Contemporary management of HIV: Update on antiretroviral therapy

Short-course of Infectious Disease of the Year 2017
March 16, 2017

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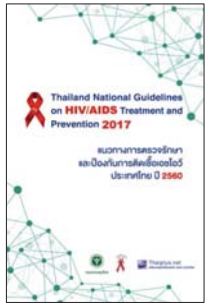
Outline

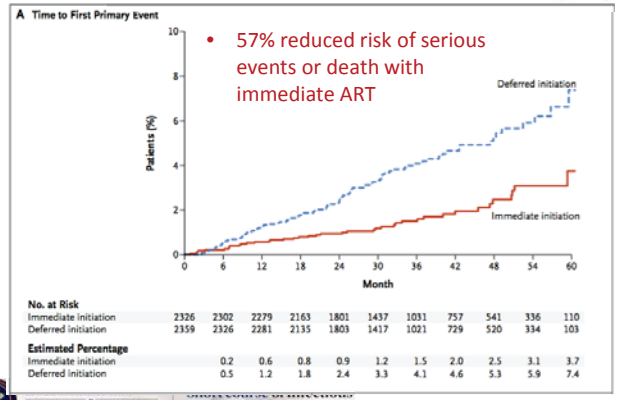
- When and what to start antiretroviral therapy (ART)
- ART in Thailand National Guideline on HIV/AIDS 2017
- What are the new ART in Thailand 2017
- Management in 1st line ART failure
- Case discussion



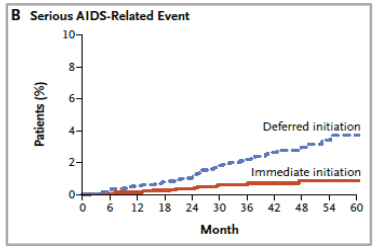
When to start

Initiation of Antiretroviral Therapy in Early Asymptomatic HIV Infection

The INSIGHT START Study Group*



- 57% reduced risk of serious events or death with immediate ART



- 72% reduced risk of serious AIDS events with immediate ART
- SAE: TB, Kaposi's sarcoma, Malignant lymphoma

N Engl J Med 2015; 373:795

When to start

- Thailand National Guideline on HIV/AIDS Treatment and Prevention 2017

เกณฑ์การเริ่มยาต้านเอชไอวีในประเทศไทย

- ให้ยาต้านเอชไอวีในผู้ติดเชื้อทุกรายในทุกจำนวน CD4

ควรพิจารณาประเด็นต่อไปนี้ร่วมด้วย

- ผู้ติดเชื้อที่จะเริ่มยาต้านเอชไอวีต้องเข้าใจถึงประโยชน์และผลข้างเคียงของการรักษา เข้าใจประเด็นความสำคัญของ Adherence ยินดีที่จะเริ่มยาต้านเอชไอวี และมีความมุ่งมั่นตั้งใจรับยาต้านเอชไอวีอย่างสม่ำเสมอตลอดชีวิต

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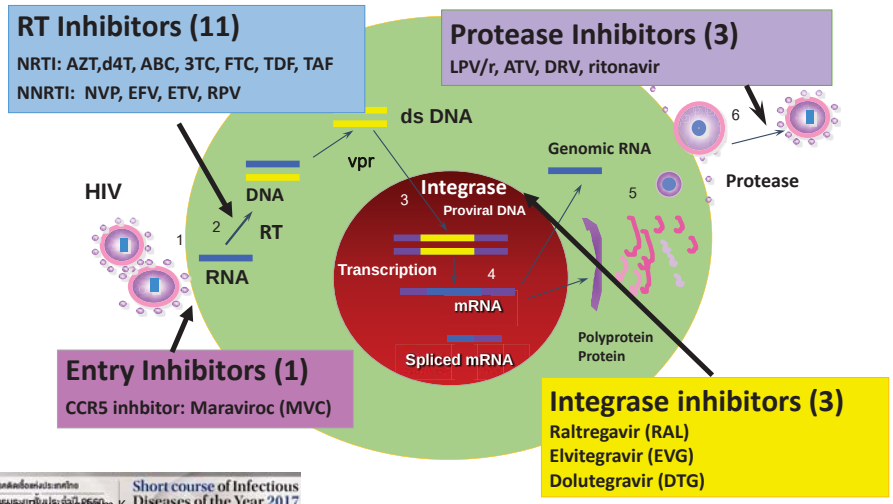
What to start



Modified from Ruxrungtham K.

