Hızlı tedavi: Artıları/Eksileri

Dr Özlem Altuntaş Aydın

Başakşehir Çam ve Sakura Şehir SUAM

DHHS

FACTOR	RECOMMENDATION FOR TREATMENT						
AIDS	Treat	Treat	Treat	Treat	Treat	Treat	Treat
CD4	<500	• Recommended at <200 • Offer at <350 • Individualize decision at >350			• Recommended <350 • Risks/Benefits >350	• Recommended <500 • Favor/Optional >500	• Recommended for any CD4 cell counts
Viral Load	>20,000		>55,000	>100,000	Any viral load		Any viral load
Other Factors					Pregnant women HBV co-infected HIVAN		ART is also recommended for HIV-infected individuals for the prevention of HIV transmission

DHHS Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents Available at: http://www.aidsinfo.nih.gov/Guideline

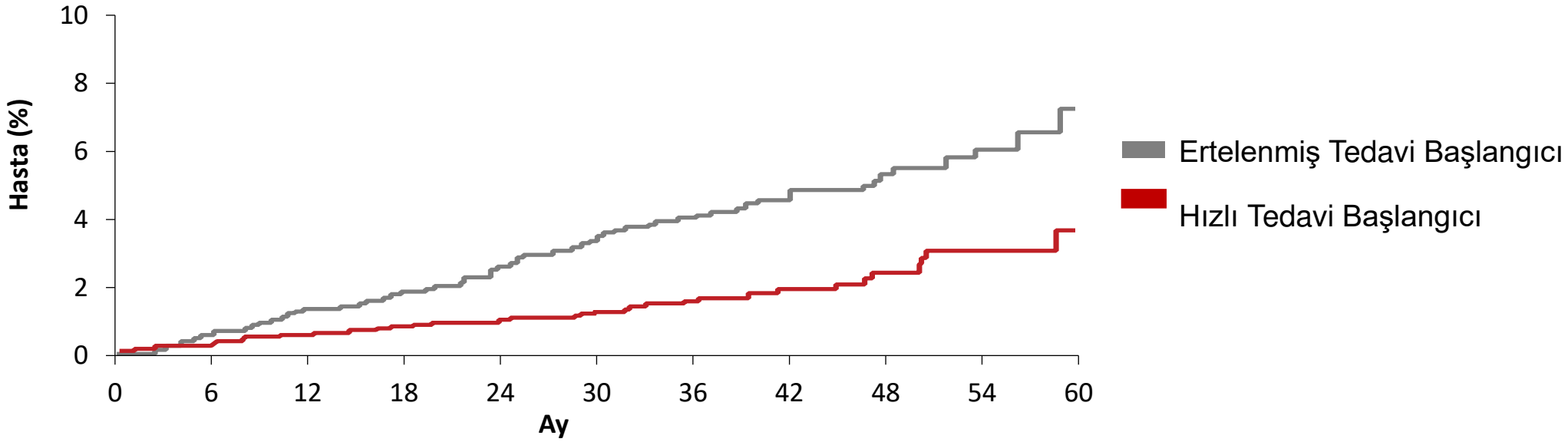
Erken tedavi

START
International

TEMPRANO
Africa Ivory Coast

İlk Birincil Olaya Kadar Geçen Süre

(Ciddi AIDS ilişkili olay veya Ciddi AIDS ilişkisiz olaylar, Ölüm dahil)



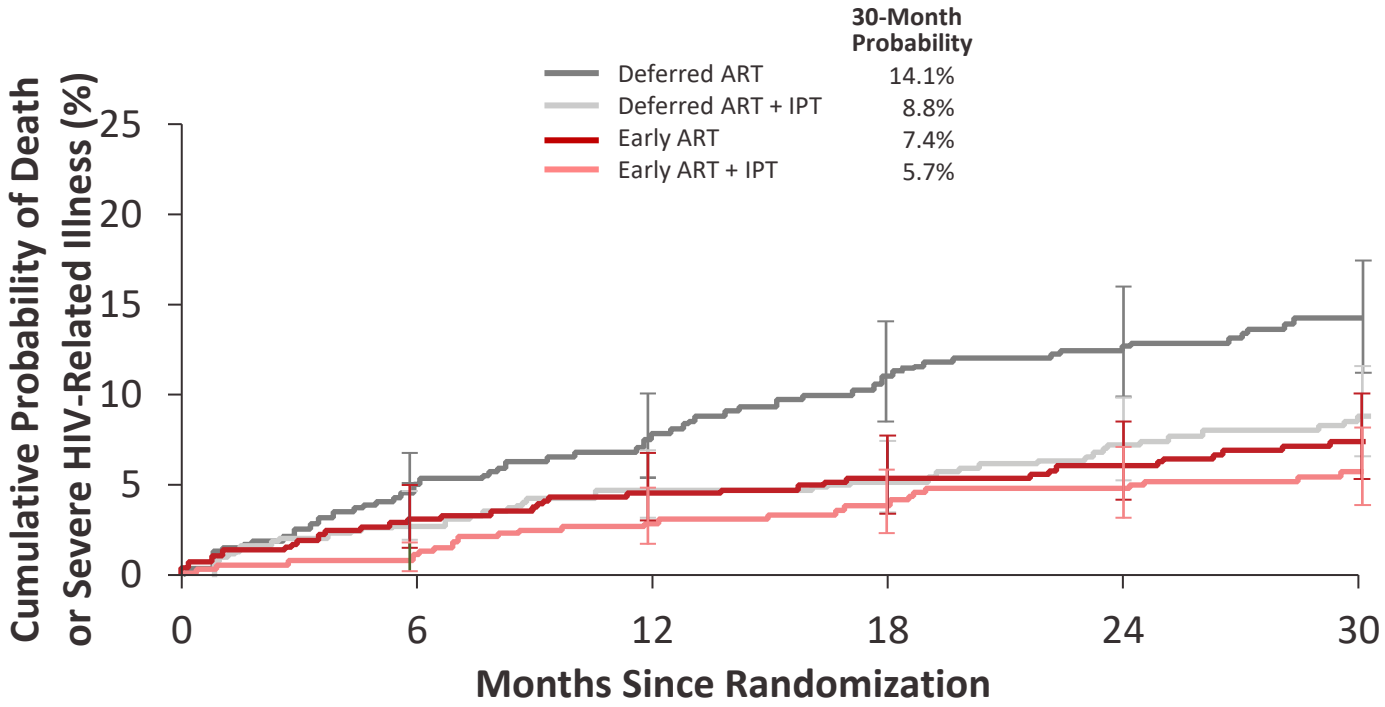
Tahmini Yüzde

Hızlı Tedavi Başlangıcı	0.2	0.6	0.8	0.9	1.2	1.5	2.0	2.5	3.1	3.7
Ertelenmiş Tedavi Başlangıcı	0.5	1.2	1.8	2.4	3.3	4.1	4.6	5.3	5.9	7.4

CD4 > 500 hücre/mm^3 hastalarda hızlı tedavi başlangıcı, CD4 <350 hücre/mm^3 seviyelerine düşüşe kadar ertelenmiş Tedavi Başlangıcından daha üstündür (HR 0.43, p değeri <0.001)

The INSIGHT START Study Group. N Engl J Med 2015;373:795-807

TEMPRANO



Erken tedavi alanlarda ölüm veya ciddi HIV-ilişkili hastalık riski daha düşük (aHR 0.56; 95% CI, 0.41 - 0.76)

The TEMPRANO ANRS 12136 Study Group. N Eng J Med. 2015;373:808-822.

J Antimicrob Chemother 2016; 71: 2654–2662
doi:10.1093/jac/dkw196 Advance Access publication 20 June 2016

Journal of Antimicrobial Chemotherapy

CD4 cell count at initiation of ART, long-term likelihood of achieving CD4 >750 cells/mm^3 and mortality risk

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†HOPS Investigators are listed in the Acknowledgements section.

Received 15 December 2015; returned 29 January 2016; revised 14 April 2016; accepted

Objectives: We sought to evaluate associations between CD4 at ART initiation (AI), ach cells/mm^3 (CD4 >750), long-term immunological recovery and survival.

Methods: This was a prospective observational cohort study. We analysed data from ART-nai 1996–2012 and followed ≥3 years after AI. We used Kaplan–Meier (KM) methods and log-ran time to achieving CD4 >750 by CD4 at AI (CD4-AI); and Cox regression models and gene equations to identify factors associated with achieving CD4 >750 and mortality risk.

Results: Of 1327 patients, followed for a median of 7.9 years, >85% received ART for ≥75% 64 died. KM estimates evaluating likelihood of CD4 >750 during 5 years of follow-up, stratifi 50–199, 200–349, 350–499 and 500–750, were 20%, 25%, 56%, 80% and 87%, resp $P<0.001$). In adjusted models, CD4-AI ≥200 (versus CD4-AI <200) was associated with a >750 (adjusted HR (aHR) = 4.77). Blacks were less likely than whites to achieve CD4 >750 aHR = 0.77). Mortality rates decreased with increasing CD4-AI ($P = 0.004$ across CD4 strat and $P = 0.009$ for non AIDS death causes). Among decedents with CD4 AI ≥50, 56% of d non AIDS causes.

Conclusions: Higher CD4-AI resulted in greater long-term CD4 gains, likelihood of achieving survival and decreased mortality regardless of cause. Over 80% of persons with CD4-AI ≥ >750 by 4 years while 75% of persons with CD4-AI <200 did not. These data confirm the l AI and support early AI.

