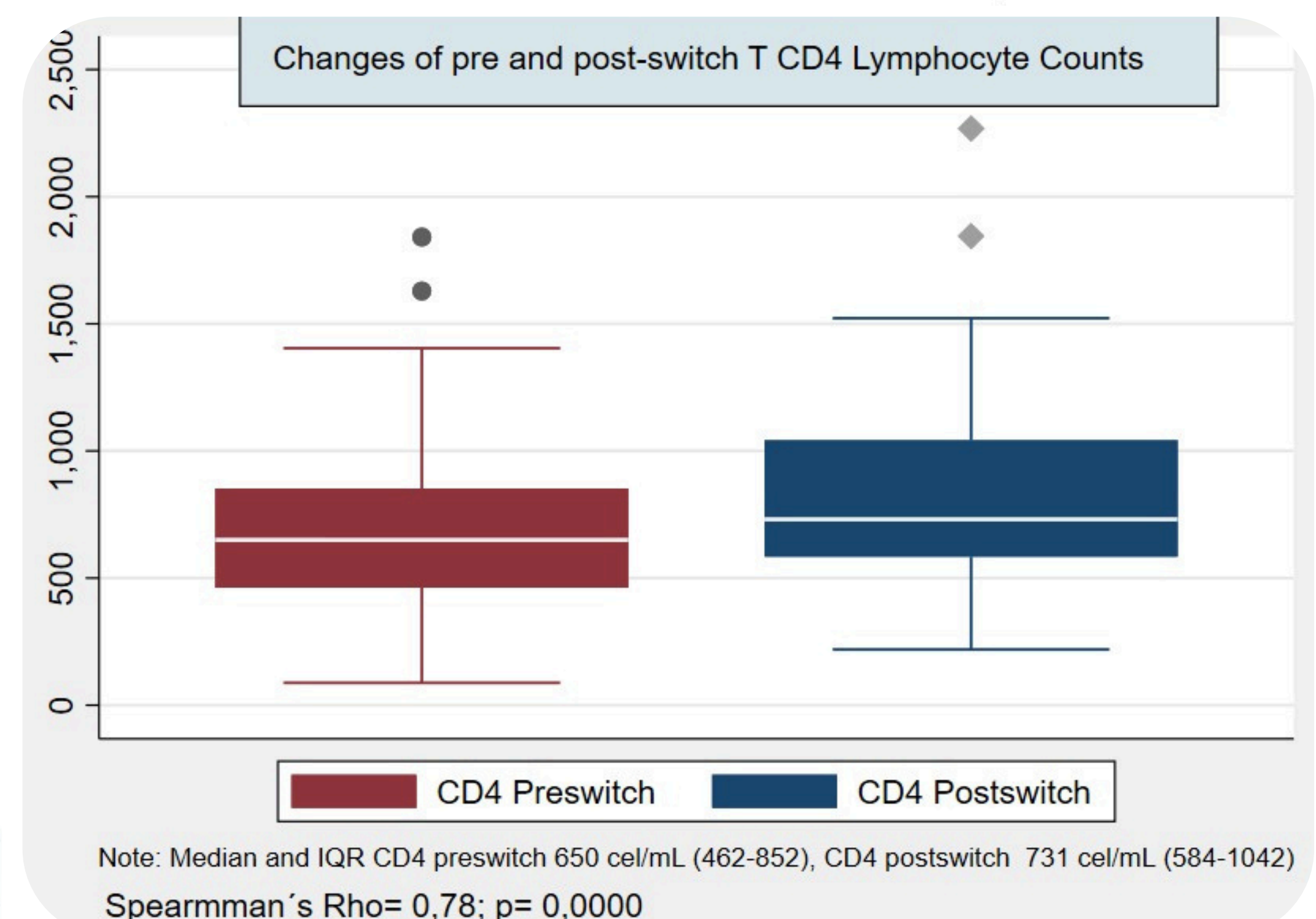
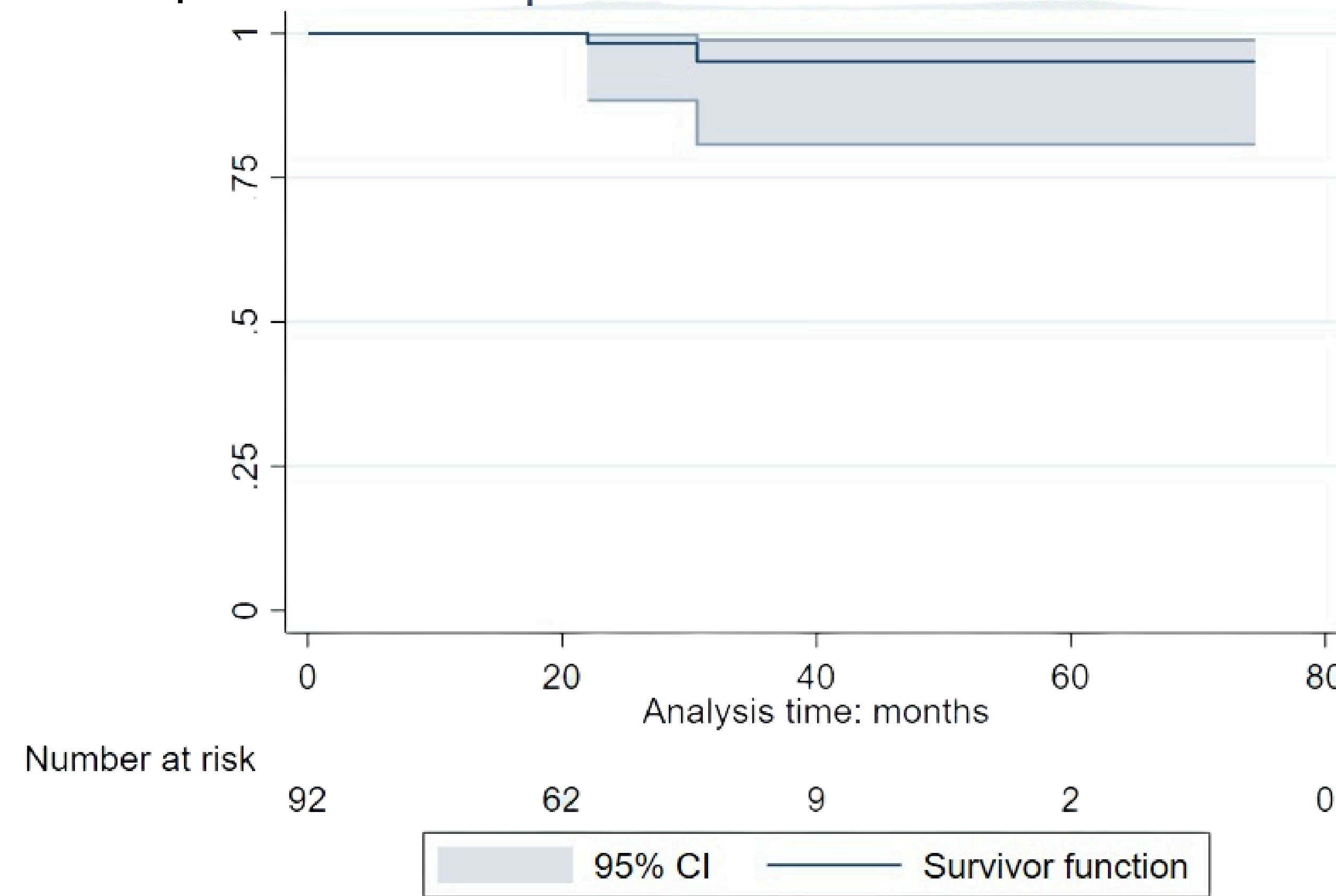
- UVL pre switch 100% and uVL post switch 96.7 %, Mc Nemar test = $3 p=0.083$, indicating that there is no difference between the proportion of PLWH with uVL before and after switch. Of the 3/93 dVL post switch , 2 PLWH VL= 51 and 43 copies and one PLWH with 373 copies/mL with and INSTI Resistance study in progress. CD4 pre switch 637 cel/mL (IQR: 462.5-818.5), CD4 post switch 755 cel/mL (IQR: 583-1029), Spearman rho :0.78 $p=0.000$