Options	Class	DHHS (2016)	IAS-USA(2016)	EACS (2016)	WHO (2016)
Preferred	INSTI	▪ DTG/ABC/3TC* ▪ DTG + TDF/FTC or TAF/FTC ▪ EVG/c/TDF/FTC or EVG/c/TAF/FTC ▪ RAL + TDF/FTC or TAF/FTC	▪ DTG + ABC/3TC ▪ DTG + TDF/FTC ▪ EVG/COBI/TDF/FTC ▪ RAL + TDF/FTC	▪ DTG/ABC/3TC ▪ DTG + TDF/FTC or TAF/FTC ▪ EVG/COBI/TAF(TDF)/FTC ▪ RAL + TAF/FTC or TDF/FTC	▪ TDF + 3TC (or FTC) + EFV
	Boosted PI	▪ DRV/r + TDF/FTC or TAF/FTC		▪ DRV/r or DRV/c + TAF/FTC or TDF/FTC	
Alternative	NNRTI	▪ EFV/TDF/FTC ▪ EFV + TAF/FTC ▪ RPV*/TAF(TDF)/FTC ▪ ATV/c or ATV/r+ TAF/FTC orTDF/FTC ▪ DRV/c or DRV/r + TAF/FTC orTDF/FTC or ABC/3TC	▪ DRV/r+ + TDF/FTC or TAF/FTC or ABC/3TC ▪ EFV/TDF/FTC ▪ RPV/TAF or TDF/FTC	▪ RPV/TAF(TDF)/FTC Only if CD4 count > 200 cells/µL and HIV-VL < 100,000 copies/mL	▪ AZT + 3TC + EFV (or NVP) ▪ TDF + 3TC (or FTC) + DTG ▪ TDF + 3TC (or FTC) + EFV400 ▪ TDF + 3TC (or FTC) + NVP

*Test for HLA-B*5701 negative

First-line ART regimens for adults : Thailand National Guideline 2017

NRTIs backbone		NNRTIs		ยาตัวที่สามอื่น ๆ
แนะนำ		แนะนำ		แนะนำ
TDF/FTC TDF + 3TC[1]		EFV หรือ RPV[2]		LPV/r
หรือทางเลือก		หรือ		หรือ
ABC + 3TC AZT + 3TC	+	NVP	+ ในกรณีที่ผู้ป่วยไม่สามารถกินยา NNRTIs ได้	ATV/r
				หรือทางเลือก
				ยากลุ่ม INSTI • RAL หรือ • EVG/c/TDF/FTC[3] หรือ • DTG[4]

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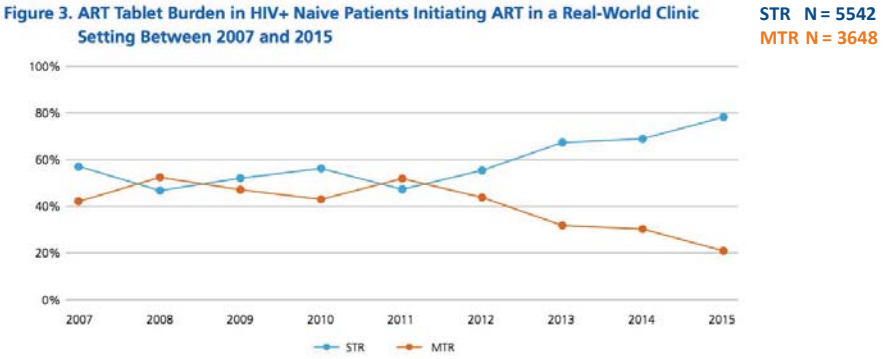
Single-Tablet vs Multitablet ART Regimen Use in Tx-Naive HIV+ Pts



- Treatment-naïve patients initiating on an STR were more likely to achieve viral suppression and less likely to experience virologic rebound than patients initiating on a MTR.

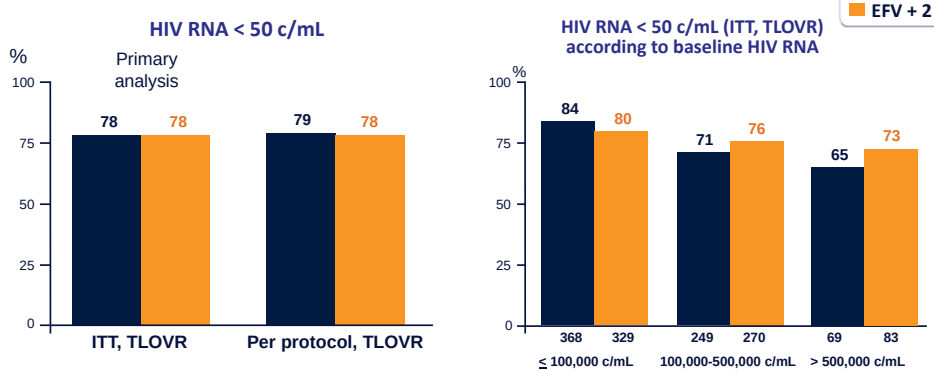
Mills A, et al. ID Week 2016. Abstract 1512.