OPEN ACCESS Freely available online

PLOS ONE

Closing the Gap: Increases in Life Expectancy among Treated HIV-Positive Individuals in the United States and Canada

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Abstract

Background: Combination antiretroviral therapy (ART) has significantly increased survival among HIV-positive adults in the United States (U.S.) and Canada, but gains in life expectancy for this region have not been well characterized. We aim to estimate temporal changes in life expectancy among HIV-positive adults on ART from 2000–2007 in the U.S. and Canada.

Methods: Participants were from the North American AIDS Cohort Collaboration on Research and Design (NA-ACCORD), aged ≥20 years and on ART. Mortality rates were calculated using participants' person-time from January 1, 2000 or ART initiation until death, loss to follow-up, or administrative censoring December 31, 2007. Life expectancy at age 20, defined as the average number of additional years that a person of a specific age will live, provided the current age-specific mortality rates remain constant, was estimated using abridged life tables.

Results: The crude mortality rate was 19.8/1,000 person-years, among 22,937 individuals contributing 82,022 person-years and 1,622 deaths. Life expectancy increased from 36.1 [standard error (SE) 0.5] to 51.4 [SE 0.5] years from 2000–2002 to 2006–2007. Men and women had comparable life expectancies in all periods except the last (2006–2007). Life expectancy was lower for individuals with a history of injection drug use, non-whites, and in patients with baseline CD4 counts <350 cells/mm^3.

Conclusions: A 20-year-old HIV-positive adult on ART in the U.S. or Canada is expected to live into their early 70 s, a life expectancy approaching that of the general population. Differences by sex, race, HIV transmission risk group, and CD4 count remain.

Erken tedavi

START
International

TEMPRANO
Africa Ivory Coast

Hızlı tedavi

RapIT
South Africa

Same Day ART
Haiti

Retrospective Cohort
China

SLATE
South Africa and Kenya

RAPID
San Francisco

Duke/UNC Acute HIV Consortium
North Carolina

Emory/Grady REACH
Atlanta

CrescentCare FQHC
New Orleans

RESEARCH ARTICLE

Initiating Antiretroviral Therapy for HIV at a Patient's First Clinic Visit: The RapIT Randomized Controlled Trial

Sydney Rosen[1,2]*, Mhairi Maskew[2], Matthew P. Fox[2,3], Cynthia Nyoni[2], Constance Mongwenyana[2], Given Malete[2], Ian Sanne[2], Dorah Bokaba[4], Celeste Sauls[2], Julia Rohr[1], Lawrence Long[2]

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Citation: Rosen S, Maskew M, Fox MP, Nyoni C, Mongwenyana C, Malete G, et al. (2016) Initiating Antiretroviral Therapy for HIV at a Patient's First Clinic Visit: The RapIT Randomized Controlled Trial. PLoS Med 13(5): e1002015. doi:10.1371/journal.pmed.1002015

Academic Editor: Agnes Binagwaho, Rwanda Ministry of Health, RWANDA

Received: November 17, 2015

Accepted: March 22, 2016

Published: May 10, 2016

Data Availability Statement: Data will be made publicly available in the Dryad repository (http://www.datadryad.org/) after the protocol has been closed (anticipated closure June 2018). Until then, data will remain under the supervision of the University of the Witwatersrand Human Research Ethics Committee (HREC). Requests should be sent to the HREC Research Administrator at: https://www.wits.ac.za/research/about-our-research/ethics-and-research-integrity/human-research-ethics-committee-medical/.

Funding: Funding for this study was provided by the U.S. National Institutes of Health (National Institute of Allergy and Infectious Diseases) under the terms of grant 1U01AI100015 to Boston University. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Competing Interests: The authors have declared that no competing interests exist.

Abbreviations: ALT, alanine aminotransferase; aRR, adjusted risk ratio; ART, antiretroviral therapy; ARV, antiretroviral; IQR, interquartile range; CI, confidence interval; HR, hazard ratio; PHC, primary health clinic; POC, point-of-care; RapIT, Rapid Initiation of Treatment; RD, risk difference; RR, relative risk; TB, tuberculosis.

Abstract

Background

High rates of patient attrition from care between HIV testing and antiretroviral therapy (ART) initiation have been documented in sub-Saharan Africa, contributing to persistently low CD4 cell counts at treatment initiation. One reason for this is that starting ART in many countries is a lengthy and burdensome process, imposing long waits and multiple clinic visits on patients. We estimated the effect on uptake of ART and viral suppression of an accelerated initiation algorithm that allowed treatment-eligible patients to be dispensed their first supply of antiretroviral medications on the day of their first HIV-related clinic visit.

Methods and Findings

RapIT (Rapid Initiation of Treatment) was an unblinded randomized controlled trial of single-visit ART initiation in two public sector clinics in South Africa, a primary health clinic (PHC) and a hospital-based HIV clinic. Adult (≥18 y old), non-pregnant patients receiving a positive HIV test or first treatment-eligible CD4 count were randomized to standard or rapid initiation. Patients in the rapid-initiation arm of the study ("rapid arm") received a point-of-care (POC) CD4 count if needed; those who were ART-eligible received a POC tuberculosis (TB) test if symptomatic, POC blood tests, physical exam, education, counseling, and antiretroviral (ARV) dispensing. Patients in the standard-initiation arm of the study ("standard arm") followed standard clinic procedures (three to five additional clinic visits over 2–4 wk prior to ARV dispensing). Follow up was by record review only. The primary outcome was viral suppression, defined as initiated, retained in care, and suppressed (≤400 copies/ml) within 10 mo of study enrollment. Secondary outcomes included initiation of ART ≤90 d of study enrollment, retention in care, time to ART initiation, patient-level predictors of primary outcomes, prevalence of TB symptoms, and the feasibility and acceptability of the intervention. A survival analysis was conducted comparing attrition from care after ART initiation between the groups among those who initiated within 90 d. Three hundred and seventy-seven patients were enrolled in the study between May 8, 2013 and August 29, 2014 (median CD4 count 210 cells/mm^3). In the rapid arm, 119/187 patients (64%) initiated treatment and were virally suppressed at 10 mo, compared to 96/190 (51%) in the standard arm (relative risk [RR] 1.26 [1.05–1.50]). In the rapid arm 182/187 (97%) initiated ART ≤90 d, compared to 136/190 (72%) in the standard arm (RR 1.36, 95% confidence interval [CI], 1.24–1.49). Among 318 patients who did initiate ART within 90 d, the hazard of attrition within the first 10 mo did not differ between the treatment arms (hazard ratio [HR] 1.06; 95% CI 0.61–1.84). The study was limited by the small number of sites and small sample size, and the generalizability of the results to other settings and to non-research conditions is uncertain.

Conclusions

Offering single-visit ART initiation to adult patients in South Africa increased uptake of ART by 36% and viral suppression by 26%. This intervention should be considered for adoption in the public sector in Africa.

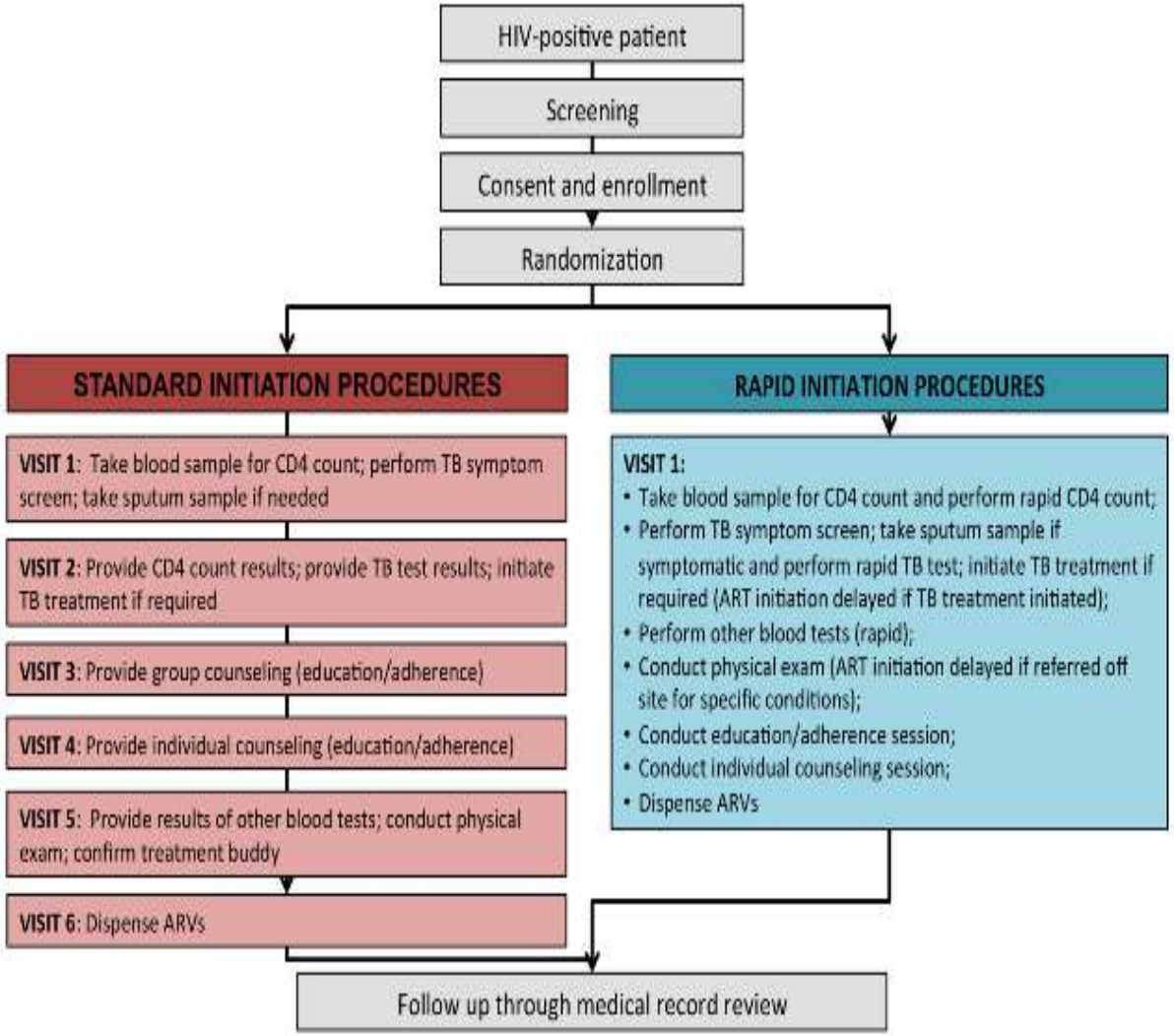


Fig 1. Standard initiation of treatment and rapid initiation procedures and visit schedule.

