Olgular Eşliğinde ART Seçimi

GENVOYA Tek Tablet Rejimi

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Enfeksiyon Hastalıkları ve Klinik Mikrobiyoloji

Olgu 1

- 30 y, erkek, lise mezunu, kuaför
- MSM (çok sayıda cinsel partneri var)
- Kendi isteğiyle test yaptırmış
- Şikayeti yok
- Alışkanlıklar: Sigara (6 paket/yıl)
- Özgeçmiş: Özellik yok
- Soygeçmiş: Annesi DM, HT
- FM doğal

II. vizit

Laboratuvar;

- CD4 hücre sayısı: 359 hücre/mm^3
- HIV RNA: 68.916 kopya/mL

- Hemogram N, Biyokimya N, PPD (-)
- Radyolojik incelemeler doğal
- HBsAg (-), **Anti-HBc IgG(+)** Anti-HBs (-), Anti-HCV (-)
- VDRL(-), TPHA(+)

ART Kararı ve Bilgilendirme

- Naif, erken tanılı, eşlik eden hastalığı olmayan, asemptomatik, genç hasta
- HIV enfeksiyonu tanısının 3. haftasında
- ART ve tedavi uyumunun önemi hakkında ayrıntılı bilgi verildi
- Tedaviye hazır ve istekli
- Tek tablet kullanmak istediğini ifade etti

Rehberler

- DHHS (Departement of Human and Health Services)
- EACS (European AIDS Clinical Society)

Klinik evre ve CD4 sayısına bakılmaksızın tüm hastalara ART başlanmalıdır

___Ağır ve ilerlemiş HIV enfeksiyonu ve CD4 sayısı ≤ 350/mm^3 olanlar öncelikli

Initiation of Antiretroviral Therapy

Last Updated: October 17, 2017; Last Reviewed: October 17, 2017

Panel's Recommendations for Initiating Antiretroviral Therapy in Treatment-Naive Patients

Panel's Recommendations
• Antiretroviral therapy (ART) is recommended for all individuals with HIV, regardless of CD4 T lymphocyte cell count, to reduce the morbidity and mortality associated with HIV infection **(AI)**. • ART is also recommended for individuals with HIV to prevent HIV transmission **(AI)**. • When initiating ART, it is important to educate patients regarding the benefits and considerations of ART, and to address strategies to optimize adherence. On a case-by-case basis, ART may be deferred because of clinical and/or psychosocial factors, but therapy should be initiated as soon as possible.
Rating of Recommendations: *A = Strong; B = Moderate; C = Optional* ***Rating of Evidence***: *I = Data from randomized controlled trials; II = Data from well-designed nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion*

Diagnosis

Since many individuals may fail to engage in care during the delay between initial HIV diagnosis (or first clinic visit) and the time ART is prescribed, some groups have proposed rapid ART initiation on the same day of HIV diagnosis as a strategy to increase engagement in care and increase the proportion of individuals who achieve and maintain ART-mediated viral suppression. This strategy was recently tested in a randomized controlled trial of 377 individuals in South Africa who had recently received HIV diagnoses. Those randomized to receive immediate ART on the day of diagnosis were significantly more likely

HIV-enfekte bireylerin bakımda kalmasını sağlamak için tanı aldığında (veya ilk vizitte) ART başlanması öneriliyor

diagnosis might modestly shorten the time to achieving viral suppression.[55] It should be emphasized, however, that ART initiation on the same day of HIV diagnosis is resource-intensive, requiring "on-call" clinicians, nurses, social workers, and laboratory staff to coordinate the patient transportation, clinical evaluation, counseling, accelerated insurance coverage, required intake

HIV İLE ENFEKTE HASTALARIN ÇOĞUNDA ÖNERİLEN TEDAVİLER

(virolojik etkinlik, tolere edilebilir, düşük yan etki profili ve kolay kullanım)

İNİ+2 NRTİ

- **DTG/ABC/3TC** (AI)
- **DTG + tenofovir/FTC** (TDF ve TAF için AI)
- **EVG/cobi/tenofovir/FTC** (TDF ve TAF için AI)
- **RAL + tenofovir/FTC** (TDF, AI ve TAF, AII)

* 2x400 mg ya da 1x 1200 mg (600 mg'lık tabletler)

DHHS; 2017

HIV İLE ENFEKTE HASTALARIN ÇOĞUNDA ÖNERİLEN TEDAVİLER

(virolojik etkinlik, tolere edilebilir, düşük yan etki profili ve kolay kullanım)

İlk Seçenekler

İNİ

- DTG/ABC/3TC
- DTG+TAF/FTC veya TDF/FTC
- EVG/cobi/TAF/FTC veya EVG/cobi/TDF/FTC
- RAL+TAF/FTC veya TDF/FTC

NNRTİ

- RPV/TAF/FTC veya RPV/TDF/FTC

(viral yük<100.000 kopya/ml ve CD4 hücre sayısı >200/mm^3)

Pİ

- DRV/c+TAF/FTC veya TDF/FTC
- DRV/r+TAF/FTC veya TDF/FTC

EACS 2017

FARKLI KLİNİK SENARYOLARA YAKLAŞIM

KLİNİK DURUM	ÖNERİLER
CD4 <200 hücre/mm³ veya HIVRNA>100.000 kopya/ml	• RPV temelli rejimler • DRV/r +RAL kullanılmamalı
HIVRNA>100.000 kopya/ml	• ABC/3TC + EFV veya ATV/r veya RAL kullanılmamalı
HLA-B*5701 pozitif	• ABC temelli rejimler kullanılmamalı

KLİNİK DURUM	ÖNERİLER
e-GFR<60 ml/dak	• **TDF'den kaçınılmalı (RTV ile birlikte kullanıldığında yüksek risk)** • **ATV'den kaçınma düşünülmeli** • **ABC veya TAF kullanılmalı** • **TAF** KrKl ≥ 30 mL/dak ise kullanılabilir · **KrKl <50 mL/dak, ABC/3TC temelli rejimler kullanılmamalı (3TC doz ayarı)** • **ABC veya TAF kullanılamadığında diğer tercihler:** ❑ **LPV/r + 3TC** veya ❑ **DRV/r + RAL** (HIV RNA<100,000kopya/mL ve CD4 >200/mm³)

KLİNİK DURUM	ÖNERİLER
Tüberküloz	**TAF rifamisinle kullanılmamalı** (TAF düzeyi düşer) Eğer **rifampin** kullanılacaksa: • EFV: doz ayarlaması gerekmez • RAL: doz 2x800 mg/gün'e geçilir • DTG: 2x50 mg/gün (İNSTİ direnç mutasyonu yoksa) Eğer PI'ya dayalı şema kullanılıyorsa: rifampin yerine rifabutin verilir

KLİNİK DURUM	ÖNERİLER
Psikiyatrik hastalık	• **EFV ve RPV temelli rejimlerden kaçınılmalı** • Öncesinde psikiyatrik hastalık öyküsü olan **İNİ temelli ART kullanılan hastalar yakından izlenmeli**
HIV ilişkili demans	• EFV temelli rejimlerden kaçınılmalı • **DRV veya DTG temelli rejimler tercih edilmeli**
Narkotik replasman tedavisi	• Hasta metadon kullanıyorsa EFV temelli rejimlerden kaçınılmalı • EFV kullanılıyorsa metadon dozunun arttırılması gerekebilir

KLİNİK DURUM	ÖNERİLER
Karaciğer hastalığı ve siroz	• Bazı ARV'ler kontrendike veya doz ayarı gerekir • **Child B ve C'de ABC kontrendike**
Osteoporoz	• TDF'den kaçınılmalı • **ABC/3TC veya TAF kullanılmalı**

KLİNİK DURUM	ÖNERİLER
Yüksek kardiyak risk	• **ABC veya LPV/r temelli rejimlerden kaçınılmalı** • DTG,RAL veya RPV temelli rejimler tercih edilebilir • PI tercih edilecekse ATV temelli rejimler DRV temelli rejimlere göre daha avantajlı
QT uzaması	• EFV veya RPV temelli rejimlerden kaçınılmalı
Hiperlipidemi	**Lipid düzeyleri üzerine olumsuz etkileri olan rejimler:** • **PI/r veya PI/c** • **EFV** • **EVG/c** DTG, RAL veya RPV 'in lipid profili üzerine yan etkileri daha düşük **(TDF, ABC veya TAF'a kıyasla tercih)**

HIV/HBV Enfeksiyonu

- **TDF/FTC veya TAF/FTC içeren kombinasyonlar kullanılmalı (AI)**
- Eğer TDF/FTC veya TAF/FTC kullanılamıyorsa ART'ye entekavir eklenmeli (BI)
- Bazı hastalarda Peg-IFN kullanılabilir (CII)
- Adefovir, telbivudin önerilmiyor (CII)

Strategies to Achieve Treatment Goals

Selection of Initial Combination Regimen

Several ARV regimens are recommended for use in ART-naive patients (see What to Start). Most of the recommended regimens have comparable efficacy but vary in pill burden, potential for drug interactions and/or side effects, and propensity to select for resistance mutations if ART adherence is suboptimal. Regimens should be tailored for the individual patient to enhance adherence and support long-term treatment success. Considerations when selecting an ARV regimen for an individual patient include potential side effects, patient comorbidities, possible interactions with conconcomitant medications, results of pretreatment genotypic drug-resistance testing, and regimen convenience (see Table 7).

