Nº: CPC070

VIROLOGICAL RESPONSE AT 24 WEEKS AND SAFETY OF DARUNAVIR/RITONAVIR IN HIV INFECTED PATIENTS

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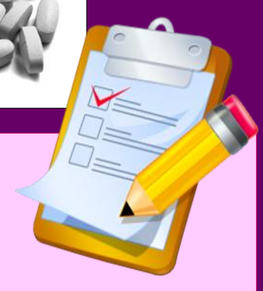
BACKGROUND

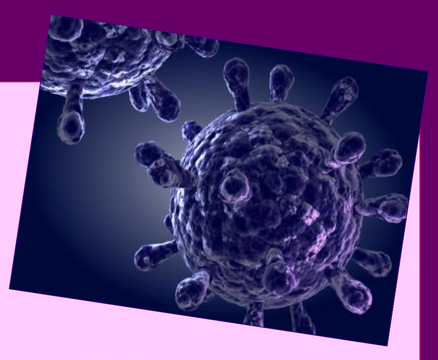
The effectiveness of darunavir boosted with ritonavir (DRV/r) has not been deeply investigated in routine clinical practice.

PURPOSE

To evaluate the effectiveness and safety of treatment with DRV/r combined with an optimised antiretroviral regimen at week 24.



MATERIAL AND METHOD



- **A retrospective study was performed in non-naive HIV-1-infected patients who started DRV/r from January-2008 to September-2011.**
- **The following parameters were evaluated: plasma HIV-RNA (viral load-VL, copies/ml) and CD4+ T-cell counts, Child-Pugh-stage and plasma ALT/AST. They were taken at baseline and week 24.**

Primary endpoints:

i) ***Effectiveness*: %patients with VL<50copies/ml at week 24.**

ii) ***Safety*: discontinued therapy due to intolerance or toxicity.**

Secondary endpoints:

i) ***Effectiveness*: CD4 cell increase after week 24.**

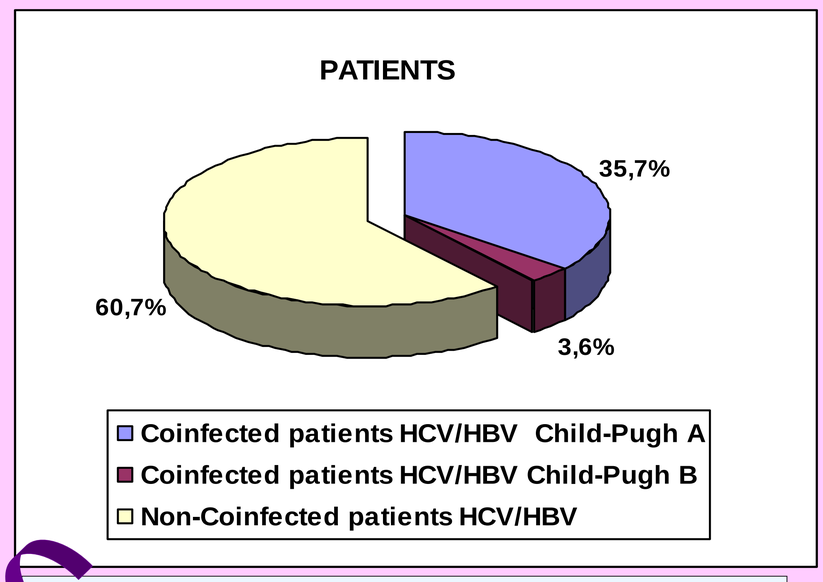
ii) ***Safety*: hepatotoxicity [ALT/AST concentrations (UI/L)>5N (55/41) in HCV/HBV non-coinfected and >3.5 from baseline in coinfected at week 24].**