What are the new ART in Thailand National Guideline 2017

Characteristics	Rilpivirine (Endurant®)
ARV Class	Second-generation Non-nucleoside Reverse Transcriptase Inhibitors (NNRTI)
Dose	Film-coated tablets 25 mg with meal (500 Kcal)
Metabolism	Cytochrome P450 (CYP)3A Decrease RPV : omeprazole, rifampicin
Adverse effects	• Skin and Hypersensitivity Reactions • Depressive disorders • Hepatotoxicity • Mild increase serum creatinine but eGFR not reduction

ECHO & THRIVE Study: W96 results

Response to treatment at week 96



* TDF/FTC = 80%, ZDV/3TC = 15%, ABC/3TC = 5%

Cohen CJ. AIDS 2013;27:939-50

ECHO & THRIVE Study: W96 results

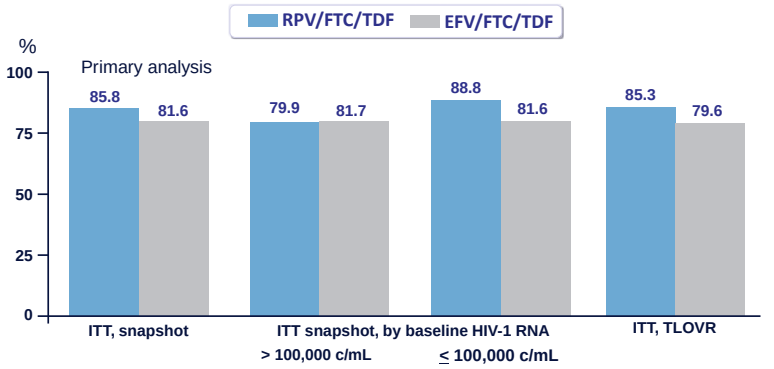
Adverse events and treatment-emergent grade 2-4 laboratory abnormalities

	RPV + 2 NRTI	EFV + 2 NRTI	P
Treatment-related adverse event of grade ≥ 2	116 (17%)	226 (33%)	< 0.0001
AE leading to permanent discontinuation	28 (4%)	58 (9%)	-
Serious AE	65 (9%)	71 (10%)	-
Treatment-related AE of grade ≥ 2 in ≥ 10% in either group			
Any neurologic AE	119 (17%)	259 (38%)	< 0.0001
Dizziness	55 (8%)	182 (27%)	< 0.0001
Any psychiatric AE	107 (16%)	166 (24%)	< 0.0001
Abnormal dreams or nightmares	57 (8%)	90 (13%)	0.003
Rash	29 (4%)	103 (15%)	< 0.0001
Any grade 2-4 laboratory abnormality	317 (46%)	395 (58%)	
LDL-cholesterol	7%	18%	
Total cholesterol	7%	22%	
AST / ALT	6% / 6%	10% / 11%	

Cohen CJ. AIDS 2013;27:939-50

StaR Study: RPV/FTC/TDF vs EFV/FTC/TDF

Response to treatment (HIV RNA < 50 c/mL) at week 48



Median CD4/mm^3 increase at W48: + 200 RPV/FTC/TDF vs + 191 EFV/FTC/TDF

Cohen C. AIDS 2014;28:989-97

First-line ART regimens for adults : Thailand National Guideline 2017

กรณีจะใช้ RPV ก่อนเริ่มยาควรมีการตรวจปริมาณ VL ก่อนเริ่มยาเสมอ	กรณีไม่ได้เริ่มยาต้านเอชไอวีมาก่อน • ถ้า VL > 500,000 copies/mL ไม่ควรใช้เนื่องจากจะมีความเสี่ยงต่อการเกิดการรักษาล้มเหลว • กรณีที่ไม่สามารถตรวจ VL ก่อนรักษาได้ อาจพิจารณาใช้ยานี้ในผู้ป่วยที่ CD4 > 350 cells/mm^3 กรณีเริ่มยาต้านเอชไอวีมาก่อน • กรณีต้องเปลี่ยนสูตรยาเป็น RPV เนื่องจากผลข้างเคียงของยาอื่นหรือปรับเปลี่ยนเพื่อสะดวกในการกินยา สามารถเปลี่ยนเป็นยา RPV ได้ แต่ต้องมี VL < 50 copies/mL อย่างน้อย 6 เดือน และไม่เคยดื้อยากลุ่ม NNRTIs มาก่อน

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First-line ART regimens for adults : Thailand National Guideline 2017

กรณีจะใช้ RPV ก่อนเริ่มยาควรมีการตรวจปริมาณ VL ก่อนเริ่มยาเสมอ	กรณีเริ่มยาต้านเอชไอวีมาก่อน • กรณีเพิ่งเริ่ม EFV และมี adherence ดีต่อ EFV ดี แต่มีผลข้างเคียงไม่สามารถกิน EFV ต่อได้ เช่น มีอาการข้างเคียงของระบบส่วนกลางหลังจากที่เริ่มยาได้ 2 สัปดาห์ สามารถเปลี่ยนเป็น RPV ได้ แม้ว่า VL ก่อนเริ่มยา > 500,000 copies/mL