Improving Adherence

Suboptimal adherence may result in reduced treatment response. Incomplete adherence can result from complex medication regimens; patient-related factors, such as active substance abuse, depression, or the experience of adverse effects; and health system issues, including interruptions in patient access to medication and inadequate treatment education and support. Conditions that promote adherence should be maximized before and after initiation of ART (see Adherence to Antiretroviral Therapy).

DHHS; 2017

Tek tablet rejimlerde tedavi uyumu

HIV Med. 2017 Nov 6. doi: 10.1111/hiv.12562. [Epub ahead of print]

Antiretroviral pill count and clinical outcomes in treatment-naïve patients with HIV infection.

Young J[1], Smith C[2], Teira R[3], Reiss P[4], Jarrín Vera I[5], Crane H[6], Miro JM[7], D'Arminio Monforte A[8], Saag M[9], Zangerle R[10], Bucher HC[1,11]; Antiretroviral Therapy Cohort Collaboration (ART-C

Collaborators (14)

Author information

Abstract

OBJECTIVES: Treatment guideli regimens might be as effective a efavirenz, emtricitabine and teno

METHODS: We selected treatme Therapy Cohort Collaboration. Th these data using Cox regression either a one-pill regimen or a thre

RESULTS: Among 11 739 treatm when patients switched to the sa in the risk of AIDS or death [haza add to that increase (HR 1.19; 95 three-pill regimen for 1 year to av

CONCLUSIONS: This particular s formulations.

AIDS Patient Care STDS. 2017 Sep;31(9):370-376. d

Relationship Between Single T Non-Antiretroviral Medications Virus.

Yager J[1], Faragon J[2], McGuey L[1], Hoye-Simek A

Author information

1 1 Department of Pharmacy Practice, Alb

2 2 Departments of Pharmacy and Medicir

3 3 Division of Infectious Diseases, Samue

Abstract

Several antiretrovirals (ART) have been cof adherence between STR and multiple tablet determine whether ART adherence influenc Veterans' Healthcare Administration (VISN- virus (HIV) infection, receipt of ≥3 ART medi adherence to ART medications and non-AR calculate medication possession ratios. Amo standard deviation (SD) ART adherence wa < 0.001. Use of STR [adjusted odds ratio (a optimal (≥90%) adherence to ART. Mean ± S ± 16.0%), p = 0.17. Optimal adherence to AF optimal adherence to non-ART medications. associated with adherence to non-ART med

Odds of Viral Suppression by Single-Tablet Regimens, Multiple-Tablet Regimens, and Adherence Level in HIV/AIDS Patients Receiving Antiretroviral Therapy.

Sutton SS[1], Magagnoli J[2], Hardin JW[3].

Author information

Abstract

STUDY OBJECTIVE: To evaluate the odds of achieving viral suppression in human immunodeficiency virus (HIV) patients using antiretroviral therapy as a single-tablet regimen (STR) or multiple-tablet regimen (MTR).

DESIGN: Retrospective cohort study.

DATA SOURCES: South Carolina Medicaid medical and pharmacy paid claims data were obtained from the South Carolina Revenue and Fiscal Affairs Office; laboratory data were obtained from the South Carolina Department of Health and Environmental Control.

PATIENTS: A total of 1536 patients who were dispensed a complete STR (477 patients) or MTR (1059 patients) regimen lasting at least 60 days between January 1, 2006, and December 31, 2013.

MEASUREMENTS AND MAIN RESULTS: The analysis examined adherence levels and regimen type on odds of viral load suppression. Regimen adherence levels (90-94%, 85-89%, 80-84%, and less than 80%) were compared with the gold standard adherence for HIV of 95% or greater. Patients were followed from index date until the earliest date of regimen discontinuation, treatment switch, end of study period, last date of eligibility, or death. Differences in outcomes were evaluated by χ^2 , Wilcoxon rank sum statistical tests, and multivariate regression models controlling for covariates. For STR regimens we find that, when compared with 95% or greater adherence, there is no statistical difference in the odds of viral suppression with adherence levels greater than or equal to 80%. However, adherence levels greater than or equal to 95% were associated with a greater odds of viral suppression when compared with less than 80% STR adherence (odds ratio [OR] 2.57, Dunnett 95% confidence interval [CI] 1.04-6.32). For MTR regimens, there was no statistical difference in the odds of viral suppression for the adherence level 90-94% compared with the 95% or greater adherence (OR 3.59, Dunnett 95% CI 0.805-16.043). However, the 95% or greater adherence has greater odds of viral suppression compared with all other MTR adherence levels. In addition, no difference was found in the odds of viral suppression between STR and MTR for all adherence levels.

CONCLUSIONS: Compared with 95% or greater adherence, STR regimens achieve viral suppression with adherence levels of 80% or

Olgumuzdaki dikkat edilmesi gereken…

İzole anti-HBC pozitifliği

- Yalancı pozitiflik mi?
- Geçirilmiş enfeksiyon mu?
- Okült HBV enfeksiyonunun habercisi olabilir mi?
- Nasıl yaklaşmalı?
- Aşılama? HBV DNA istenmesi?

İzole anti-HBc Pozitifliği

- HIV-enfekte olgularda sık (% 7-19)
- İzole anti-HBc pozitifliği olan HIV-enfekte bireylerde HBV viremi insidansı (% 1-36)
- Klinik önemi hala net değil
- Gelişmiş ve HBV prevalansı düşük ülkelerde yalancı pozitiflik sık
- HIV/HCV koenfeksiyonunda daha sık

U.S. Department of Health and Human Services . 2017 Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV

HIV Clin Trials. 2013 Jan-Feb;14(1):17-20. doi: 10.1410/hct1401-17.

Isolated anti-HBc among HIV-infected patients in Istanbul, Turkey.

Karaosmanoglu HK[1], Aydin OA, Nazlican O.

Author information

Abstract

BACKGROUND: Isolated antibody to hepatitis B core antigen (anti-HBc) is frequent in HIV-infected patients, and it may be a marker of occult hepatitis B. We aimed to determine the prevalence and associated risk factors of isolated anti-HBc among HIV-infected patients in Turkey, which is classified as an intermediate HBV, low HIV endemic region.

METHOD: HIV/AIDS patients followed by the Infectious Diseases and Clinical Microbiology Outpatient Clinic of Haseki Training and Research Hospital between January 2006 and March 2011 were included in this study. Medical records were reviewed to determine the prevalence of isolated anti-HBc and to identify the risk factors associated with isolated anti-HBc. The frequency of isolated anti-HBc in 209 HIV-infected patients was compared with 83 volunteer blood donors.

RESULTS: Of 209 HIV-infected patients, 40 subjects (19.1%) had isolated anti-HBc compared with control group, which consisted of 83 volunteer blood donors who had similar age (P = .13) and sex (P = .29). In the control group, only 2 (2.4%) had isolated anti-HBc. Isolated anti-HBc was significantly more frequent in HIV-infected patients (P < .001). The characteristics such as age, gender, injecting drug use, anti-HCV seropositivity, and CD4 cell counts were not significantly different between HIV-infected patients with or without isolated anti-HBc. Only 3 (7.5%) of HIV-infected patients had occult infection.

