The VMVN Study:
Virological Monitoring in Vietnam

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Health Advancement in Vietnam

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Background

- Routine VL (RVL) monitoring is recommended for patients on ART.
- Randomized clinical trials (in Uganda, Zambia, and Thailand) failed to demonstrate a benefit of VL monitoring in clinical outcomes
- We conducted a clinical trial of RVL monitoring vs Targeted VL monitoring in a patient population starting ART in Vietnam.
- **Hypothesis:** RVL monitoring would result in higher rates of virological suppression and decreased incidence of death or new or recurrent AIDS-defining illnesses within 3 years

Estill J,. PLoS One. 2013; 8:e57611; Kimmel AD, J Acquir Immune Defic Syndr 54: 258–268; Keiser O. AIDS 25: 1761–1769; Saag MS. 19th CROI. Seattle, WA, USA, 5–8 March 2012; Jourdain G. PLoS Med. 2013; Mermin J. BMJ, 2011, 343:d6792.; Okoboi S. BMC Public Health (2016) 16:101.

Methods

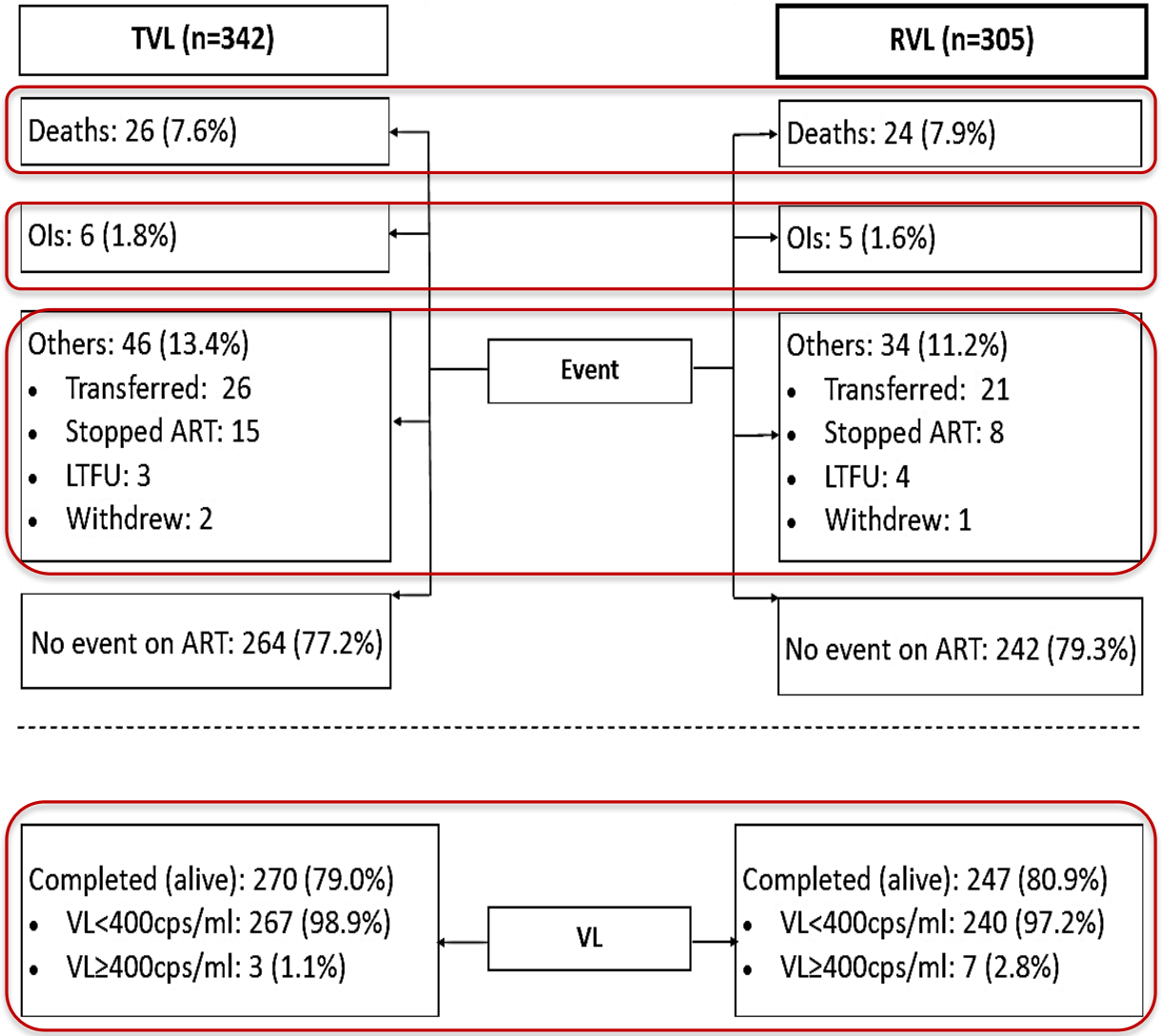
- Prospective, randomized controlled trial of RVL monitoring every 6 months versus standard targeted VL (TVL, VL testing to confirm suspected treatment failure) in patients starting ART between 4/2011 and 4/2014.
- 647 subjects initiating ART were randomized to either RVL monitoring (n=305) or TVL monitoring (n=342) and followed for 3 years.
- Both arms were management according to national guidelines; only difference was VL monitoring
- Primary endpoints were death or WHO clinical stage IV events after 6 months of ART and rate of virological suppression at 3 years.
- Proportions were calculated and compared using Chi-squared test or Fisher's exact test.
- Survival analysis was used to compare time to occurrence of death or stage IV event between two groups.