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ECHO & THRIVE Study: RPV resistance data at W96

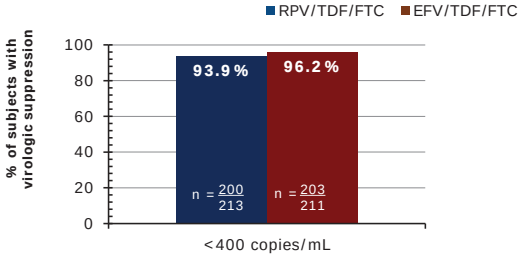
		RPV + 2 NRTI, N = 340	EFV + 2 NRTI, N = 682
Virologic failure		96 (14%)	52 (8%)
Rebounder		52	34
Never suppressed		44	18
Resistance data at time of failure		86	42
Emergent NNRTI mutations		46 (53%)	20 (48%)
Most frequent mutations	E138K K103N	31 -	- 14
Emergent NRTI mutations		48 (56%)	11 (26%)
Most frequent mutations	M184I M184V	32 -	- 6

- Virologic failure and treatment-emergent RT mutations were similar at low baseline viral load but more frequent at high baseline viral load in RPV-treated than in EFV-treated patients

Cohen CJ. AIDS 2013;27:939-50 ; Rimsky L. JAIDS 2012;59:39-46 ; Rimsky L. AntivirTher 2013;18:967-77

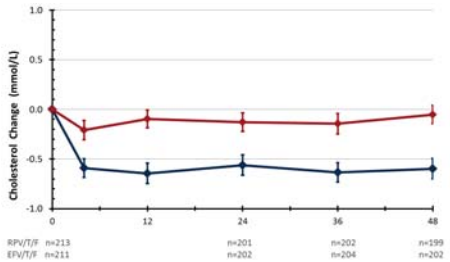
SALIF: Switch to RPV/TDF/FTC Noninferior to EFV/TDF/FTC in Virologically Suppressed Patients on First-line NNRTI-Based ART

Plasma HIV-1 RNA <400 copies/mL (FDA Snapshot) at Week 48; ITT



RPV/TDF/FTC is non-inferior to EFV/TDF/FTC

Lipids mean changes from baseline

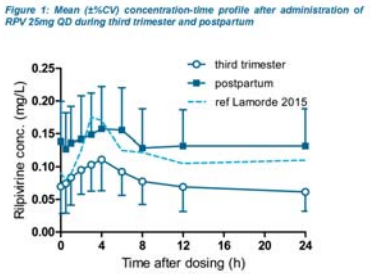


Lipid profile was improved in RPV/TDF/FTC

Wohlfeiler P, et al. SALIF trial. The 21st International AIDS Conference;2016; Durban, South Africa. Abstract THAB0104.

Precaution when switching to RPV

- RPV resistance is overall recognized in nearly 20% of patients failing other NNRTIs. It is more common following ETR (27.6%) or NVP (25%) failures than EFV (14.5%)[1]
- Limited data are available on rilpivirine during pharmacokinetics during pregnancy
  - RPV was about 50% lower in the third trimester of pregnancy [2]



1. Anta L, et al. AIDS. 2013;27(1):81-5, 2. Angela Colbers, et al. CROI 2017. Abstract 754

What are the new ART in Thailand National Guideline 2017

Characteristics	Abacavir (ZIagen®)
ARV Class	Nucleoside Reverse Transcriptase Inhibitors (NRTI)
Dose	• Film-coated tablets 300 mg • ABC 600 mg/3TC 300 mg (Kivexa®) • No dose adjustment in renal impairment • Contraindication : Child-Pugh score > 6
Metabolism	• Alcohol dehydrogenase (ADH) and uridine diphosphate glucuronosyltransferase (UGT)
Adverse effects	• Abacavir associated hypersensitivity Screening for the HLA-B*5701 is recommended before initiating therapy with abacavir

What are the new ART in Thailand National Guideline 2017

ถ้าไม่สามารถเริ่มยาต้านเอชไอวีตามสูตรแนะนำสูตรแรกได้ เนื่องจากมีข้อห้าม หรือทนยา TDF ไม่ได้	• ให้พิจารณา NRTIs ทางเลือกคือ ABC + 3TC หรือ AZT + 3TC แทน • โดยสูตรที่มี ABC นั้น ควรพิจารณาให้ในผู้ที่ก่อนเริ่มการรักษามีระดับ VL<100,000 copies/mL (ยกเว้นให้ร่วมกับ dolutegravir)