CONCLUSION: Prevalence of isolated anti-HBc in Turkish HIV-infected patients was 19.1%, which was significantly more frequent than in blood donors. Isolated anti-HBc could be associated with occult infection. Thus, all HIV-infected patients should be screened for anti-HBc before starting antiretroviral therapy.

İzole anti-HBc saptandığında…

- HIV-enfekte olguların çoğunda HBV DNA negatif[1]
- Bu nedenle rutin HBV DNA testi önerilmiyor[2]
- Te doz aşılama ardından 1 ay sonra kontrol
- Anti-HBs <100 ise aşılamayı tamamla
- Aşı yanıtı düşük (~%50)

1.Gandhi RT, et al. J Acquir Immune Defic Syndr. 2003;34:439-41.

2 U.S. Department of Health and Human Services . 2017 Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV

Olgu 1
Tedavi Seçimi

- Genç, eşlik eden hastalığı olmayan, multiple partneri olan MSM
- İzole anti-HBc pozitifliği- okült HBV enf riski
- HBV DNA istendi ve aşılama önerildi
- Hasta tanısının 3.haftasında
- Hasta tercihi; tek tablet rejim

- Etkinliği yüksek , toksisitesi az, tek tablet, **HBV etkili**

TAF/FTC+EVG/c
GENVOYA

Olgu 2
I. Vizit

- 57 y, erkek, ilkokul mezunu,tekstilci
- Kan bağışı sırasında tanı almış
- Özgeçmiş: 5 yıldır HT
- Soygeçmiş: Annede HT, baba 60 y MI nedeniyle ex
- Alışkanlıklar: Sigara 40 paket/yıl, Enalapril 0.5 mg kullanımı
- FM: Servikal birkaç adet 0.5-1 cm arası yumuşak, mobil, ağrısız LAP

II. vizit

Laboratuvar;

- CD4 hücre sayısı: 236 hücre/mm^3
- HIV RNA: 98.960 kopya/mL
- HLA-B 5701 (-)

- Hemogram: Hb: 10.8, WBC:4400, Plt: 144.000
- Biyokimya: T.Kol : 186mg/dl, **HDL : 35mg/dl**, LDL:103mg/dl, **TG : 240mg/dl**
- PPD (-)
- Radyolojik incelemeler doğal
- HBsAg (-), Anti-HBc (-), Anti-HBs (-), Anti-HCV (-)
- Serolojik incelemeler doğal

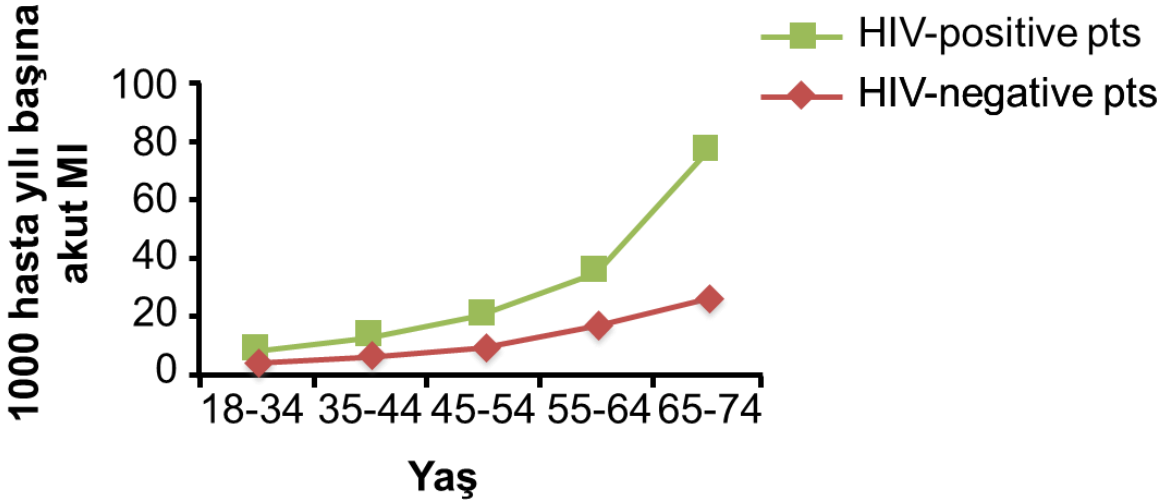
ART Kararı ve Bilgilendirme

- Naif, geç tanılı, ileri yaşta, asemptomatik olgu
- ART başlanmasına karar verildi
- ART ve tedavi uyumunun önemi hakkında ayrıntılı bilgi verildi

- Hangi ART rejimi?

HIV ve KVH İlişkisi

- HIV pozitiflerde akut MI oranı yüksek [1]
- HIV enfeksiyonu iskemik inme için risk faktörü[2]
- HIV-enfekte erkeklerde koroner arter plak oluşumu prevalansı yüksek[1,3]



1. Triant VA, et al. J Clin Endocrinol Metab. 2007;92:2506-2512. 2. Chow FC, et al. J Acquir Immune Defic Syndr. 2012;60:351-358. 3. Post WS, et al. Ann Intern Med. 2014;160:458-467.

HIV ve KVH Mortalite

- Amerika'da ikinci (~ %15)[1] , Avrupa'da üçüncü (~ %8)[2] HIV-dışı ölüm sebebi
- Farklı kohortlarda KVH'lara bağlı ölüm %6 ile %15 arasında değişmekte[1-4]
- HIV'e bağlı ölümler azaldıkça, KVH'lara bağlı ölümler artmakta[5]
  - Bununla birlikte risk faktörlerinin azaltılması, ART'nin lipid profili üzerine olumlu etkileri ve immün iyileşme ile MI ve inme riski azalmakta[6-9]
- Amerika'da, MI nedeniyle hastenede yatan HIV enfekte hastalar;

  kontrollere oranda yüksek mortalite(HR: 1.38; *P* = .04)[10]

1. Palella FJ, et al. J Acquir Immune Defic Syndr. 2006;43:27-34. 2. Lewden C, et al. J Acquir Immune Defic Syndr. 2008;48: 590-598. 3. Smith CJ, et al. Lancet. 2014;384:241-248. 4. Sackoff JE, et al. Ann Intern Med. 2006;145:397-406. 5. Hanna D, et al. CROI 2014. Abstract 729. 6. Klein DB, et al. CROI 2014. Abstract 737. 7. Klein DB, et al. Clin Infect Dis. 2015;60:1278-1280. 8. Marcus JL, et al. CROI 2014. Abstract 741. 9 Marcus JL, et al. AIDS. 2014;28:1911-1919. 10. Pearce D et al AM J Cardiol 2012.

VİRÜSE AİT FAKTÖRLER

- Dislipidemi
- Inflamasyon ve immün aktivasyon
- Ko-enfeksiyonlar: HCV…

HASTAYA AİT FAKTÖRLER
KLASİK VE SOSYAL FAKTÖRLER

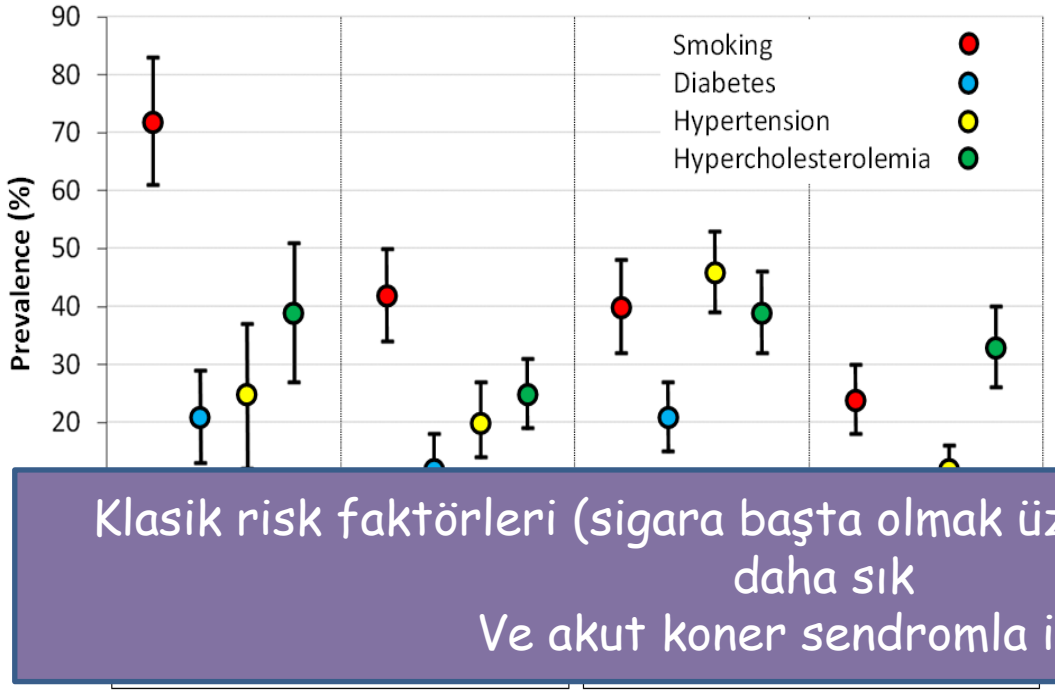
- Geleneksel risk faktörlerinde artış;
  Sigara,dislipidemi,HT,obezite,DM
- Kokain, yaşam biçimi, stres…