Table 1: Characteristics of the participants at baseline

Age at diagnosis (Mean and Standard Deviation)	36,6 (10,6)
Years between diagnosis and 3TC DTG (Median and IQR)	9,9 (RIC:4.8-14.8)
Pre-TARV with INSTI	63 (63,6)
Pre-TARV with INNRTI	19 (19,1)
Pre-TARV with booted IP	15 (15,1)
Undetectable Viral Load pre- dual therapy	100%
Undetectable Viral Load post-dual therapy	96,77%

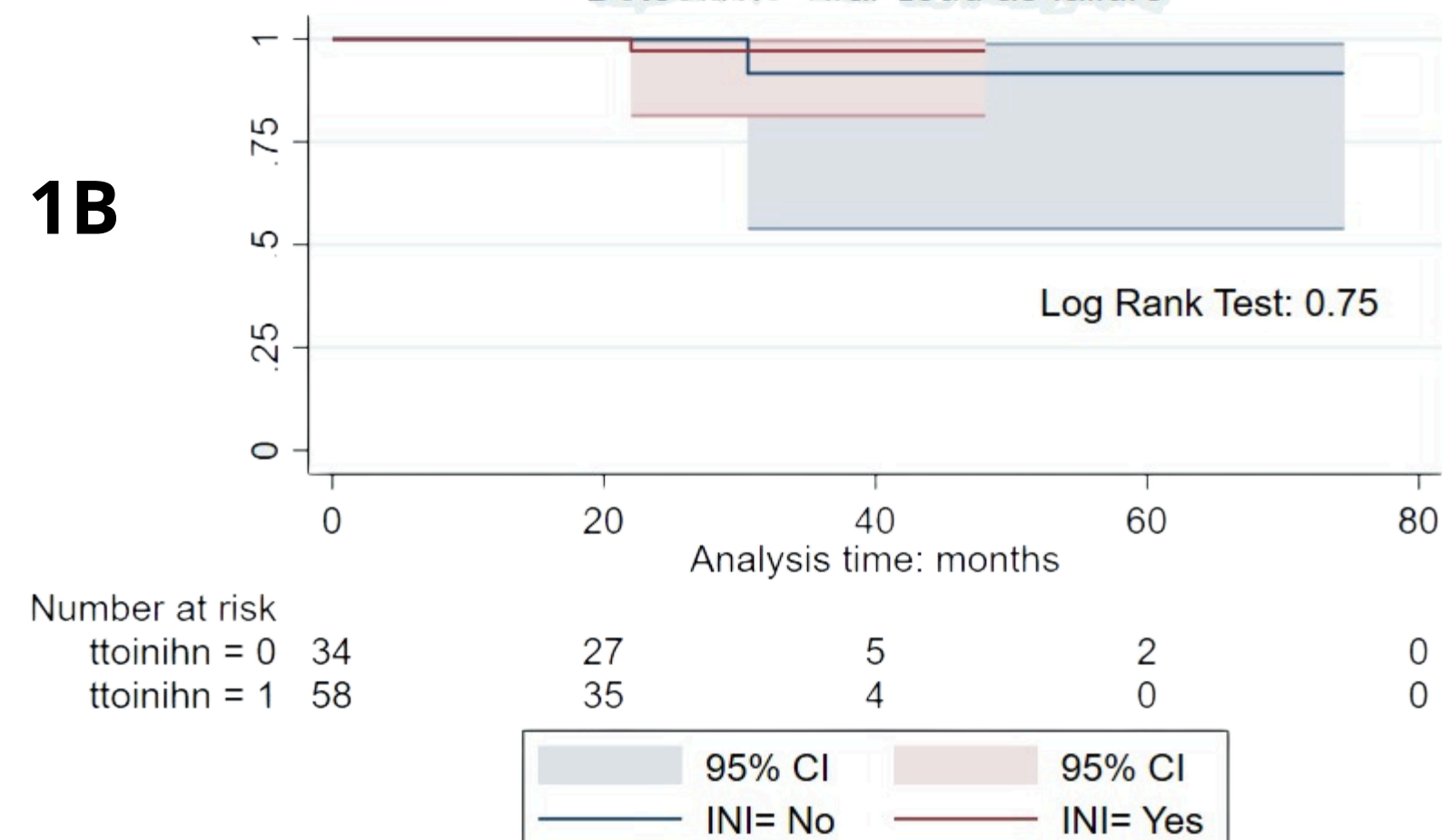
IQR: Interquartile Range - Undetectable Viral Load: <40 copies