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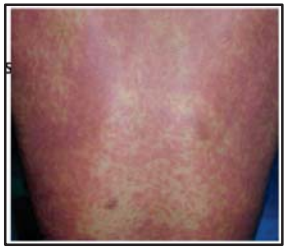
Abacavir associated hypersensitivity (HSR)

- Clinically suspected defined occurrences of 2 of the following symptoms within 6 weeks :
  - Fever (86%)
  - Rash (43%)
  - Gastrointestinal (43%)
  - Constitutional (57%)
  - Respiratory symptoms (29%)



Abacavir associated hypersensitivity (HSR)

- Prevalence of HLA-B*5701 allele
  - Asian : 0.3-3 %[1-2]
  - Caucasian : 5-8 %[3-5]
- If HLA-B*5701 testing not available : Advice patients to observe HSR
- Treatment : discontinue abacavir as soon as hypersensitivity reaction suspected
- Abacavir should not be restarted (more severe, life-threatening, hypotension, death)

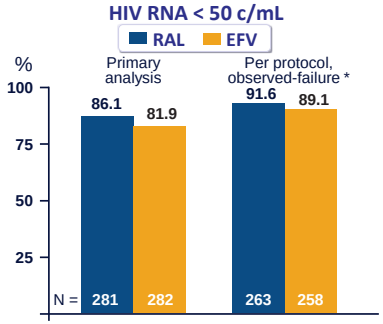
HIV, et al. J Antimicrob Chemother. 2007;60(3):599-604. 2.Baniasadi S, et al. Tanaffos. 2016;15(1):48-52. 3. Hetherington S, et al.Clin Ther. 2001;23(10):1603-14. 4.Lin C, et al. Pharmacogenet Genomics. 2010;20(5):307-14. 5.Jilich D, et al. Cent Eur J Public Health. 2011;19(3):128-30.

What are the new ART in Thailand

Characteristics	Raltegravir (Isentress®)
ARV Class	Integrase strand transfer inhibitors (INSTIs)
Dose	• Film-coated tablets 400 mg BID
Metabolism	• Uridine diphosphate glucuronosyltransferase (UGT) 1A
Adverse effects	• Nausea, dizziness, increase CPK

STARTMRK Study: raltegravir vs efavirenz, in combination with TDF/FTC

Response to treatment at week 48



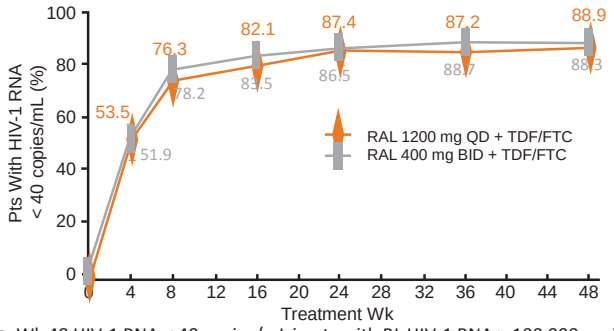
HIV RNA < 50 c/mL at W48 (observed-failure analysis) by baseline factors

Baseline	RAL	EFV
RNA ≤ 5 log_{10} c/mL	92.5%	89.1%
RNA > 5 log_{10} c/mL	90.9%	89.2%
CD4 > 200/mm³	94.4%	92.4%
CD4 ≤ 200/mm³	88.3%	85.6%
HIV-1 B subtype	90.3%	88.5%
Non-B subtype	96.3%	90.9%

Adverse event & discontinue drug : EFV > RAL

Lennox JL. Lancet 2009;374:796-806

ONCEMRK: RAL 1200 mg QD Noninferior to RAL 400 mg BID at Wk 48



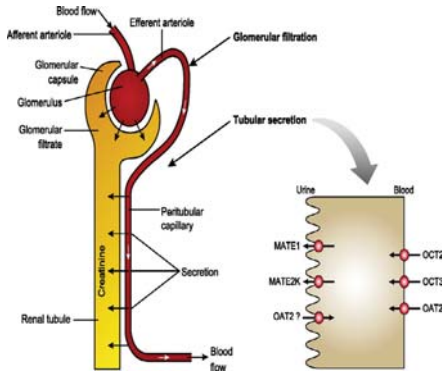
- Wk 48 HIV-1 RNA < 40 copies/mL in pts with BL HIV-1 RNA > 100,000 copies/mL: RAL QD, 86.7%; RAL BID, 83.8% (Δ 2.9; 95% CI: -6.5-14.1)
- RAL QD associated with overall safety profile similar to RAL BID

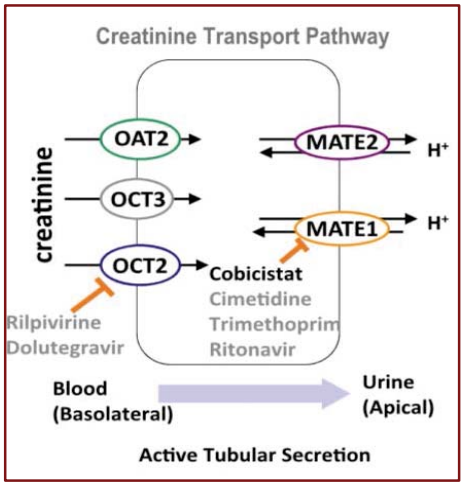
Cahn P, et al. AIDS 2016. Abstract FRAB0103LB.