doi:10.1371/journal.pmed.1002015.g001

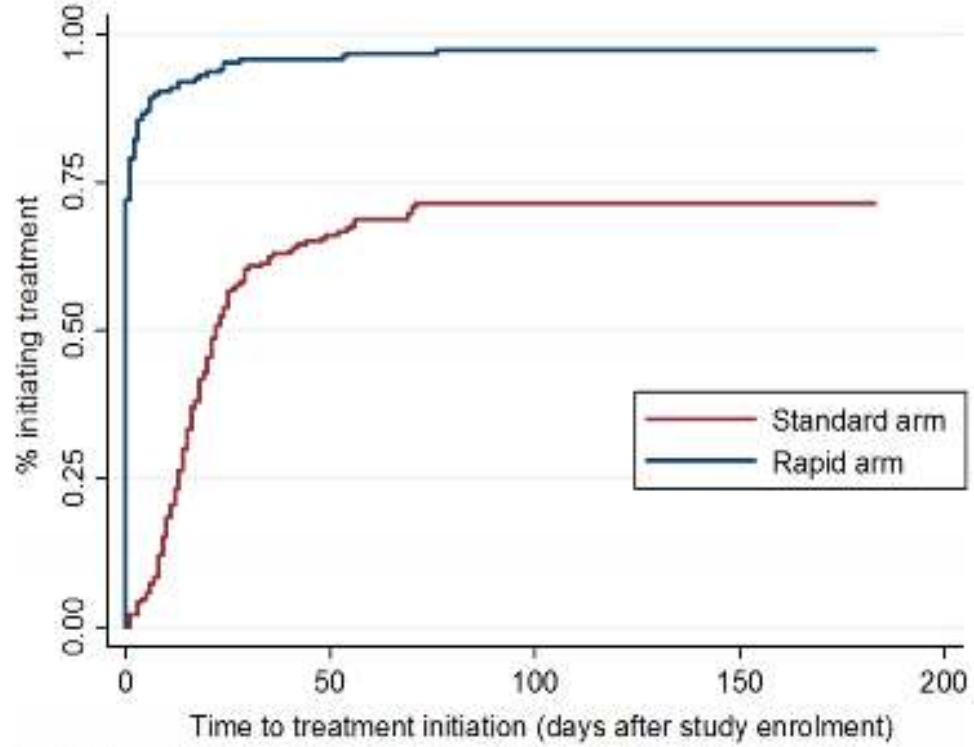
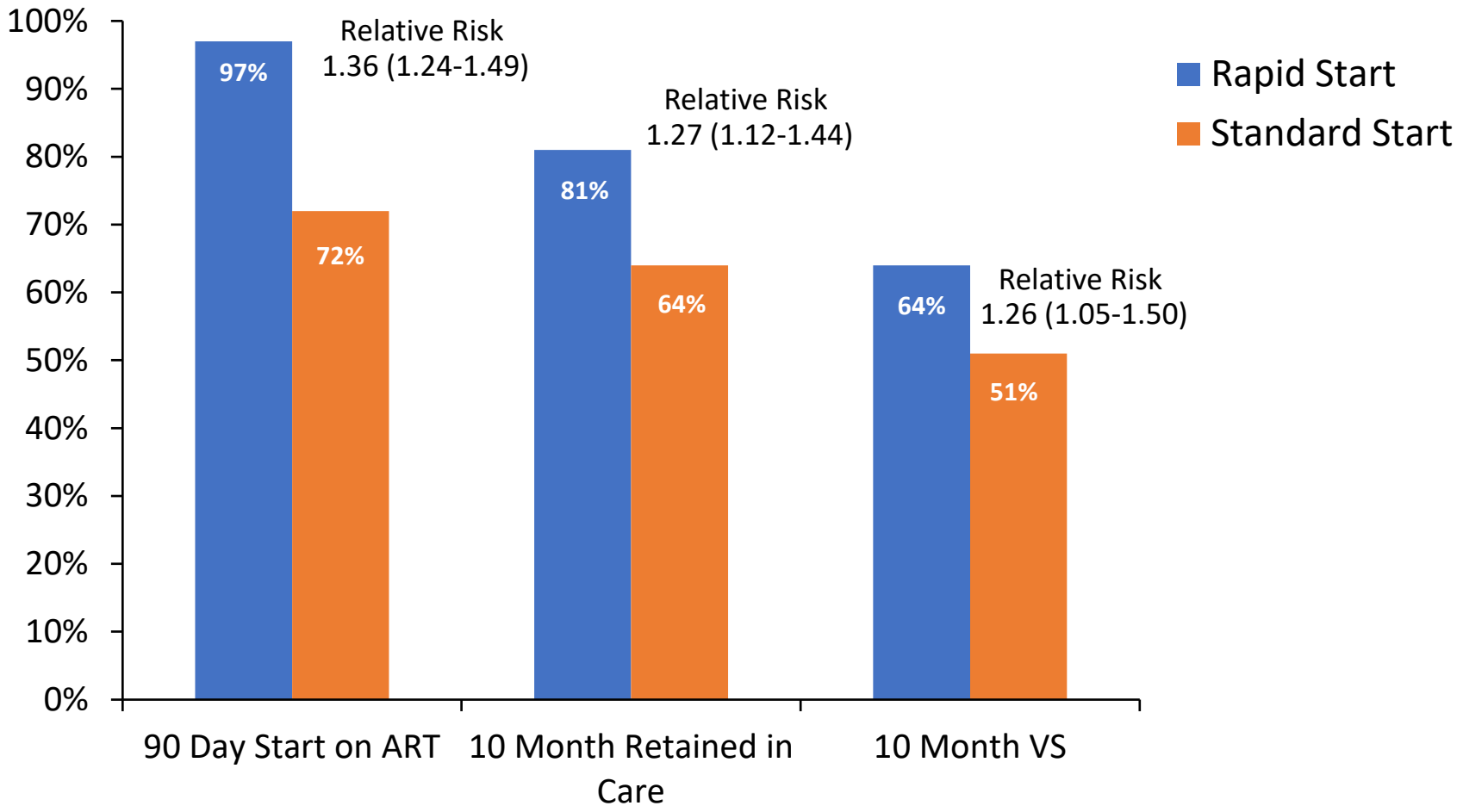


Fig 3. Time to ART initiation, by study arm. Cumulative incidence of ART initiation in each study arm, by number of days since study enrollment.

RapIT (Rapid Initiation of Treatment, Johannesburg, Güney Afrika)



Rosen, S, PLOS Medicine, 13(5): e1002015. doi:10.1371/journal.pmed.1002015 May 10, 2016

RESEARCH ARTICLE

Same-day HIV testing with initiation of antiretroviral therapy versus standard care for persons living with HIV: A randomized unblinded trial

Serena P. Koenig[1,2]*, Nancy Dorvil[1], Jessy G. Dévieux[3], Bethany L. Hedt-Gauthier[4], Cynthia Riviere[1], Mikerlyne Faustin[1], Kerlyne Lavoile[1], Christian Perodin[1], Alexandra Apollon[1], Limatha Duverger[1], Margaret L. McNairy[5,6], Kelly A. Hennessey[1], Ariadne Sourourtzidis[7], Pierre-Yves Cremieux[7], Patrice Severe[1], Jean W. Pape[1,6]

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OPEN ACCESS

Citation: Koenig SP, Dorvil N, Dévieux JG, Hedt-Gauthier BL, Riviere C, Faustin M, et al. (2017) Same-day HIV testing with initiation of antiretroviral therapy versus standard care for persons living with HIV: A randomized unblinded trial. PLoS Med 14(7): e1002357. https://doi.org/10.1371/journal.pmed.1002357

Academic Editor: Elvin H. Geng, University of California, San Francisco, UNITED STATES

Received: January 24, 2017

Accepted: June 16, 2017

Published: July 25, 2017

Data Availability Statement: We have included the anonymized dataset as a Supporting Information file (S1 Data).

Funding: This project was supported by the National Institute of Allergy and Infectious Diseases, grant number R01AI104344. The funder had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Competing interests: The authors have declared that no competing interests exist.