KARDİYOVASKULER HASTALIK

TEDAVİYE AİT FAKTÖRLER

- Antiretroviral tedavi ve Toksisiteler

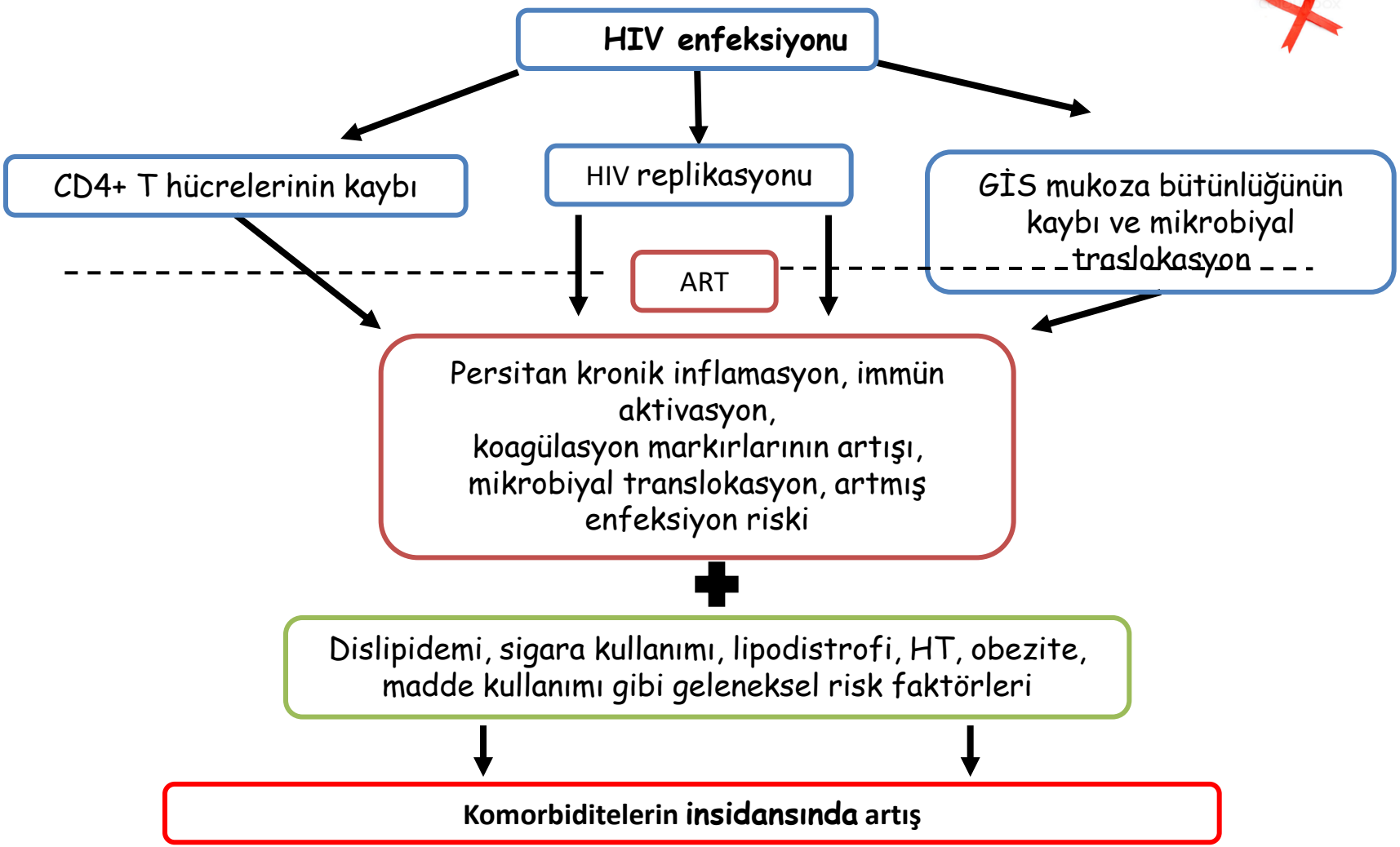
HIV + bireylerde klasik risk faktörleri



Klasik risk faktörleri (sigara başta olmak üzere) HIV + bireylerde daha sık
Ve akut koner sendromla ilişkili

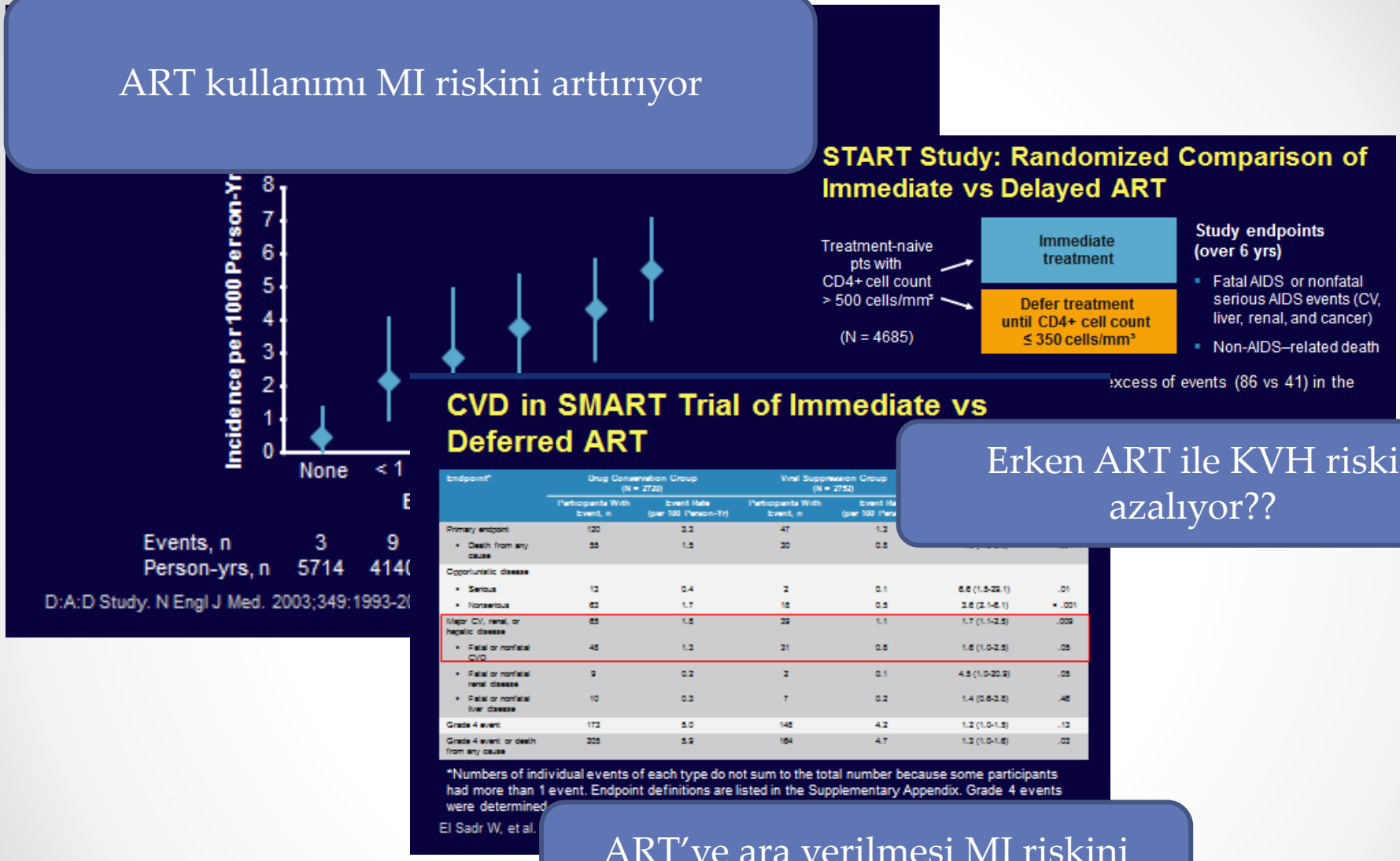
Calvo M. et al. HIV Medicine. 2013; 14: 40–48

Kronik inflamasyon ve artmış komorbidite riski



Deeks SG. Annu Rev Med. 2011;62:141-155.