What are the new ART in Thailand

Characteristics	Elvitegravir (EVG)
ARV Class	Integrase strand transfer inhibitors (INSTIs)
Dose	• Fix dose combination : EVG 150 mg./cobicistat (COBI) 150 mg./FTC 200 mg./TDF 300 mg. (Stribild®) with meal • Initiate CrCl > 70 mg/dl
Metabolism	• Cytochrome P450 (CYP)3A and UGT1A
Adverse effects	• Nausea, Diarrhea • Cobicistat => increased serum creatinine without actual change in GFR rate

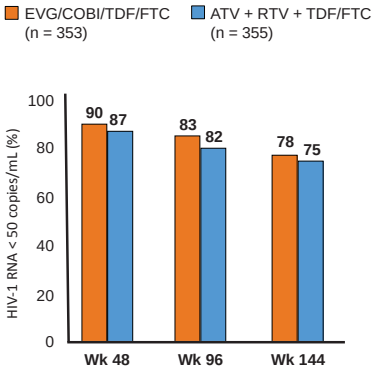
Cobicistat : Inhibition of tubular secretion of creatinine





Nathan B, et al. Infect Dis Ther. 2013

Study 103: EVG/COBI/TDF/FTC Noninferior to ATV + RTV + TDF/FTC Through Wk 144 ; ART naïve



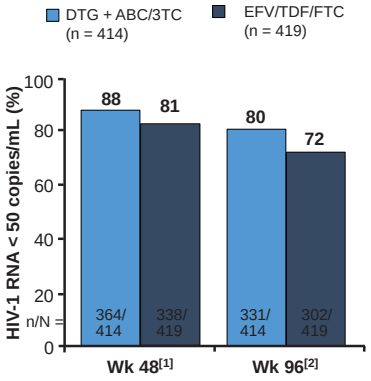
Outcomes at Wk 144[3]	EVG/COBI/ TDF/FTC	ATV + RTV + TDF/FTC
Treatment-related d/c, %	6	9
Virologic failure, %	8	7
Mean CD4+ cell count increase, cells/mm³	280	293

Clumeck N, et al. J Acquir Immune Defic Syndr. 2014;65:e121-124.

What are the new ART in Thailand

Characteristics	Dolutegravir (Tivicay®)
ARV Class	Second-generation Integrase strand transfer inhibitors (INSTIs)
Dose	Film-coated tablets 50 mg
Metabolism	UGT1A
Adverse effects	• Insomnia , Headache • Neuropsychiatric side effect

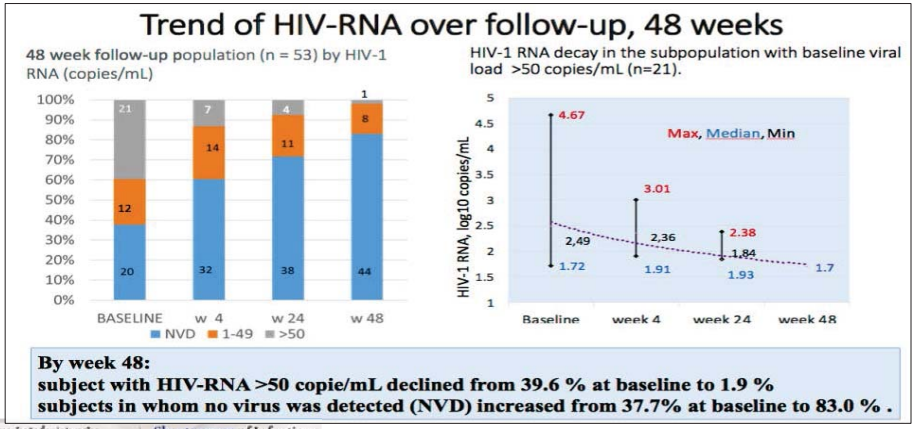
SINGLE: DTG + ABC/3TC Superior to EFV/TDF/FTC at Both Wk 48 and 96 ; ART naïve



- Treatment-related study discontinue
  - 3% in DTG vs 11% in EFV arm
- Virologic Failure at Wk 96: 25 (6%) in each arm
- CD4 increase at Wk 96
  - DTG: +325 vs EFV +281 cells/mm^3 (*P* = .004)
- Drug resistance
  - DTG : 0 pts
  - EFV : 1 pt with NRTI and 6 pts with NNRTI resistance