Abbreviations: ART, antiretroviral therapy; GHESKIO, Haitian Group for the Study of Kaposi's Sarcoma and Opportunistic Infections; IQR, interquartile range; LTFU, lost to follow-up; PPD, purified protein derivative; RR, risk ratio; SEARCH, Sustainable East Africa Research in Community Health; UNAIDS, The Joint United Nations Programme on HIV/AIDS; WHO, World Health Organization.

Abstract

Background

Attrition during the period from HIV testing to antiretroviral therapy (ART) initiation is high worldwide. We assessed whether same-day HIV testing and ART initiation improves retention and virologic suppression.

Methods and findings

We conducted an unblinded, randomized trial of standard ART initiation versus same-day HIV testing and ART initiation among eligible adults ≥18 years old with World Health Organization Stage 1 or 2 disease and CD4 count ≤500 cells/mm^3. The study was conducted among outpatients at the Haitian Group for the Study of Kaposi's Sarcoma and Opportunistic Infections (GHESKIO) Clinic in Port-au-Prince, Haiti. Participants were randomly assigned (1:1) to standard ART initiation or same-day HIV testing and ART initiation. The standard group initiated ART 3 weeks after HIV testing, and the same-day group initiated ART on the day of testing. The primary study endpoint was retention in care 12 months after HIV testing with HIV-1 RNA <50 copies/ml. We assessed the impact of treatment arm with a modified intention-to-treat analysis, using multivariable logistic regression controlling for potential confounders. Between August 2013 and October 2015, 762 participants were enrolled; 59 participants transferred to other clinics during the study period, and were excluded as per protocol, leaving 358 in the standard and 347 in the same-day ART groups. In the standard ART group, 156 (44%) participants were retained in care with 12-month HIV-1 RNA <50 copies, and 184 (52%) had <1,000 copies/ml; 20 participants (6%) died. In the same-day ART group, 184 (53%) participants were retained with HIV-1 RNA <50 copies/ml, and 212 (61%) had <1,000 copies/ml; 10 (3%) participants died. The unadjusted risk ratio (RR) of being retained at 12 months with HIV-1 RNA <50 copies/ml was 1.21 (95% CI: 1.04, 1.38; $p = 0.015$) for the same-day ART group compared to the standard ART group, and the unadjusted RR for being retained with HIV-1 RNA <1,000 copies was 1.18 (95% CI: 1.04, 1.31; $p = 0.012$). The main limitation of this study is that it was conducted at a single urban clinic, and the generalizability to other settings is uncertain.

Conclusions

Same-day HIV testing and ART initiation is feasible and beneficial in this setting, as it improves retention in care with virologic suppression among patients with early clinical HIV disease.

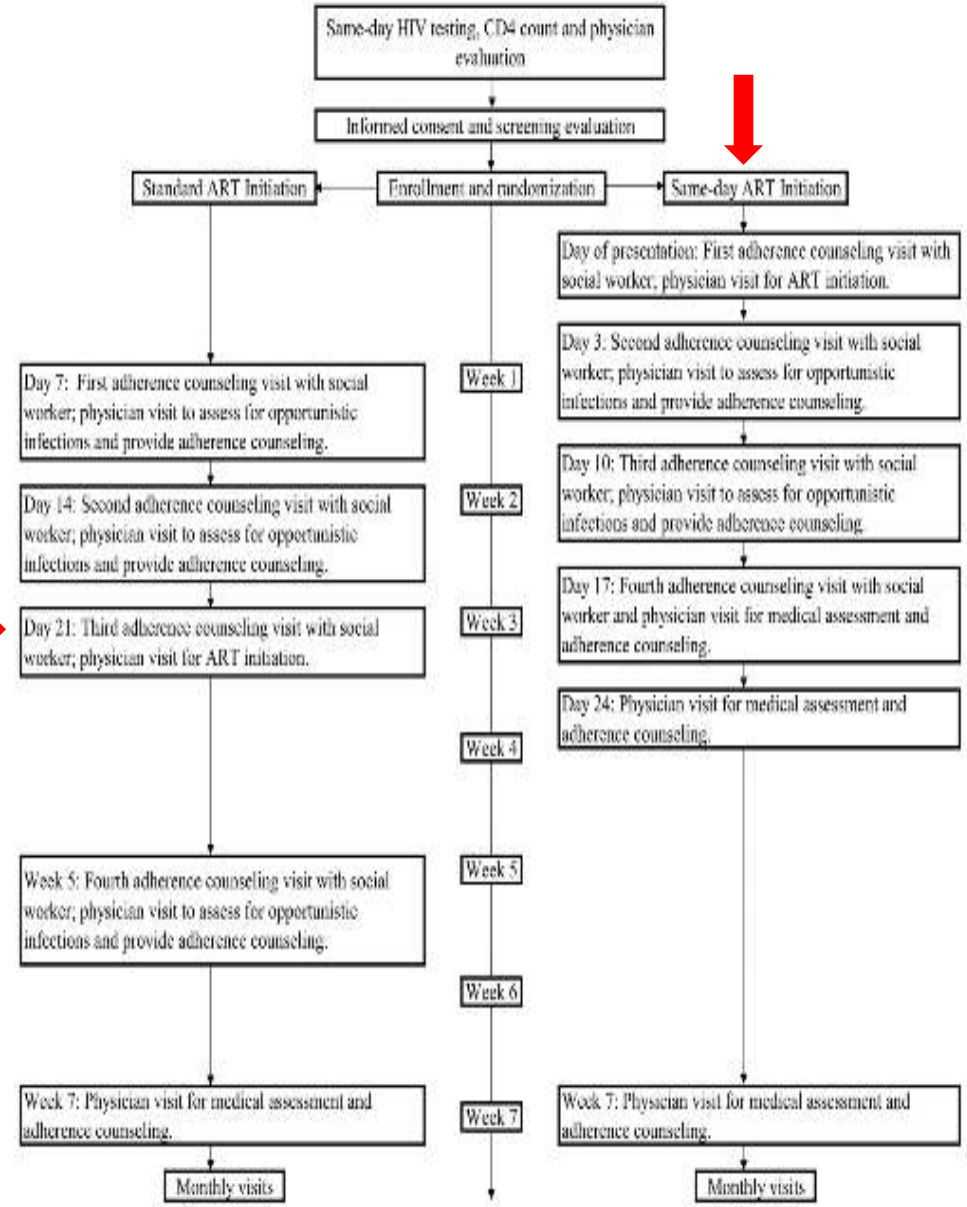
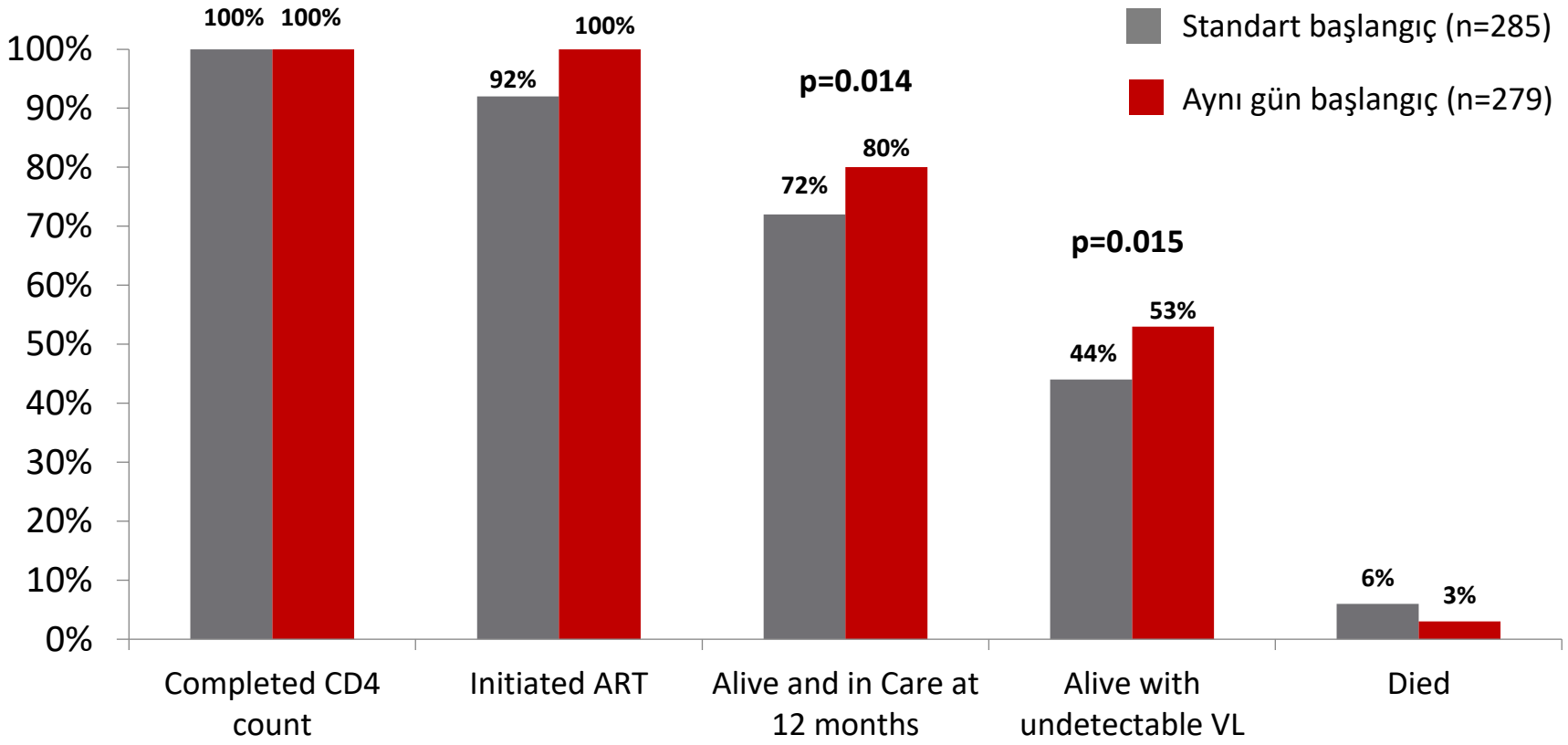


Fig 1. Study interventions for the standard ART and same-day ART groups.