ART kullanımı MI riskini arttırıyor



Erken ART ile KVH riski azalıyor??

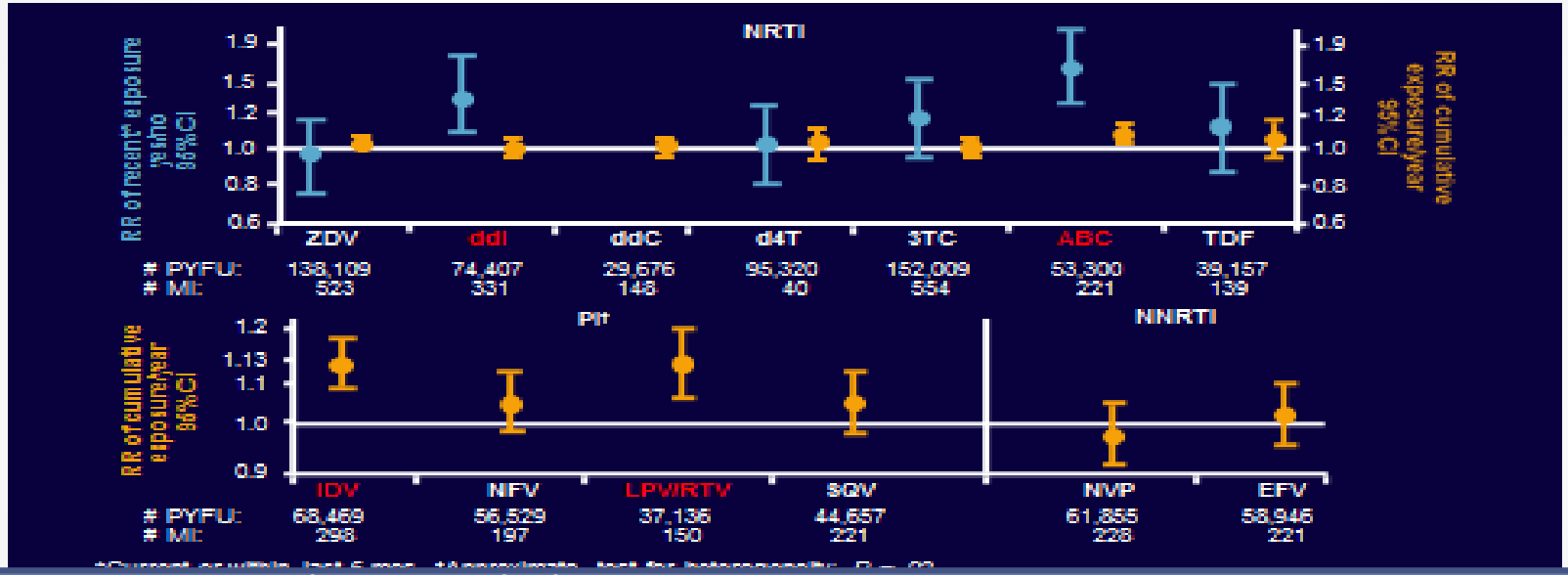
ART'ye ara verilmesi MI riskini arttırıyor

D:A:D Study. N Engl J Med. 2003;349:1993-2003

El Sadr W, et al. N Engl J Med. 2006;355:2283-2296.

NIH. Press release. May 27, 2015.

D:A:D Kohortu : ART-MI ilişkisi



- N = 33,308 hasta 11 kohort
- İlk sonuçlar(2008); LPV/r kümülatif kullanımda ve

  ABC ve ddI <6ay kullanımda MI riski yüksek
- Kohortun devamı (2013), uzun dönem takip, yeni hastalar, risk (KBY vb) analizlerinde bağımsız MI riski yüksek

OPEN ACCESS PEER-REVIEWED

RESEARCH ARTICLE

Risk of Cardiovascular Disease from Antiretroviral Therapy for HIV: A Systematic Review

Clay Bavinger, Eran Bendavid, Katherine Niehaus, Richard A. Olshen, Ingram Olkin, Vandana Sundaram, Nicole Wein, Mark Holodniy, Nanjiang Hou, Douglas K. Owens, Manisha Desai

Published: March 26, 2013 • https://doi.org/10.1371/journal.pone.0059551

between abacavir use and MI is not definitive.

Abstract
Introduction
Methods
Results
Discussion
Supporting Information
Acknowledgments
Author Contributions
References

Reader Comments (0)
Media Coverage (0)
Figures

Exposure to PIs

Some of the studies investigating PIs found an association between cumulative use of PIs and cardiovascular disease, and others found an association with recent exposure. Our meta-analysis based on three observational studies indicated that recent PI use was associated with an odds ratio of 2.13 for MI. We caution, however, that this combined estimate is based upon studies that did not meet important criteria for quality [23]–[25]. In contrast to the findings from observational studies, Coplan et al. conducted a meta-analysis of RCTs [20] and found no association between nelfinavir and risk of MI (point estimate not reported) or between indinavir exposure and risk of MI (0.7, 95% CI: 0.1, 7.75). Similar issues present here as with the meta-analysis of RCTs presented by Ding et al. that evaluated the association between abacavir and MI [9]. These include drawing inference from studies of short duration that are not designed to evaluate endpoints such as MI and that consequently are underpowered to detect such associations.

Finally, we found a significant increase in risk associated with cumulative lopinavir and indinavir use. These results are based upon only two studies, and their quality was fair [6], [8]. We therefore caution against interpreting these findings as conclusive.

Methodological Challenges

When possible, we combined estimates from studies to assess the risk of cardiovascular disease associated with ART. There were significant challenges, however, to achieving this in our study. Barriers included heterogeneity across the studies with regard to definitions of drug exposure (e.g., time-varying or fixed; cumulative exposure or recent exposure), populations investigated, designs employed (e.g., longitudinal or cross-sectional), and finally, specification of the statistical models (e.g., assessing cumulative or recent exposure separately or jointly). While

ABAKAVİR- MI RİSKİ

Study	Study Design	Age, Yrs (range)	Event (n)	Pts, N	TDF CV Effect	ABC CV Effect	Time on ABC, Mos	Risk of MI (95% CI)
D:A:D[1]	Cohort	40 (35-47)	MI, validated (387)	22,625	No	Yes	≥ 6	1.70 (1.17-2.47)
D:A:D 2013[2]	Cohort	39 (33-46)	MI (493)	32,663		Yes		1.47
SMART[3]	RCT	45 (39-51)	MI, validated (19)	2752	No	Yes	Current	4.3 (1.4-13.0)
STEAL[4]	RCT	45.7 ±8.8	MI (3)	357	No	Yes	96	2.2
QPHID[5]	CC	47 (22-67)	MI (125)	7053	No	Yes	6	1.79 (1.16-2.76)
Danish[6]	Cohort	39 (33-47)	MI (67)	2952	No	Yes	> 6	2.00 (1.07-3.76)
VA (Choi)[7]	Cohort	48	CV event (501)	10,931	No	Yes	6	1.64 (0.88-3.08)
Swiss[8]	Cohort	Not given	CVD event (350)	11,625	No	Yes	> 1-6	3.36 (2.04-5.53)
MAGNIFICENT[9]	CC	50 (22-85.5)	CVD event (571)	571	No	Yes	Current	1.56 (1.17-2.07)
NA-ACCORD[10]	Cohort		MI, validated (301)	16,733		Yes	> 6	1.33
Swiss HIV Cohort[11]	Cohort	45	CVD event (365)	11,856		Yes	> 6	2.06 (1.43-2.98)

1. Friis-Moller N, et al. Eur J Cardiovasc Prev Rehabil. 2010;17:491-501. 2. Friis-Moller N, et al. Eur J Prev Cardiol. 2015;[Epub ahead of print].
3. SMART/INSIGHT Study Group. AIDS. 2008;22:F17-24. 4. Martin A, et al. Clin Infect Dis. 2009;49:1591-1601. 5. Durand M, et al. JAIDS. 2011;57:245-253. 6. Obel N, et al. HIV Medicine. 2010;11:130-136. 7. Choi AI, et al. AIDS. 2011;25:1289-1298. 8. Young J, et al. IAS 2013. Abstract MOPE070.
9. Rotger M, et al. Clin Infect Dis. 2013;57:112-121. 10. Palella F, et al. CROI 2015. Abstract 749LB. 11. Young J, et al. JAIDS. 2015;[Epub ahead of print].