1. Walmsley S, et al. N Engl J Med. 2013;369:1807-1818. 2.Walmsley S, et al. CROI 2014. Abstract 543.

Dolutegravir plus Ritonavir-Boosted Darunavir in Highly cART-Experienced Subjects : Salvage regimens



Capetti AF, et al. Antivir Ther. 2016

Higher rates of neuropsychiatric adverse events leading to dolutegravir discontinuation in women and older patients

- Retrospective study HIV-positive pts (N = 1704) initiating INSTI
- Risk Factor for Neuropsychiatric-Associated Discontinuation :
  - Female, Age (> 60 yrs) , Abacavir concurrent initiation

Discontinuation Reason	Drug (Exposures)		
	Dolutegravir (n = 985)	Elvitegravir (n = 287)	Raltegravir (n = 678)
Neuropsychiatric AE,* n (%)	49 (5.0)	3 (1.0)	14 (2.1)
▪ Insomnia/sleep disturbances	36 (3.7)	2 (0.7)	4 (0.6)
▪ Poor concentration/slow thinking	8 (0.8)	0 (0)	0 (0)
▪ Dizziness	13 (1.3)	1 (0.3)	3 (0.4)
▪ Headache/paresthesia	16 (1.6)	1 (0.3)	6 (0.9)
▪ Depression	7 (0.7)	0 (0)	1 (0.1)

Sabranski M, et al. HIV Glasgow 2016. Abstract O214.

Meal and Antiretroviral drugs

Take with meal (Increase absorbsion)	Take without meal (Decrease side effect)	Without regard to meals
• Rilpivirine • Elvitegravir/ cobi • Atazanavir • Darunavir	• Efavirenz	• Dolutegravir • Raltegravir • Lopinavir
		

Management in Virologic Failure to 1st line treatment

- Virologic failure
  - The inability to achieve or maintain suppression of viral replication to an HIV RNA level <200 copies/mL after 6 mo of treatment
- Assessment
  - Adherence : Side effect
  - Review treatment history, prior and current drug-resistance testing results
  - Drug interaction
  - Drug-resistance testing should be performed while the patient is taking the failing antiretroviral regimen

Management in Virologic Failure to 1st line treatment

ยาสูตรแรก	Mutation ที่คาดว่าน่าจะเกิดขึ้น	ยาสูตรที่สองที่แนะนำ
NNRTIs + NRTIs	• NNRTIs-associated mutation (EFV, NVP) ± M184I/V ± NRTIs mutation • กรณีที่ใช้ RPV อาจตรวจพบ E138K ± M184I/V ± NRTIs mutation	• กรณีที่ใช้ AZT เป็นยาสูตรแรก พิจารณาใช้ TDF + 3TC (FTC) + boosted PIs หรือ boosted PIs + INSTI (RAL หรือ DTG) • กรณีที่ใช้ TDF เป็นยาสูตรแรก พิจารณาใช้ AZT + 3TC (FTC) + boosted PIs หรือ boosted PIs + INSTI (RAL หรือ DTG)

Thailand national guidelines on HIV/AIDS treatment and prevention 2017

Case 1 : MSM with HIV infection

- A 35-yr-old male presents to clinic with a recent diagnosis of HIV infection, working as a flight attendant
- History of secondary syphilis S/P BPG last year
- Multiple anonymous sexual partners, MSM
- No history of IVDU
- CD4 = 750 cells/mm^3 ;HIV RNA = 150,000 copies/ml
- VDRL = non-reactive
- HBsAg, Anti-HCV = negative
- Cr = 0.6 mg/dL (eGFR 104 ml/min/1.73m^2)

Case 1 : MSM with HIV infection

Which ART regimen would you suggest?

A. TDF/FTC/EFV
B. TDF/FTC +RPV
C. ABC/3TC/DTG (if HLA_B*5701=negative)
D. TDF/FTC/EVG/c
E. TDF/FTC + DRV/r

- CD4 = 750 cells/mm^3
- HIV RNA = 150,000 copies/ml
- Cr = 0.6 mg/dL (eGFR 104 ml/min/1.73m^2)

Case 1 : MSM with HIV infection

Which ART regimen would you suggest?