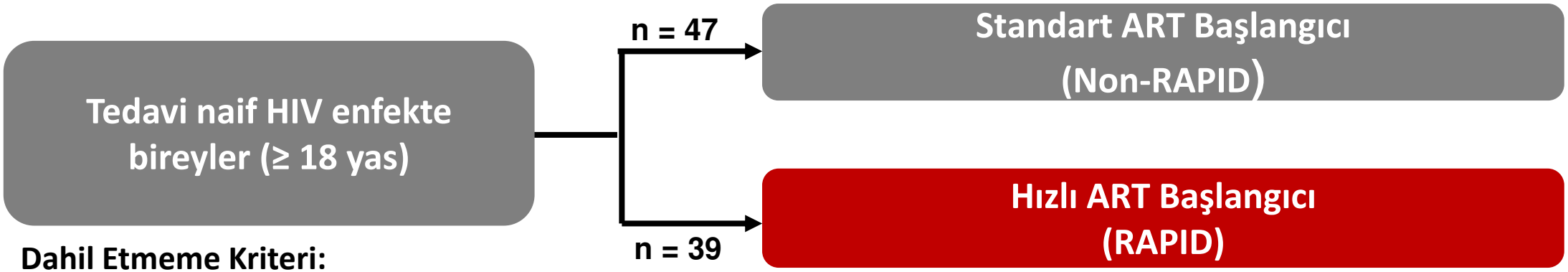
Aynı gün ART (Port-au-Prince, Haiti)



Aynı gün ART ile
daha yüksek oranda tedavide kalım ve virolojik supresyon
Ölüm oranında azalma

San Francisco RAPID Çalışması

Retrospektif historik kohortlarla kombine edilmiş tek merkezli çalışma (2013 – 2014)



Dahil Etmeme Kriteri:

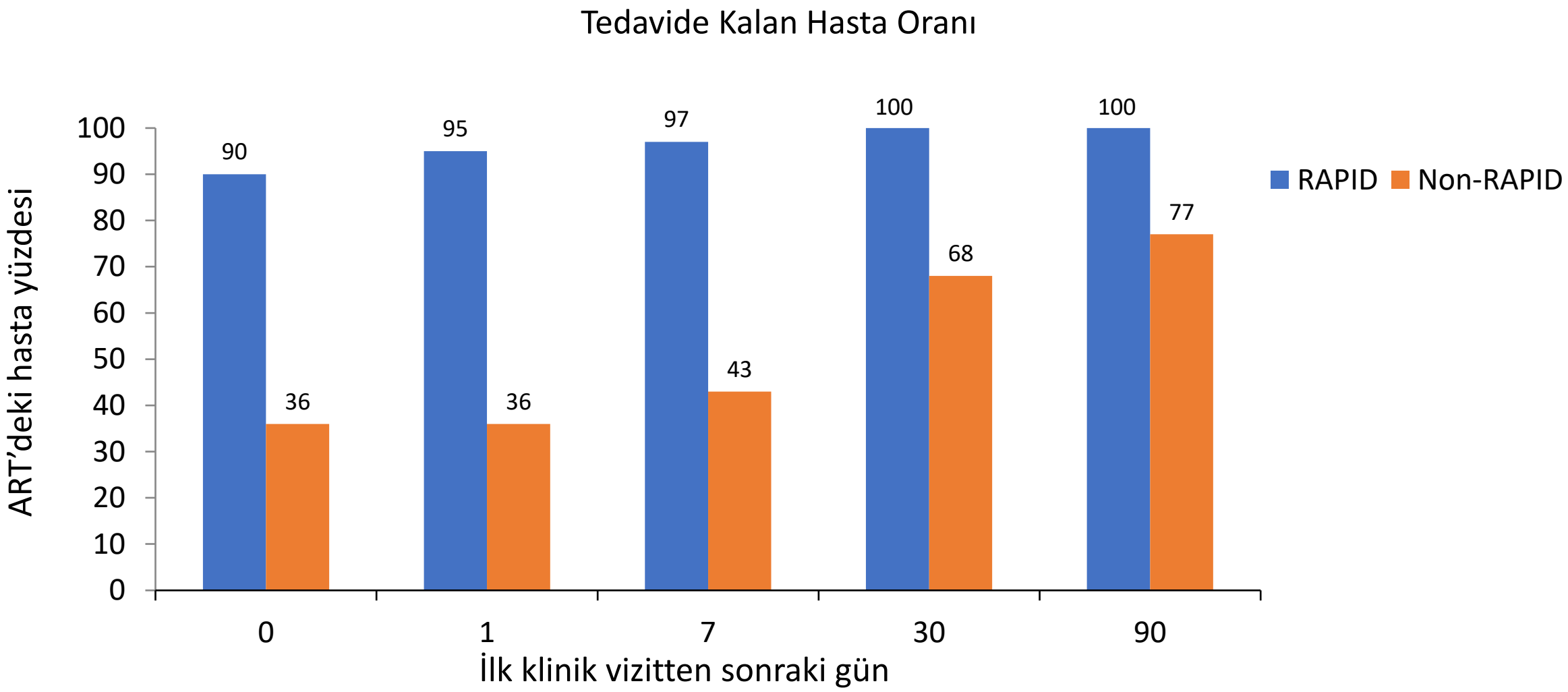
- Tanı > 6 aydan daha önce

Amaç: ART'nin mümkün olan en kısa sürede önerilmesi tercihen aynı gün

- **Primer Analizler (RAPID vs. non-RAPID)**
  - Viral Süpresyona kadar geçen süre (<200 kopya/mL)
  - İlk klinik vizite, ilk birinci basamak visite ve ART başlangıcına kadar olan süre
- **Sekonder Analizler (pre-RAPID/post-RAPID)**
  - Viral Süpresyona kadar geçen süre (<200 kopya/mL)

Pilcher C, et al. JAIDS 2017;74:44-51

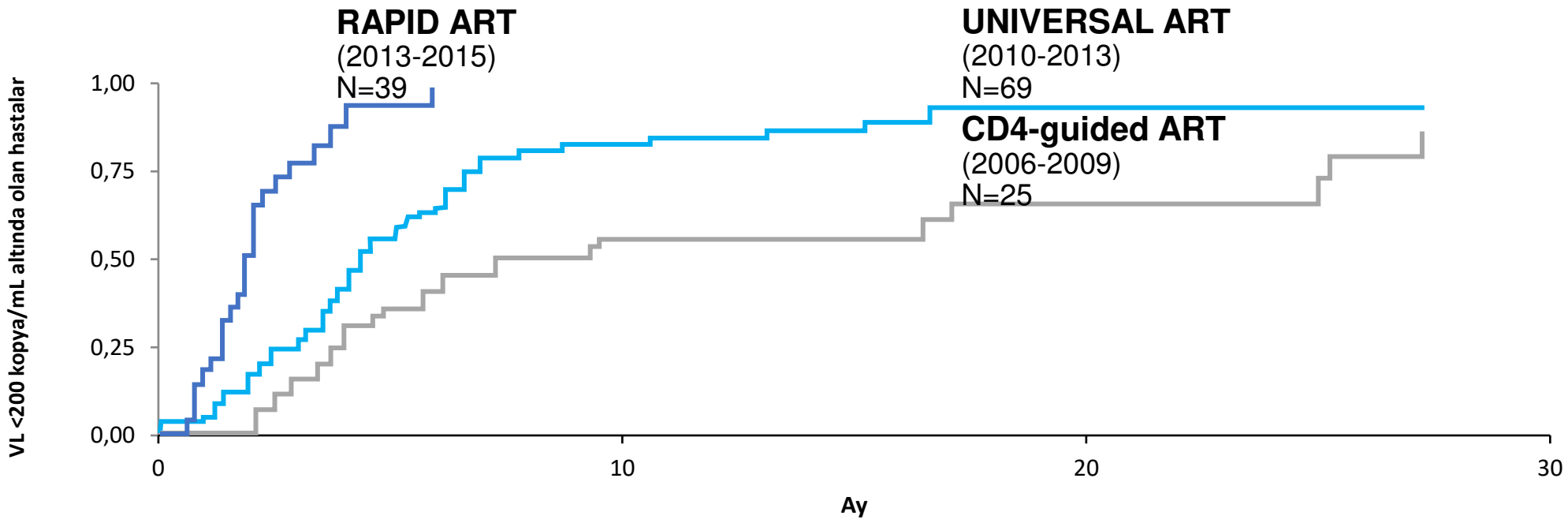
San Francisco RAPID Çalışması



Gün 0 = İlk dozunu klinikteki ilk ziyaretlerinde alanlar
Gün 1 = İlk dozunu klinikteki ilk ziyaretlerinden sonraki 24 saatte alanlar

San Francisco RAPID Çalışması

Viral Süpresyona Kadar Geçen Süre



Tedavi Stratejisi (Uygulandığı Yıllar)	Hastalar (n)	Viral Supresyon kada geçen süre (ay) (<200 c/mL)	P değeri vs RAPID
RAPID (2013-2015)	39	1.8	
Universal ART (2010-2013)	69	4.3	<0.0001
CD4 Guided (2006-2009)	25	7.2	<0.0001

AIDS. 2019 April 01; 33(5): 825–832. doi:10.1097/QAD.0000000000002124.