ABAKAVİR- MI RİSKİ

Study	Study Design	Age, Yrs (Range)	Event (n)	Pts, N	TDF CV Effect	ABC CV Effect	Time on ABC, Mos	Adj Risk of MI (95% CI)
FHDB[1]	CC	47 (41-54)	MI (289)	74,958	No	No*	> 6	1.27‡ (0.64-2.49)
ALLRT/ ACTG[2]	Cohort	37 (27-50)	MI (36)	5056	No	No†	72	0.70 (0.2 -2.4)
VA[3]	Cohort	46	MI (278)	19,424	No	No*	24	1.18 (0.92-1.50)
FDA[4]	Meta-analysis of RCTs	36-42	MI (24)	9868	No	No	19	1.02 (0.56-1.84)

1. Lang S, et al. Arch Intern Med. 2010;170:1228-1238. 2. Ribaudo HJ, et al. Clin Infect Dis. 2011;52:929-940.
3. Bedimo RJ, et al. Clin Infect Dis. 2011;53:84-91. 4. Ding X, et al. J Acquir Immune Defic Syndr. 2012;61:441-447.

KVH RİSK HESAPLAMASI

Framingham 10 yıllık MI veya Koroner Ölüm riski Hesaplaması	Pooled Equations 10 yıllık ASCVD riski hesaplaması	DAD 5 yıllık Koroner Kalp Hastalığı Riski Hesaplaması
Cinsiyet	Cinsiyet	Cinsiyet
Yaş	Yaş	Yaş
--------	Irk (beyaz/siyah)	KKH Aile Öyküsü
Total Kolestrol	Total Kolestrol	Total Kolestrol
Ant		
		IDV veya LPV alıdığı yıl sayısı
		IDV, LPV, veya Abacavir kullanıyor

Framingham risk skoru (10 yıllık)
Yüksek risk >%20
D:A:D risk skoru (5 yıllık)
Yüksek risk >%5

Risk Evaluation Tools

Gender: (•) Male ( ) Female

Age: 57

Height: 176 (•) cm ( ) inches

Weight: 85 (•) kg ( ) pounds

Risk Assessments:
- [x] Framingham
- [x] DAD 5 Year Estimated Risk
- [ ] EuroSIDA
- [ ] GFR
- [ ] NNH for abacavir

Currently Cigarette Smoker?: (•) Yes ( ) No

Diabetic ?: ( ) Yes (•) No

Framingham

Created	CHD-5	CHD-10	CVD-5	CVD-10	MI-5	MI-10
01-14-2018	10.2%	20.6%	14.6%	29.3%	7.1%	14.4%

The algorithms used for the tool above are the exact same as published by:

Anderson KM, Odell PM, Wilson PW, Kannel WB.: Cardiovascular disease risk profiles.Am Heart J. 1991 Jan;121(1 Pt 2):293-8. Abstract link

The algorithm was used for modelling the risk of MI in the D:A:D study:

Law M, Friis-Moller N, Weber R, Reiss P, Thiebaut R, Kirk O, d'Arminio Monforte A, Pradier C, Morfeldt L, Calvo G, El-Sadr W, De Wit S, Sabin CA, Lundgren JD, for the DAD Study Group.: Modelling the three year risk of myocardial infarction among participants in the D:A:D study. HIV Med. 2003; 4(1):1-10. Abstract link

Updated: 15 Dec 2006

DAD

Created	CHD-5
01-14-2018	10.8%

The algorithms used for the tool above are the exact same as published by:

N Friis-Møller, R Thiébaut, P Reiss, R Weber, AD Monforte, S De Wit, W El-Sadr, E Fontas, S Worm, O Kirk, A Phillips, C Sabin, JD Lundgren, M Law; for the DAD study group: Predicting the risk of cardiovascular disease in HIV-infected patients: the Data Collecton on Adverse Effects of Anti-HIV Drugs Study. Eur J Cardiovasc Prev Rehabil. 2010 Jun 10. Abstract link

Updated: 24 Jan 2011

HLA-B*5701-negative are far less likely to experience an HSR, but they should be counseled about the symptoms of the reaction. Patients who discontinue ABC because of a suspected HSR should never be rechallenged, regardless of their HLA-B*5701 status.

Cardiovascular Risk:

- An association between ABC use and myocardial infarction (MI) was first reported in the D:A:D study. This large, multinational, observational study group found that recent (ie, within 6 months) or current use of ABC was associated with an increased risk of MI, particularly in participants with pre-existing cardiac risk factors.[23,24]
- Since the D:A:D report, several studies have evaluated the relationship between ABC therapy and cardiovascular events. Some studies have found an association.[25-28] Others, including an FDA meta-analysis of 26 randomized clinical trials that evaluated ABC, have not.[29-33]
- No consensus has been reached on the association between ABC use and MI risk or the mechanism for such an association.

Other Factors and Considerations:

- ABC/3TC is available as a coformulated tablet and as a coformulated single-tablet regimen with DTG.
- ABC and 3TC are available separately in generic tablet formulations.
- ABC does not cause renal dysfunction and can be used instead of TDF in patients with underlying renal

The Panel's Recommendations:

- ABC should only be prescribed for patients who are HLA-B*5701 negative.
- On the basis of clinical trial safety and efficacy data, experience in clinical practice, and the availability of ABC/3TC as a component of coformulated products, the Panel classifies DTG/ABC/3TC as a Recommended regimen **(AI)** (see discussion of DTG in this section regarding the clinical efficacy data for ABC/3TC plus DTG).
- ABC/3TC use with EFV, ATV/r, ATV/c, or RAL is only recommended for patients with pretreatment HIV RNA <100,000 copies/mL. See Table 6 for more detailed recommendations on use of ABC/3TC with these drugs.

- ABC should be used with caution or avoided in patients with known high cardiovascular risk.

DHHS 2017

EACS 2017

Adverse Effects of ARVs & Drug Classes

Bold: Frequent effects
Red: Severe effects
Black: Neither Frequent nor Severe[i]

	Skin	Digestive	Liver	CV	Musculo-skeletal	Genito-urinary	Nervous	Body fat	Metabolic	Other
NRTIs										
ABC	Rash*	Nausea* Diarrhoea*		IHD						*Systemic hypersensitivity syndrome (HLA B*5701 dependent)
ZDV[ii]	Nail pigmen-tation	Nausea	Steatosis		Myopathy, Rhabdomy-olysis				Dyslipi-daemia, Hyperlacta-taemia	Anaemia
d4T[iii]		Pancreatitis	**Steatosis**				**Peripheral neuropathy**	**Lipoatrophy**	**Dyslipi-daemia,** Hyperlacta-taemia	
ddI[iii]			Steatosis, Liver fibrosis	IHD					Hyperlacta-taemia	
3TC										
FTC										
TDF[iii]					↓ BMD, Osteomalacia ↑ Fractures risk	↓ eGFR, Fanconi syndrome				
TAF[iii]										
NNRTIs										
EFV	Rash		Hepatitis				**Depression, Sleep disturbances, Headache,** Suicidal ideation		**Dyslipi-daemia,** Gynaeco-mastia	**↓ plasma 25(OH) vitamin D,** Teratogenesis
ETV	Rash									
NVP	Rash*		Hepatitis*							*Systemic hypersensitivity (CD4 count-and gender-depend-ent)
RPV	Rash		Hepatitis			↓ eGFR[iv]	Depression, Sleep disturbances, Headache			
PIs										
ATV[v]			**Hyperbiliru-**			↓ eGFR,			Dyslipi-	