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- CD4 = 750 cells/mm^3
- HIV RNA = 150,000 copies/ml
- Cr = 0.6 mg/dL (eGFR 104 ml/min/1.73m^2)

He preferred one pill once daily regimen and no CNS side effect

Case 2: A man with DM, CKD, HTN, DLP and HIV infection

- A 50-yr-old man presented to clinic with diagnosis of HIV infection from pre-employment blood testing, ART naïve
- Medical history F/U at private hospital
  - DM type2 with DN,DR : Insulin 10-0-20 unit
  - Hyperlipidemia : atorvastatin 20 mg/day
  - Hypertension: enalapril 10 mg/day
- CD4 = 300 cells/mm^3, HIV-RNA = 30,100 copies/ml
- Cr 1.9 mg/dL (eGFR 40 ml/min/1.73m^2), FBS 119 mg/dL, LDL 90 mg/dL
- HBsAg, Anti-HCV = negative
- Insomnia and depression due to self stigma

Case 2: A man with DM, CKD, HTN, DLP and HIV infection

Which ART regimen would you suggest?

A. TDF/FTC/EFV
B. TDF/FTC +RPV
C. ABC/3TC/EFV (if HLA_B*5701=negative)
D. ABC/3TC/RPV (if HLA_B*5701=negative)
E. TDF/FTC/EVG/c

- CD4 = 300 cells/mm^3
- HIV RNA = 30,100 copies/ml
- Cr = 1.9 mg/dL (eGFR 40 ml/min/1.73m^2)

Case 2: A man with DM, CKD, HTN, DLP and HIV infection

Which ART regimen would you suggest?

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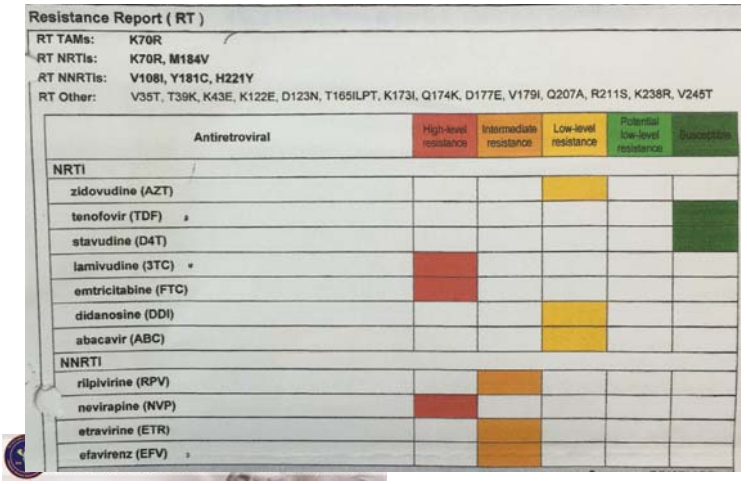
B. TDF/FTC +RPV
C. ABC/3TC/EFV (if HLA_B*5701=negative)
D. ABC/3TC/RPV (if HLA_B*5701=negative)
E. TDF/FTC/EVG/c

- CD4 = 300 cells/mm^3
- HIV RNA = 30,100 copies/ml
- Cr = 1.9 mg/dL (eGFR 40 ml/min/1.73m^2)

Case 3: A woman with 1st line ART failure

- A 50-yr-old HIV-positive woman presented at the clinic for routine visit
- She was diagnosed with HIV since 2013 baseline CD4 = 79 cells/mm^3 and started on a first line regimen of GPO VIR Z (AZT/3TC/NVP) since 2014
- She reported that she had poor adherence
- Current VL= 6,500 copies/ml; CD4 = 163 cells/mm^3

Case 3: A woman with 1st line ART failure



Resistance Report (RT)

RT TAMs: K70R
RT NRTIs: K70R, M184V
RT NNRTIs: V108I, Y181C, H221Y
RT Other: V35T, T39K, K43E, K122E, D123N, T165ILPT, K173I, Q174K, D177E, V179I, Q207A, R211S, K238R, V245T

Antiretroviral	High-level resistance	Intermediate resistance	Low-level resistance	Potential low-level resistance	Susceptible
NRTI					
zidovudine (AZT)			■		
tenofovir (TDF)					■
stavudine (D4T)					
lamivudine (3TC)	■				
emtricitabine (FTC)	■				
didanosine (DDI)			■		
abacavir (ABC)			■		
NNRTI					
rilpivirine (RPV)		■			
nevirapine (NVP)	■				
etravirine (ETR)		■			
efavirenz (EFV)		■			

Genotypic resistance:
RT NRTIs : K70R, M184V
RT NNRTIs : V108I,Y181C, H221Y
PI : No mutation
ETR score : 3.5

Case 3: A woman with 1st line ART failure

Which ART regimen would you recommend?

A. TDF/FTC + ETR
B. TDF/FTC+ Boosted PI
C. TDF/FTC/EVG/c
D. LPV/r + 3TC
E. DRV/r +DTG

Case 3: A woman with 1st line ART failure

Which ART regimen would you recommend?

A. TDF/FTC + ETR
B. TDF/FTC+ Boosted PI
C. TDF/FTC/EVG/c
D. LPV/r + 3TC
E. DRV/r +DTG

Questions