RAPID antiretroviral therapy: high virologic suppression rates with immediate antiretroviral therapy initiation in a vulnerable urban clinic population

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[a]Division of HIV, Infectious Diseases and Global Medicine

[b]Department of Epidemiology and Biostatistics, University of California, San Francisco (UCSF)

[c]San Francisco Department of Public Health, San Francisco, California, USA

Abstract

Objective: Little is known about long-term viral suppression rates for patients who start antiretroviral therapy (ART) soon after diagnosis. We describe virologic outcomes from the San Francisco-based Ward 86 Rapid ART Program for Individuals with an HIV Diagnosis (RAPID) ART program.

Design: Retrospective review of clinic-based cohort.

Methods: In 2013, Ward 86 adopted immediate ART at the first visit after HIV diagnosis. Patients were referred from testing sites, offered same or next-day intakes, and received multidisciplinary evaluation, support, and insurance enrollment/optimization. Patients were provided ART starter packs and close follow-up. Demographics and labs were extracted from medical records. Subsequent viral loads were obtained from public health surveillance data. Kaplan–Meier curves summarized distribution of times to first viral suppression; viral suppression rates at last viral load recorded were calculated.

Results: Of 225 patients referred to RAPID ART from 2013 to 2017, 216 (96%) were started on immediate-ART: median age 30; 7.9% women; 11.6% African-American, 26.9% Hispanic, 36.6% white; 51.4% with substance use; 48.1% with mental health diagnoses; 30.6% unstably housed; baseline median CD4+ cell count 441 cells/μl median viral load 37011. By 1 year after intake, 95.8% achieved viral suppression to less than 200 cells/μl at least once. Over a median follow-up time of 1.09 years (0–3.92), 14.7% of patients had viral rebound, but most (78%) resuppressed. Viral suppression rates were 92.1% at last recorded viral load.

Conclusion: In an urban clinic with high rates of mental illness, substance use and housing instability, immediate ART provided through a RAPID program resulted in viral suppression at last viral load measurement for more than 90% of patients over a median of 1.09 years. RAPID ART for vulnerable populations is acceptable, feasible, and successful with multidisciplinary care and municipal support.

Baseline Characteristic	Retrospective Cohort (N = 216)
Median age at HIV diagnosis, yrs (range)	30 (16-61)
Female/transgender female, n (%)	17 (7.9)/1 (0.5)
Race/ethnicity, n (%) ▪ Black ▪ Latinx/Hispanic ▪ White	 25 (11.6) 58 (26.9) 79 (36.6)
Health challenges, % ▪ Substance use disorder ▪ Major mental health disorder ▪ Homeless/unstable housing	 51.4 48.1 30.6
Median CD4+ cell count, cells/mm^3	441 (3-1905)
Median HIV-1 RNA, copies/mL	37,011 (0 to > 10 million)

Güney Afrika, Haiti, Amerika Birleşik Devletleri

- Sağlık hizmetleri farklı
- Tedavi/takip katılımının önünde engeller
- Altta yatan tüberküloz vb durumlar
- Kullanılan ART rejimleri

ART'nin aynı gün başlatılması

- mümkün
- klinik sonuçları iyileştirebilir

RESEARCH ARTICLE

Too fast to stay on track? Shorter time to first anti-retroviral regimen is not associated with better retention in care in the French Dat'AIDS cohort

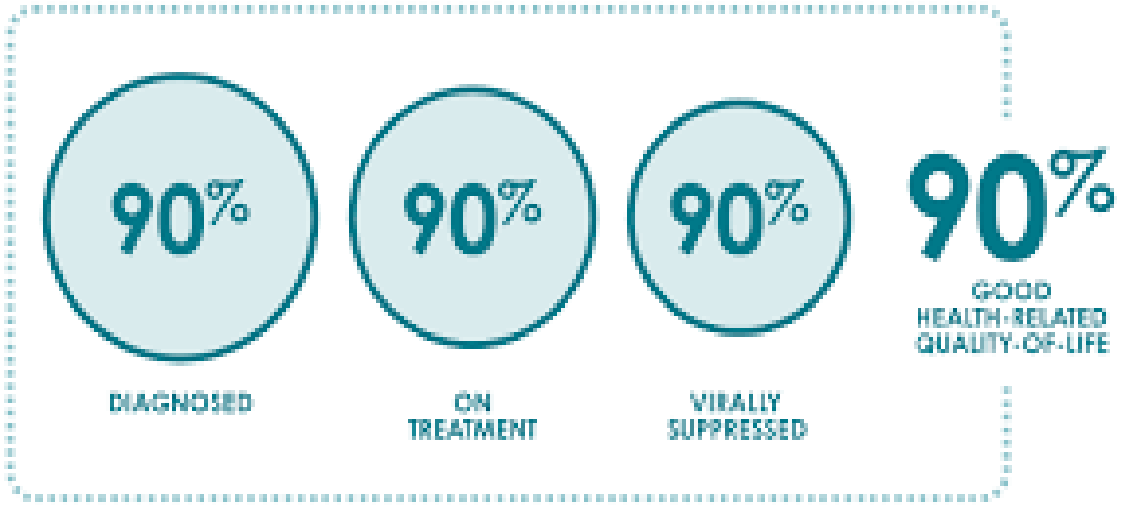
L. Cuzin[1,2]*, L. Cotte[3], C. Delpierre[2], C. Allavena[4], M-A. Valantin[5], D. Rey[6], P. Delobel[7,8], P. Pugliese[9], F. Raffi[4,10], A. Cabié[1,11], on behalf of the Dat'AIDS Study group¶

- PLWH, ART'nin avantajları, kısıtlamaları konusunda bilgilendirilmeli
- MSM ve kadınlar viral supresyonun bireysel ve toplum açısından öneminin daha farkında
- Heteroseksüel erkekler daha az motive, bilgilendirme yapılmalı
- Aktif tüberkülozu dışlamak önemli

ART konusunda aceleci davranmamalı, doğru en kısa zamanı bulmalı

Rehberler ne diyor?

- HIV enfeksiyonu onaylandıktan sonra ART mümkün olan en kısa sürede başladığında "hızlı" olarak kabul edilir
- **Hızlı (rapid) ART:** HIV tanısından sonra mümkün olan en kısa sürede (7 gün içinde)
- **Hemen (same day) ART:** Tanı günü veya ilk vizitte



Düşük/orta ve Yüksek gelirli ülkelerdeki HIV (+) bireylerin

- Tanı sırasındaki profilleri
  (tanı şekli, immün durumu, cinsel tercih, ek hastalık varlığı vb)
- Sağlık okur-yazarlığı
- Erişilen tedavi
  (yan etkiler, ilaç-ilaç etkileşimi)
- Takip olanakları
  (merkeze mesafe, ulaşım)

Yüksek gelirli

- Daha erken dönemde tanı almış
- Her türlü sağlık imkanlarının ulaşılabilir olduğu
- İstenildiği anda ART'ye erişilebilen ülkelerde

ART başlanırken hastanın daha iyi değerlendirilmesinden sonra **mümkün olan en kısa zamanda** ART başlanması ön planda

Ekonomik düzeyi daha düşük ülkelerde ise hızlı başlangıç stratejilerinin olumlu sonuçları görülmüş ve ilk olarak WHO rehberinde hızlı tedavi ön plana çıkmıştır

World Health Organization

3.2 Recommendations for rapid ART initiation

Recommendations

Rapid ART initiation[a] should be offered to all people living with HIV following a confirmed HIV diagnosis and clinical assessment.

(Strong recommendation: high-quality evidence for adults and adolescents; low-quality evidence for children)

a Rapid initiation is defined as within seven days from the day of HIV diagnosis; people with advanced HIV disease should be given priority for assessment and initiation.

ART initiation should be offered on the same day to people who are ready to start.

(Strong recommendation: high-quality evidence for adults and adolescents; low-quality evidence for children)

Good practice statement

ART initiation should follow the overarching principles of providing people-centred care. People-centred care should be focused and organized around the health needs, preferences and expectations of people and communities, upholding individual dignity and respect, especially for vulnerable populations, and should promote engaging and supporting people and families to play an active role in their own care by informed decision-making.

The introduction of the "treat all" recommendation (ART for all people living with HIV regardless of CD4 cell count) supports the rapid initiation of ART, including the offer of same-day initiation where there is no clinical contraindication.

People with no contraindication to rapid ART initiation should be fully informed of the benefits of ART and offered rapid ART initiation, including the option of same-day initiation. Rapid ART start is especially important for people with very low CD4 cell count, for whom the risk of death is high. People should not be coerced to start immediately and should be supported in making an informed choice regarding when to start ART.