Olgu 2
Tedavi Seçimi

- ✓ İleri yaş komorbiditeler….
- ✓ KVH riski yüksek

- **Kullanımı kolay, etkin, güvenli, tek tablet bir rejim**

GENVOYA Tek Tablet Rejim

Olgu 3
I. Vizit

- 55 y, kadın, dul, ilkokul mezunu, ev hanımı
- **Şikayeti:** Ara ara ishal, hazımsızlık
- **Hikaye:** 2003 yılında HIV enf tanısı almış

(CD4 hücre sayısı:165 hücre/mm^3, HIV RNA: 175.000 kopya/mL)

ZDV/3TC+IDV/r tedavisi başlanmış

2011 yılında CD4 hücre sayısı:565hücre/mm^3, HIV RNA: negatif olup tedavi TDF/FTC+LPV/r ile değiştirilmiş

2011 yılında hastaya Diffüz Büyük B Hücreli Lenfoma tanısı konulmuş (8 Kür KT)

- **Hikaye:** 2013 yılında lenfoma nüks- KT

KT sırasında kr:1.31 (üst değer 0.9),

GFR:37.7 ml/dak

Nefroloji Kons: renal yetersizlik KT ve kontrast maddelere bağlı düşünüldü

TDF/FTC dozu gün aşırı 1X1 olarak değiştirildi

2014 kr normal, GFR:73 ml/dak

2015 kr tekrar yükseldi (1.3-1.6)

2015 yılında tedavi **DRV/r+RAL olarak** yeniden düzenlendi

- **Özgeçmiş:** 7 yıldır Diffüz Büyük B Hücreli Lenfoma remisyonda
- **Soygeçmiş:** Annede HT
- **Alışkanlıklar:** Sigara 20 paket/yıl

Laboratuvar; (2017)

- CD4 hücre sayısı: 746 hücre/mm^3
- HIV RNA: negatif

- Hemogram: N
- Biyokimya: T.Kol : 180 mg/dl, HDL : 38mg/dl, LDL : 96mg/dl, TG : 231mg/dl
- HBsAg (-), Anti-HBc (-), Anti-HBs (+), Anti-HCV (-)
- DEXA N

Framingham

Created	CHD-5	CHD-10	CVD-5	CVD-10	MI-5	MI-10
01-15-2018	5.2%	11.8%	7.5%	16.9%	2.5%	6.3%

The algorithms used for the tool above are the exact same as published by:

Anderson KM, Odell PM, Wilson PW, Kannel WB.: Cardiovascular disease risk profiles.Am Heart J. 1991 Jan;121(1 Pt 2):293-8. Abstract link

The algorithm was used for modelling the risk of MI in the D:A:D study:

Law M, Friis-Moller N, Weber R, Reiss P, Thiebaut R, Kirk O, d'Arminio Monforte A, Pradier C, Morfeldt L, Calvo G, El-Sadr W, De Wit S, Sabin CA, Lundgren JD, for the DAD Study Group.: Modelling the three year risk of myocardial infarction among participants in the D:A:D study. HIV Med. 2003; 4(1):1-10. Abstract link

Updated: 15 Dec 2006

DAD

Created	CHD-5
01-15-2018	9.9%

The algorithms used for the tool above are the exact same as published by:

N Friis-Møller, R Thiébaut, P Reiss, R Weber, AD Monforte, S De Wit, W El-Sadr, E Fontas, S Worm, O Kirk, A Phillips, C Sabin, JD Lundgren, M Law; for the DAD study group: Predicting the risk of cardiovascular disease in HIV-infected patients: the Data Collecton on Adverse Effects of Anti-HIV Drugs Study. Eur J Cardiovasc Prev Rehabil. 2010 Jun 10. Abstract link

Updated: 24 Jan 2011

Geçmişte PI kullanımı D.A.D risk skorunu artırıyor

TEDAVİ

- 1. Modifiye edelim
- 2. Aynı ARV rejimi ile devam edelim

Virolojik Suprese Hastada Tedavi Modfikasyonu Stratejileri

1. **Toksisite varlığı ↓**

   Lipoatrofi (d4T, AZT), SSS yan etkileri(EFV), **diyare (PI/r)** , sarılık (ATV), **nefrotoksisite** veya **osteoporoz (TDF),**

2. **Uzun dönem toksisitelerden korunmak. ↓**
3. **İlaç-ilaç etkileşimleri**
4. **Planlanan gebelik**
5. **Yaşlanma ve komorbiditeler ↓**

   KVH riski, metabolik parametreler

6. **Basitleştirme; ↓**

   Tedavi uyumunu artırmak için ilaç yükünü azaltma

EACS European AIDS Clinical Society. 2017 EACS Guidelines 9.0

1.Toksisite varlığı..

KLİNİK DURUM	ÖNERİLER
e-GFR<60 ml/dak	• TDF'den kaçınılmalı (RTV ile birlikte kullanıldığında yüksek risk) • ATV'den kaçınma düşünülmeli • ABC veya TAF kullanılmalı • TAF KrKl ≥ 30 mL/dak ise kullanılabilir • KrKl <50 mL/dak, ABC/3TC temelli rejimler kullanılmamalı (3TC doz ayarı) • ABC veya TAF kullanılamadığında diğer tercihler: ❑ LPV/r + 3TC veya ❑ DRV/r + RAL (HIV RNA<100,000kopya/mL ve CD4 >200/mm^3)

Önceki tedavi modifikasyonu

Appendix B: Drug Characteristics Tables

Antiretroviral Dosing Recommendations in Patients with Renal or Hepatic Insufficiency

Last Updated: October 17, 2017; Last Reviewed: October 17, 2017

Appendix B, Table 7. Antiretroviral Dosing Recommendations in Patients with Renal or Hepatic Insufficiency

See the reference section at the end of this table for CrCl calculation formulas and criteria for Child-Pugh classification.

Appendix B, Table 7. Antiretroviral Dosing Recommendations in Patients with Renal or Hepatic Insufficiency

Generic Name (Abbreviation) *Trade Name*	Usual Daily Dose[a]	Dosing in Renal Insufficiency[b]	Dosing in Hepatic Impairment
NRTIs Stribild should not be initiated in patients with CrCl <70 mL/min. Use of the following fixed-dose combinations **is not recommended** in patients with CrCl <50 mL/min: Atripla, Combivir, Complera, Epzicom, Triumeq, or Trizivir. Descovy, Genvoya, Odefsey, and Truvada **are not recommended** in patients with CrCl <30 mL/min.			

GFR >30 mL/dak ise kullanılabilen tek tablet rejim yalnızca **Genvoya**

İshal şikayeti yaşam kalitesini etkiliyor

Table 1. Incidence of Treatment-Related Grade 2–4 Diarrhea in Head-to-Head Comparisons of Boosted Protease Inhibitor Regimens Compared With Lopinavir Plus Ritonavir

Study	Patient Population	Patients, No.[b]	Patients With Grade 2–4 Diarrhea, %[a]		*P* Value
			Boosted PI/r	LPV/r	
			ATV/r		
BMS-045 [12, 13][c]	Treatment experienced	347			
48 weeks			3	11	.01
96 weeks			3	13	<.01
CASTLE [14, 15][d]	Treatment naive	878			
48 weeks			2	11	NR
96 weeks			2	12	NR
			DRV/r		
TITAN [16, 17][e]	Treatment experienced	595			
48 weeks			8	14	NR
96 weeks			8	15	NR
ARTEMIS [18, 19][d]	Treatment naive	689			
48 weeks			4	10	<.01
96 weeks			4	11	<.001
			SQV/r		
BMS-045 [12][c]					
48 weeks	Treatment experienced	347	6	11	NR
Gemini [20][d]					
48 weeks	Treatment naive	331	7[f]	14[f]	NR
			fAPV/r		
KLEAN [21, 22][g]	Treatment naive				
48 weeks		879	13	11	NR
144 weeks		196	15	12	NR
COL100758 [23][h]	Treatment naive	115	14	18	NR

Abbreviations: ATV/r, atazanavir plus ritonavir; DRV/r, darunavir plus ritonavir; fAPV/r, fosamprenavir plus ritonavir; LPV/r, lopinavir plus ritonavir; NR, not reported; PI/r, protease inhibitor plus ritonavir; SQV/r, saquinavir plus ritonavir.