Results (1)

Select Baseline Characteristics

	Intervention N (%)	Control N (%)	P-value
Total	305 (47.1%)	342 (52.9%)	
Male Gender	190 (62.3%)	217 (63.4%)	0.761
Mean Age	34.9 +/- 8.0	35.2 +/- 9.3	0.622
Clinical Stage			
I	134 (44.0%)	166 (48.5%)	0.415
II	26 (8.5%)	22 (6.4%)	
III	37 (12.1%)	32 (9.4%)	
IV	108 (35.4%)	122 (35.7%)	
CD4 at enrollment			
< 100	140 (45.9%)	161 (47.1%)	0.490
101 - 250	73 (23.9%)	69 (20.2%)	
> 250	92 (30.2%)	112 (32.7%)	
Prior ART	10 (3.3%)	16 (4.7%)	0.366

Study Outcomes Summary



Results (2)

- Among patients on ART at 6-mo, death or stage IV event occurred in 3.6% of RVL and 3.9% of TVL (p=0.823).
- Survival analysis showed no significant difference between the two groups (p=0.825).
- 44% of study events (death, lost to follow up, withdrawal, or new or recurrent stage IV event) and 68% of deaths occurred within the first 6-months of ART.
- There was no difference in switching to 2nd-line ART (3.6% in RVL; 2.1% in TVL, p=.228).
- Trends of CD4 recovery were similar in both arms.

Proportion of patients with VL <400 cps/ml or < 1,000 cps/ml) at 36 months (n=517)			
		Intervention N (%)	Control N (%)
Total	Cut off (cps/ml)	247 (100%)	270 (100%)
1,000 cps/ml (p=0.488)	<1,000	242 (98.0%)	267 (98.9%)
	≥ 1,000	5 (2.0%)	3 (1.1%)
400 cps/ml (p=0.206)	<400	240 (97.2%)	267 (98.9%)
	≥400	7 (2.8%)	3 (1.1%)
ITT Analysis* 400 cps/ml (p=0.849)	<400	240 (78.7%)	267 (78.1%)
	≥400	65 (21.3%)	75 (21.9%)

*** ITT Analysis: Those without a VL at 36 mo of ART (deaths, LTFU) were assigned as non VL suppression**

Conclusions

- RVL monitoring every 6 months did not improve clinical outcomes compared to a TVL strategy after 3 years of follow-up.
- We found no difference in death, stage IV events, virological failure, CD4 recovery, or 2nd line switching in patients with RVL monitoring compared to those monitored with a TVL strategy.
- Most deaths occurred within the first 6-months of ART suggesting that earlier HIV diagnosis, use of enhanced OI prophylaxis, and rapid initiation of ART may be needed to improve treatment outcomes in this group.
- Overall, there were high rates of viral suppression and relatively few adverse outcomes among patients alive and on ART after 6 months.
- These data suggest that the VL monitoring strategy may have less impact on patient outcomes compared to efforts to reduce early mortality and improve ART retention.