Box 1. Key Recommendations for When to Start Antiretroviral Therapy (ART)

- Initiation of ART is recommended as soon as possible after HIV diagnosis, including immediately after diagnosis if the patient is ready to commit to treatment (evidence rating: AIa)
- Structural barriers that delay receipt of ART should be removed to allow newly diagnosed persons to receive ART at the first clinic visit after diagnosis if they and their clinicians determine that this approach is appropriate (evidence rating: AIa)
- Initiation of ART is recommended within 2 weeks of initiation of treatment for most opportunistic infections (evidence rating: AIa), except:
  - For individuals with tuberculosis and CD4 cell counts of 50/μL or above, ART should be initiated within 2 to 8 weeks of initiation of tuberculosis treatment (evidence rating: AIa)
  - For individuals with cryptococcal meningitis, ART should be initiated within 4 to 6 weeks after starting antifungal therapy (evidence rating: BIa)
- Initiation of ART is recommended immediately in the setting of a new diagnosis of cancer with attention to drug-drug interactions (evidence rating: BIIa)

Recommendations for Initiation of ART in PLWH with Chronic Infection without prior ART Exposure[i]

Recommendations take into account the level of evidence, the degree of progression of HIV disease and the presence of, or high risk for, developing various types of (co-morbid) conditions.

ART is recommended in all adult PLWH, irrespective of CD4 counts[I]

i ART is recommended irrespective of the CD4 count. In certain situations (i.e lower CD4 count or pregnancy), there is a greater urgency to start ART immediately

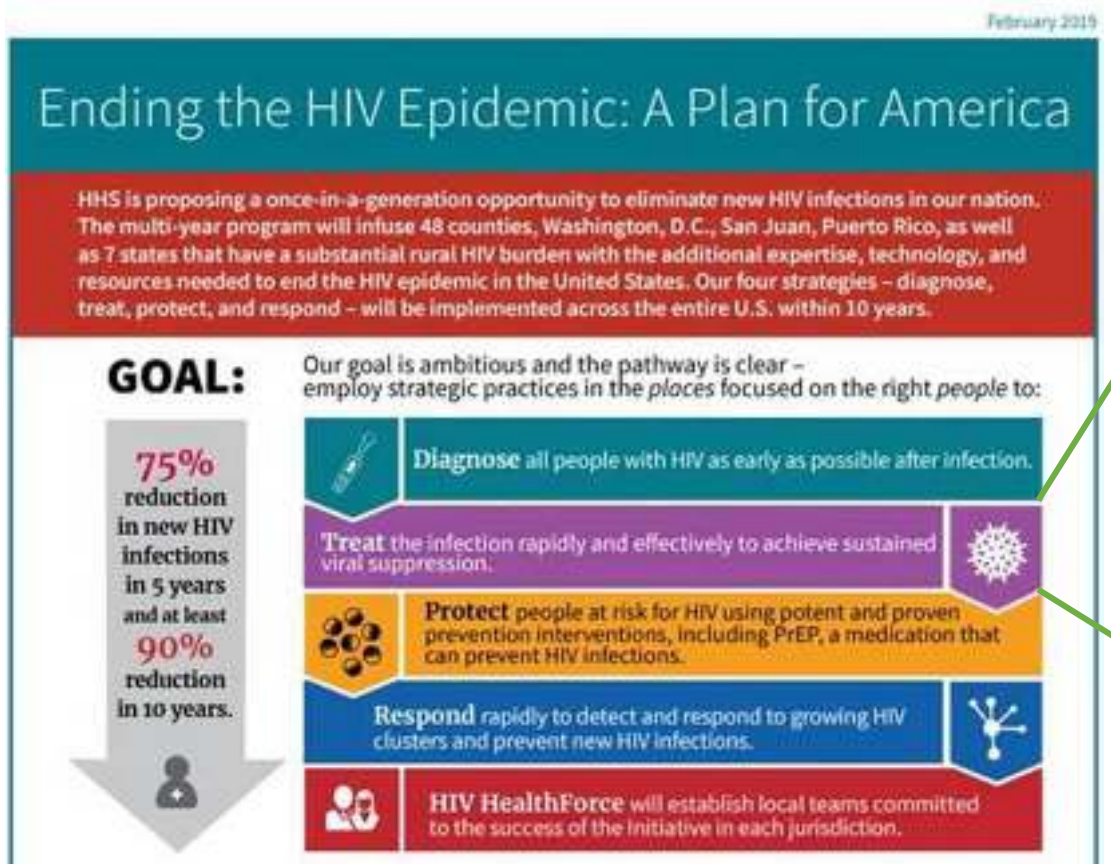
- In persons with OIs, ART initiation may have to be deferred, see page 104, for ART initiation in the presence of specific OIs. For ART initiation in persons with TB, see page 20
- A possible exception to immediate start of ART might be HIV controllers, persons with high CD4 counts and HIV-VL < 1000 copies/mL, although even in such persons ART initiation has been shown to increase CD4 count, decrease inflammation, lower the risk of clinical events and prevent HIV transmission
- Genotypic resistance testing is recommended prior to initiation of ART, ideally at the time of HIV diagnosis; otherwise before initiation of ART
- If ART needs to be initiated before genotypic testing results are available, it is recommended to select a first-line regimen with a high barrier to resistance (e.g. a PI/b, DTG or BIC combined with TDF/FTC, TAF/FTC, TDF/3TC or ABC/3TC)
- Whether rapid, possibly same-day ART start is proposed to newly diagnosed persons or postponed until complementary assessments depends on the setting and medical circumstances, medical indications to start ART more urgently and risk of loss from care. To reduce loss to follow-up between diagnosis and ART initiation, structural barriers delaying the process should be addressed

- Düşük CD4 sayısı/gebelikte acilen ART
- Fırsatçı enf olanlarda (TB vb) ertelenmek zorunda olabilir
- Hemen ART'nin istisnaları yüksek CD4 ve HIVRNA<1000 kp/ml
- ART başlamadan önce direnç testi
- Direnç testi sonucu gelmeden ART başlamak gerekiyorsa direnç bariyeri yüksek ilaçlar
- Aynı gün ted başlanması kararı hastanın klinik durumu ve tedaviden kaybedilme riskine bağlı

Initiation of Antiretroviral Therapy (Last updated December 18, 2019; last reviewed December 18, 2019)

Panel's Recommendations
• Antiretroviral therapy (ART) is recommended for all persons with HIV to reduce morbidity and mortality **(AI)** and to prevent the transmission of HIV to others **(AI)**.
• The Panel on Antiretroviral Guidelines for Adults and Adolescents recommends initiating ART immediately (or as soon as possible) after HIV diagnosis in order to increase the uptake of ART and linkage to care, decrease the time to viral suppression for individual patients, and improve the rate of virologic suppression among persons with HIV **(AII)**.
• When initiating ART, it is important to educate patients regarding the benefits of ART and to deploy strategies to optimize care engagement and treatment adherence **(AIII)**.
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*

DHHS: Hızlı ART HIV epidemisini sonlandırmaya yardımcı



Kalıcı viral supresyon

sağlamak için

hızlı ve **etkili tedavi**

uygulanmalı

DHHS. Ending the HIV Epidemic: A Plan for America. 2019. Accessed February 12, 2019.

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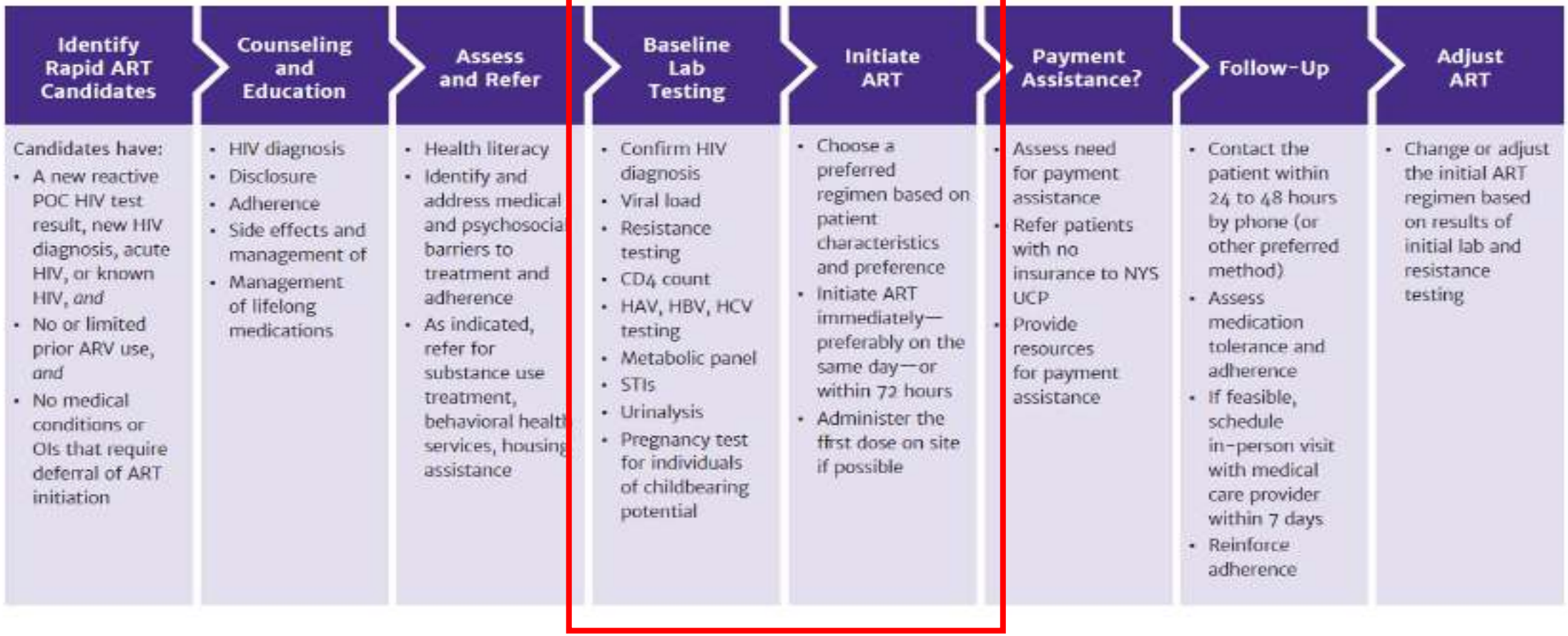
When to Initiate Antiretroviral Therapy, With Protocol for Rapid Initiation

Lead authors Asa Radix, MD, MPH, and Noga Shalev, MD, with the Medical Care Criteria Committee, updated January 2020

Note: In January 2020, the MCCC published this updated guideline, which combines two guidelines published earlier: *When to Initiate ART* and *Rapid ART Initiation*. This updated and combined guideline replaces both.