Graph 1A Kaplan–Meier survival estimate



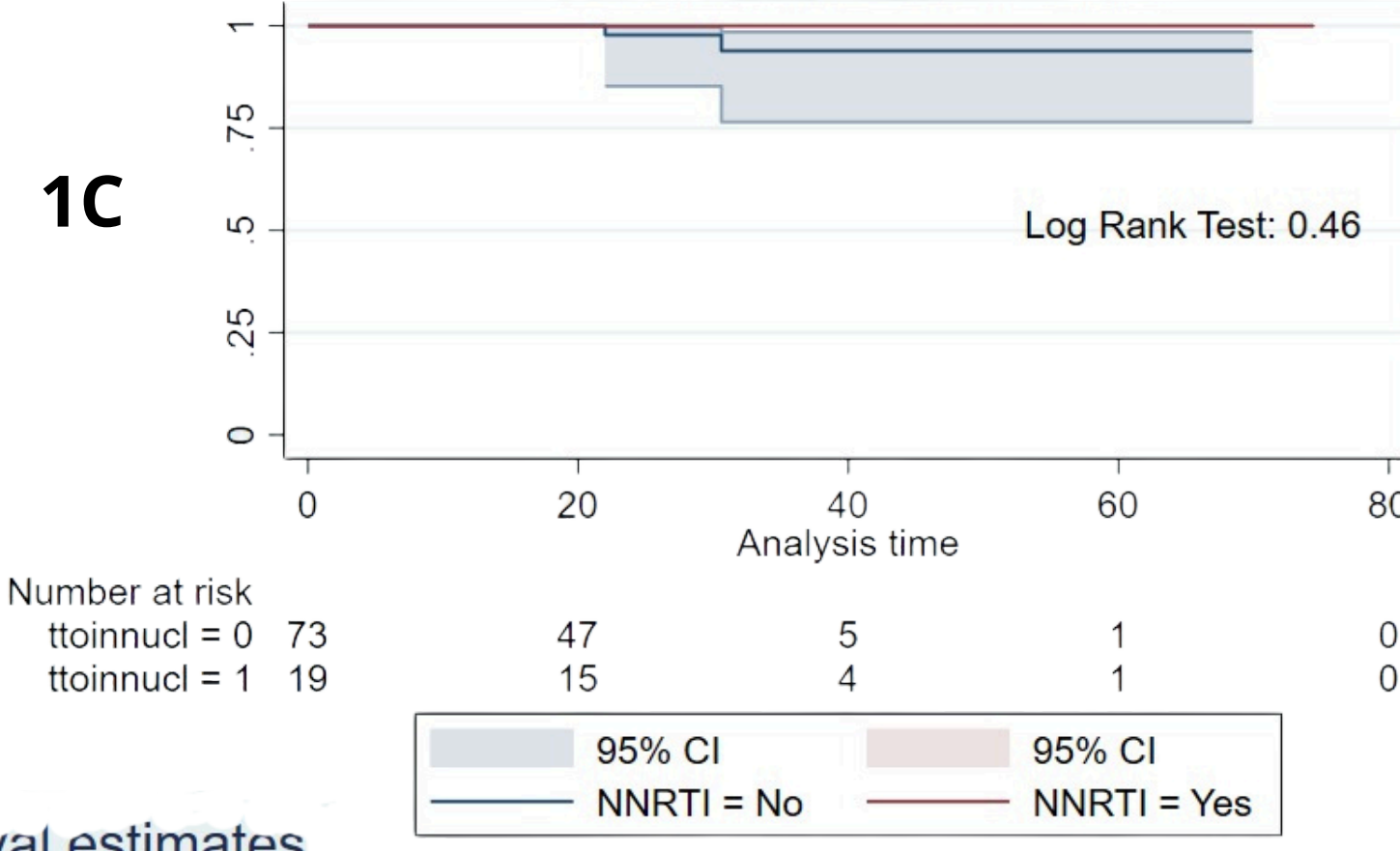
1B

Kaplan–Meier survival estimates
Detectable Viral Load as failure



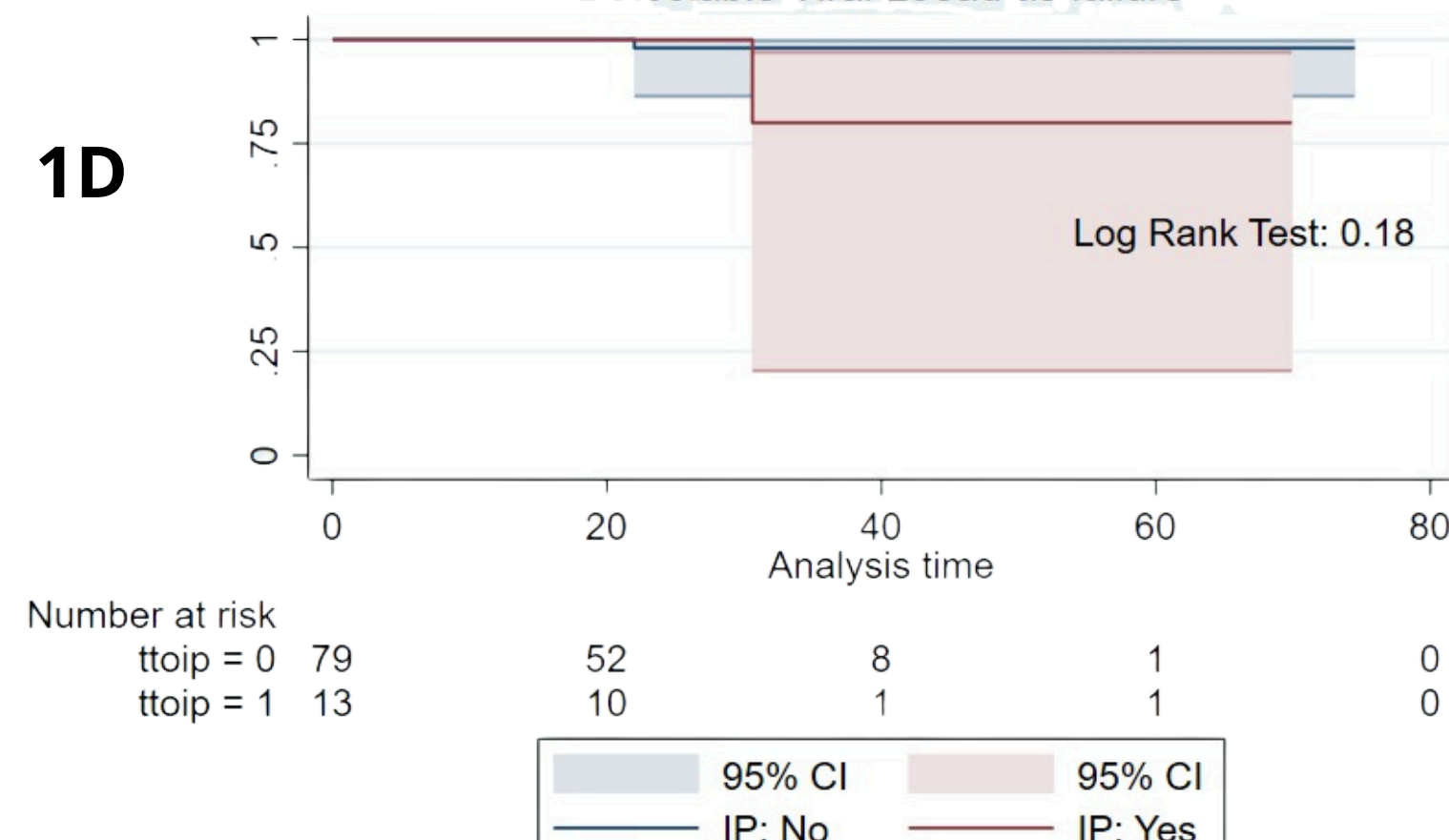
1C

Kaplan–Meier survival estimates
Detectable Viral Load as failure

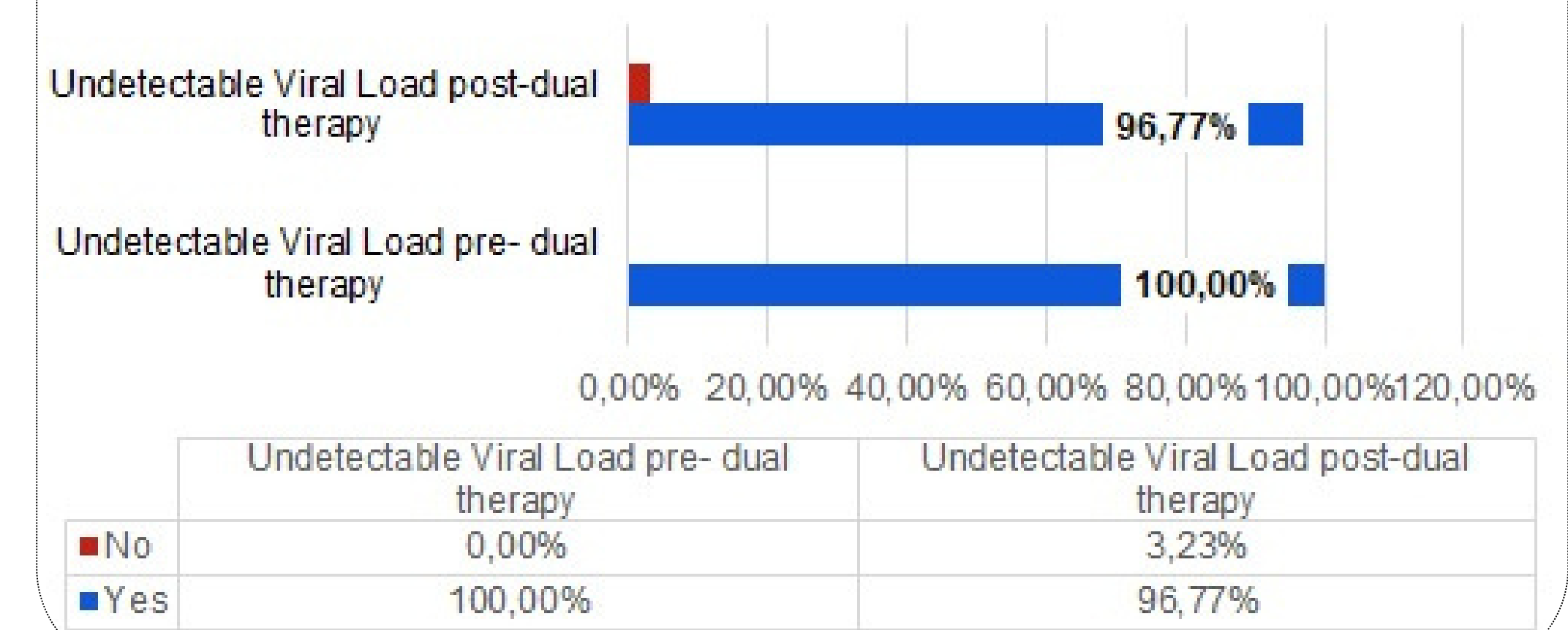


1D

Kaplan–Meier survival estimates
Detectable Viral Load as failure



Comparison of undetectable viral load results pre- and post-Dual therapy. Mc Nemar test=3.0 p=0.083



CONCLUSIONS

The use of DTG +3TC without prior resistance testing could be an alternative for switching in suppressed PLWH without previous history of treatment failure in settings where access to RT is difficult. Data from controlled clinical trials is needed to further support this strategy.

1) Cahn P, Sierra Madero J, Arribas JR, et al. Durable efficacy of dolutegravir (DTG) plus lamivudine (3TC) in antiretroviral treatment-naïve adults with HIV-1 infection—48-week results from the GEMINI studies. J Acquir Immune Defic Syndr. 2019; 81(3):310-318. doi:10.1097/QAI.0000000000002050.
2) Libre JM, Hung C-C, Brinson C, et al. Efficacy, safety, and tolerability of dolutegravir-ripirovirine for the maintenance of virological suppression in adults with HIV-1: phase 3, randomised, non-inferiority SWORD-1 and SWORD-2 studies. Lancet. 2018; 391(10123):839-849. doi:10.1016/S0140-6736(17)33095-7.
3) Hill A, Waters L, Pozniak A. Are new antiretroviral treatments increasing the risks of clinical obesity? HIV Med. 2020; 21(6):339-342. doi:10.1111/hiv.12852.