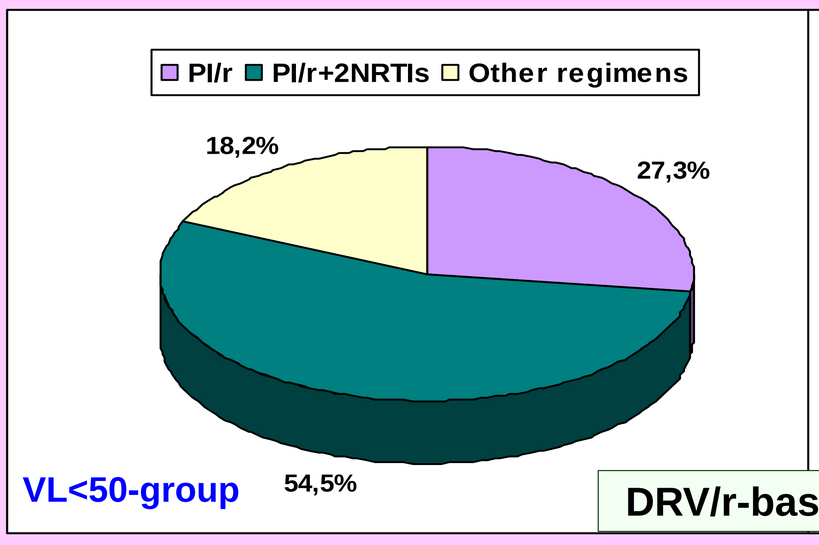
RESULTS

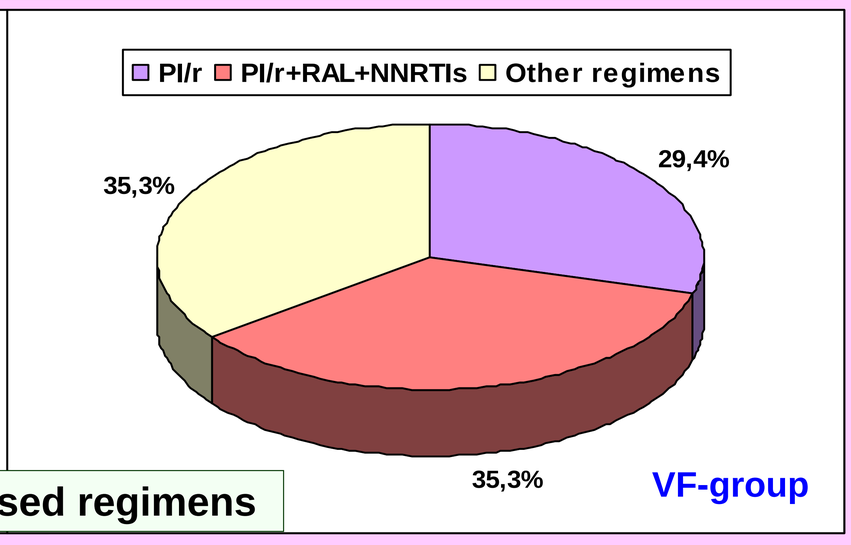
Thirty patients were enrolled in the study, of whom 28 achieved at least the week 24 of treatment.

For the effectiveness analysis they were grouped according to their baseline VL

			HIV-stage (%)				DRV/r treatment reasons (%)			
	Age (years)	*Sex (% Female)*	*A*	*B*	*C*	*Median CD4 (cell/mm³)*	*Virolgic failure (VF)*	*AEs*	*Simplification Therapy*	*Resistance Testing (PIs) (%)*
VL<50-group (n=11)	41.7 (95%CI:37.1-46.3)	54.5	54.5	9.1	36.4	527 (IQR:441-792)	0	72.7	27.3	18 (negative)
VF-group (VL>50) (n=17)	50.5 (95%CI:45.6-55.4)	29.4	11.8	23.5	64.7	205 (IQR:137-475)	100	0	0	88.2 (13.3% positive, none DRV mutation)







DRV/r-based regimens

Coinfected: median ALT/AST
ALT=125 (IQR: 48-170)/AST=113(IQR: 55-136)

Non-coinfected: median ALT/AST
ALT= 20 (IQR: 12-24)/AST= 20 (IQR: 17.5-24.5)

Variation of CD4 medians:

- **VL<50-group: -16cell/mm³ (95%CI: -88-102)**
- **VF-group: 50cell/mm³ (95%CI: 33-179)**

EFFECTIVENESS

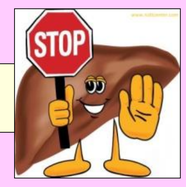
Response to treatment at W24:

- **81.8% patients in VL<50-group**
- **47% patients in VF-group**

SAFETY

6.6% (n=30) patients interrupted DRV therapy because of adverse events

No episodes of hepatotoxicity



CONCLUSION

- **In routine clinical practice, rescue DRV/r-containing regimens are well tolerated and achieve rates of virological suppression similar to those observed in pivotal clinical trials.**
- **DRV based HAART was well tolerated in HIV non-coinfected and coinfected patients with mild and moderate hepatic impairment.**