[a] Diarrhea at least possibly related to or related to study drug treatment.

[b] Safety population.

PIs										
ATV[v]			**Hyperbiliru-binaemia,** Jaundice, Cholelithiasis			↓ eGFR, Nephrolithiasis			Dyslipi-daemia	
DRV[v]	Rash			IHD		Nephrolithiasis			Dyslipi-daemia	
FPV[vi]	Rash			IHD					**Dyslipi-daemia**	
IDV[vi]	**Dry skin,** Nail dystrophy	**Nausea and Diarrhoea**[vii]	Jaundice	IHD		**Nephrolithiasis**		**↑ Abdominal fat**	**Dyslipi-daemia,** Diabetes mellitus	
LPV				IHD		↓ eGFR			**Dyslipi-daemia**	
SQV[vi]									Dyslipi-daemia	
TPV[vi]			Hepatitis				Intracranial haemorrhage		Dyslipi-daemia	
Boosting										
RTV						↓ **eGFR**[iv]				
COBI						↓ **eGFR**[iv]				

2. Yaşlılık ve komorbiditeler..

HIV and the Older Patient

Last Updated: January 28, 2016; Last Reviewed: January 28, 2016

Key Considerations When Caring for Older Patients With HIV

Key Considerations When Caring for Older Patients With HIV

- Antiretroviral therapy (ART) is recommended for all patients regardless of CD4 T lymphocyte cell count **(AI)**. ART is especially important for older patients because they have a greater risk of serious non-AIDS complications and potentially a blunted immunologic response to ART.
- Adverse drug events from ART and concomitant drugs may occur more frequently in older patients living with HIV than in younger patients with HIV. Therefore, the bone, kidney, metabolic, cardiovascular, and liver health of older patients should be monitored closely.
- Polypharmacy is common in older patients with HIV; therefore, there is a greater risk of

ART ilişkili toksisiteler ileri yaşta daha sık
Kemik, böbrek, KVS, metabolik ve
karaciğer hastalıkları yakın izlenmeli

important aspect of the care of the older patient with HIV.

DHHS 2017

Switching, Interrupting, and Discontinuing Antiretroviral Therapy in Older Patients

Given the greater incidence of comorbidities, non-AIDS complications and frailty among older patients with HIV, switching one or more ARVs in an HIV regimen may be necessary to minimize toxicities and drug-drug interactions. For example, expert guidance now recommends bone density monitoring in men aged ≥50 years and postmenopausal women, and suggests switching from tenofovir disoproxil fumarate or boosted protease inhibitors to other ARVs in older patients at high risk for fragility fractures.[45]

Few data exist on the use of ART in severely debilitated patients with chronic, severe, or non-AIDS

risks and benefits of continuing or withdrawing ART.

Non-AIDS komlikasyonlar ve komorbiditelerin insidansı yüksek
Özellikle menapoz sonrası kadınlarda TDF ve PI ile yüksek kırık riski
Tedavi değişimi ile toksisitelerin minimize edilmesi gerekebilir

HIV Clin Trials. 2017 May;18(3):118-125. doi: 10.1080/15284336.2017.1330440. Epub 2017 May 30.

Simplification to single-tablet regimen of elvitegravir, cobicistat, emtricitabine, tenofovir DF from multi-tablet ritonavir-boosted protease inhibitor plus coformulated emtricitabine and tenofovir DF regimens: v

Pharmacotherapy. 2016 Apr;36(4):385-401. doi: 10.1002/phar.1728. Epub 2016 Apr 13.

Arribas JR[1], DeJes
Nguyen T[9].

Author inforr

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Perrier M[1,2], Char
Landman R[1,3,5].

Author infor

Abs
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suppression we
due to adverse
W36 and W48, respectively. Five patient
with the selection of M184V and N155H
with pVL <20 copies/mL had a PCRneg,
with 84% of elvitegravir C 24 values >45 ng/mL, the

CONCLUSIONS: In this clinical cohort of virological
values with a high proportion maintaining virological suppression with no residual viraemia until W48.

Impact of Pill Burden on Adherence, Risk of Hospitalization, and Viral Suppression in Patients with HIV Infection and AIDS Receiving Antiretroviral Therapy.

Scott Sutton S[1], Magagnoli J[2], Hardin JW[3].

Author information

Abstract

STUDY OBJECTIVE: To evaluate the impact of pill burden on outcomes in patients with human immunodeficiency virus (HIV) infection and acquired immune deficiency syndrome (AIDS) receiving antiretroviral therapy (ART) as a single-tablet regimen (STR) or multiple-tablet regimen (MTR).

DESIGN: Retrospective cohort study.

DATA SOURCES: South Carolina Medicaid medical and pharmacy paid claims data were obtained from the South Carolina Revenue and Fiscal Affairs Office; laboratory data were obtained from the South

Medicaid eligibility; or death. Differences in outcomes were evaluated by using bivariate χ(2) and Wilcoxon rank sum tests, as well as multivariate regression models controlling for covariates measured during a 6-month baseline period. The STR and MTR cohorts were, on average, similar in terms of age at index date, Charlson Comorbidity Index score, sex, drug abuse, and mental health diagnoses, but they

Methods: A retrospective analysis was conducted on 75 HIV-1 infected, treatment-experienced adults from 2 French centers (Rennes, Saint-Malo). The inclusion criteria were:

lvitegravir (EVG) or
ɔite archived resistant

M. Dupont4, F. Fily4, M.
t5, C. Arvieux3,5, V.
nnes, France, 3COREVIH
5CHU Pontchaillou,

id-transfer inhibitor
load (VL).

Tek tablet rejime tedavi modifikasyonu ile virolojik süpresyon ve uyum artarken, hospitalizasyon ve hastalık progresyonu azalıyor

Olgu 3
Tedavi modifikasyonu

- Menapoz sonrası 55 yaşında kadın
- Osteoporoz riski yüksek
- Malignite,
- KVH riski yüksek
- PI ilişkili GIS yan etkiler…

- **Kullanımı kolay, etkin, güvenli, tek tablet bir rejim**

GENVOYA Tek Tablet Rejim

GENVOYA

TAF/FTC/EVG/c

Tek Tablet Rejimi

Klinik çalışmalar

5 ruhsat çalışması
(N = 3,490)

Çalışma 104:
Tedavi Deneyimsiz Yetişkinler
(N = 867)

Çalışma 111:
Tedavi Deneyimsiz Yetişkinler
(N = 866)

Çalışma 109:
HIV'i Baskılanmış Yetişkinler (Geçiş)
(N = 1436)

Çalışma 112:
Böbrek Yetmezliği olan Yetişkinler
(N = 248 Tedavi Deneyimli veya Deneyimsiz)

Çalışma 106:
Tedavi Deneyimsiz Adolesanlar(n = 50)
HIV'i Baskılanmış Çocuklar (n=23) *

1 kadınlarda yapılan çalışma

WAVES OLE:
HIV'i baskılanmış Yetişkin Kadınlar
(TDF'ye dayalı bir rejimden geçiş)

Karşılanmamış tıbbi ihtiyaçları destekleyen 2 ilave çalışma

Çalışma 119:
E/C/F/TAF + DRV'ye Basitleştirme
(N = 135)

Çalışma 1249:
HIV/HBV ile Koenfekte Yetişkinler
(N = 72)

* 6-11 yaş arası çocukların verileri prospektüse dahil edilmemiştir

SONUÇLAR

- Tedavi deneyimsiz hastalarda 144. hafta sonunda virolojik başarı:% 84
- HIV'i baskılanmış olup geçiş yapılan hasta grubunda 96. hafta sonunda virolojik başarı:%93
- eGFR≥30 ml/dak hasta grubunda güvenli
- Deneyimsiz ve deneyimli hastalarda proteinüride ve KMY'de anlamlı düzelme
- Tübülopati ve Fanconi sendromu olgusu yok
- Böbrek ve KMY üzerine olumsuz etkiler nedeniyle tedaviyi bırakma oranı <%1
- Hepatit B ile koenfekte hastalarda etkin

Sonuç olarak;

Genvoya tek tablet rejim

- Kullanım kolaylığı
- Yüksek etkinlik
- Güvenilir