Figure 1: Protocol for Rapid ART Initiation



NYSDOH AI Clinical Guidelines Program www.hivguidelines.org

Patient Information Before Initiating Rapid ART

Need prior to start

- Patient prepared for ART and interest in rapid initiation
- Physical examination
  - Active cryptococcal meningitis or TB infection could increase risk for IRIS and *may warrant a short ART delay*
  - Other AIDS-defining conditions could increase risk of morbidity/mortality in the setting of rapid ART initiation
- Counsel on medication adherence

Not needed prior to start

- CD4+ cell count
- HIV viral load
- HIV genotype
- Resistance test results
- Hepatitis A/B/C status
- HLA-B*5701 status
- STI screening results
- Pregnancy test results

WHO Guidelines. July 2017. DHHS Guidelines. December 2019.

Slide credit: clinicaloptions.com

Hızlı ART Başlamadan Önce Yapılacaklar

Gerekli olanlar

- Normal yaşam beklentisi, tolere edilebilir tedavi hakkında güvence verin
- Hemen ART başlatmanın nedenlerini, sonuçlarını anlatın
- Fizik muayene ve hızlı lab yapın (TB, kriptokok enf değerlendirmesi)
- İlaç uyumu konusunda bilgilendirin
- U = U gibi olumlu sonuçları sunun

Gerekli olmayanlar

- CD4+ hücre sayısı
- HIV viral yük
- HIV ge
- Diren
- Hepat
- HLA-B
- CYBH test sonuçları
- Gebelik testi sonucu

- Fizik muayene ve hızlı lab yapın (TB, kriptokok enf değerlendirmesi)

3.3 Clinical considerations when implementing rapid ART initiation or same-day initiation

ART başlangıcı için artık bir gereklilik olmamasına rağmen, ilerlemiş HIV hastalığı olup olmadığını belirlemek için başlangıç CD4 sayımı yapılmalıdır

TB veya diğer fırsatçı enfeksiyonların klinik belirti ve semptomları olmayan ve kriptokokal antijen testi negatif olan kişilere profilaksi önerileriyle birlikte aynı gün ART başlanabilir

CD4 <100 / mm^3 olanlarda aynı gün kriptokokal antijen testi sonucunun alınamadığı ortamlarda, flukonazol profilaksisine başlanması ve daha sonra kriptokokal antijen tarama sonucunun negatif çıkması durumunda tedavinin kesilmesi düşünülebilir

Recommendations for Initiation of ART in P
prior ART Exposure[i]

Recommendations take into account the level of evidence, the degree of progression of HIV disease and the presence of, or high risk for, developing various types of (co-morbid) conditions.

ART is recommended in all adult PLWH, irrespective of CD4 counts[i]

TAF/FTC
TDF/FTC
TDF/3TC
ABC/3TC

PI/b
DTG
BIC

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to increase CD4 count, decrease inflammation, lower the risk of clinical events and prevent HIV transmission

- Genotypic resistance testing is recommended prior to initiation of ART, ideally at the time of HIV diagnosis; otherwise before initiation of ART
- If ART needs to be initiated before genotypic testing results are available, it is recommended to select a first-line regimen with a high barrier to resistance (e.g. a PI/b, DTG or BIC combined with TDF/FTC, TAF/FTC, TDF/3TC or ABC/3TC)

gimens for Rapid ART Initiation in Nonpregnant Adults

	Comments	Rating
	• Available as a single-tablet formulation, taken once daily. • TAF/FTC should not be used in patients with a creatinine clearance (CrCl) <30 mL/min; re-evaluate after baseline laboratory testing results are available. • Contains 25 mg of TAF, unboosted. • Magnesium- or aluminum-containing antacids may be taken 2 hours before or 6 hours after BIC; calcium-containing antacids or iron supplements may be taken simultaneously if taken with food.	A1
	• TAF/FTC should not be used in patients with CrCl <30 mL/min; re-evaluate after baseline laboratory testing results are available. • Contains 25 mg of TAF, unboosted. • Two tablets once daily. • Magnesium- or aluminum-containing antacids may be taken 2 hours before or 6 hours after DTG; calcium-containing antacids or iron supplements may be taken simultaneously if taken with food.	A1
	• Available as a single-tablet formulation, taken once daily. • Contains 10 mg TAF, boosted. • TAF/FTC should not be used in patients with CrCl <30 mL/min; re-evaluate after baseline laboratory testing results are available. • Pay attention to drug-drug interactions.	A2
	• TAF/FTC should not be used in patients with CrCl <30 mL/min; re-evaluate after baseline laboratory testing results are available.	B1
	/FTC as PrEP Since Their Last Negative HIV Test ified based on results of genotypic resistance testing.	
	• TAF/FTC should not be used in patients with CrCl <30 mL/min; re-evaluate after baseline laboratory testing results are available. • Documented DTG resistance after initiation in treatment-naive patients is rare. • Magnesium- or aluminum-containing antacids may be taken 2 hours before or 6 hours after DTG; calcium-containing antacids or iron supplements may be taken simultaneously if taken with food. • Tenofovir disoproxil fumarate (TDF) may be substituted for TAF; TDF/FTC is available as a single tablet (brand name, Truvada). • Lamivudine (3TC) may be substituted for FTC. • 3TC/TDF is also available as a single tablet.	A3
	• ABC should be avoided unless a patient is confirmed to be HLA-B*5701 negative. • RPV should be administered ***only*** in patients confirmed to have a CD4 cell count ≥200 cells/mm³ *and* a viral load <100,000 copies/mL. • EFV is not as well tolerated as other antiretroviral medications, and nonnucleoside reverse transcriptase inhibitors have higher rates of resistance.	A3

*See *Appendix: Use of Dolutegravir in Individuals of Childbearing Capacity.*

Table 2: Preferred Regimens for Rapid ART Initiation in Pregnant Adults
See also: DHHS: Recommendations for the Use of Antiretroviral Drugs in Pregnant Women with HIV Infections and Interventions to Reduce Perinatal HIV Transmission in the United States.

Regimen	Comments	Rating
Tenofovir disoproxil fumarate/ emtricitabine *and* dolutegravir* (TDF/FTC *and* DTG; Truvada *and* Tivicay)	• Should not be initiated during the first trimester (<14 weeks), gestational age measured by last menstrual period. • TDF/FTC should not be used in patients with creatinine clearance (CrCl) <50 mL/min; re-evaluate after baseline laboratory testing results are available. • Magnesium- or aluminum-containing antacids may be taken 2 hours before or 6 hours after DTG; calcium-containing antacids or iron supplements may be taken simultaneously if taken with food.	A1

Table 2: Preferred Regimens for Rapid ART Initiation in Pregnant Adults
See also: DHHS: Recommendations for the Use of Antiretroviral Drugs in Pregnant Women with HIV Infections and Interventions to Reduce Perinatal HIV Transmission in the United States.

Regimen	Comments	Rating
Tenofovir disoproxil fumarate/ emtricitabine *and* atazanavir *and* ritonavir (TDF/FTC *and* ATV *and* RTV; Truvada *and* Reyataz *and* Norvir)	• TDF/FTC should not be used in patients with CrCl <50 mL/min; re-evaluate after baseline laboratory testing results are available. • Carefully consider drug-drug interactions with RTV. • Scleral icterus from benign hyperbilirubinemia due to ATV may be a patient concern. • The recommended dose of ATV is 300 mg once daily in the first trimester; the dose increases to 400 mg once daily in the second and third trimesters when used with either TDF or a histamine-2 receptor antagonist. • This regimen can be initiated in the first trimester.	A2
Tenofovir disoproxil fumarate/ emtricitabine *and* darunavir *and* ritonavir (TDF/FTC *and* DRV/RTV; Truvada *and* Prezista *and* Norvir)	• Twice-daily DRV/RTV dosing (DRV 600 mg plus RTV 100 mg with food) is recommended in pregnancy. • TDF/FTC should not be used in patients with CrCl <50 mL/min; re-evaluate after baseline laboratory testing results are available. • Twice-daily DRV/RTV dosing (DRV 600 mg plus RTV 100 mg with food) is recommended in pregnancy. • Regimen can be initiated in the first trimester.	A2
Tenofovir disoproxil fumarate/ emtricitabine *and* raltegravir (TDF/FTC *and* RAL; Truvada *and* Isentress)	• RAL 400 mg twice daily is recommended in pregnancy, *not* once-daily RAL HD. • TDF/FTC should not be used in patients with CrCl <50 mL/min; re-evaluate after baseline laboratory testing results are available. • Administer as TDF/FTC once daily and RAL 400 mg twice daily. • The recommended dose of RAL is 400 mg twice daily without regard to food. • This regimen can be initiated in the first trimester.	A2

Artılar – Eksiler ??

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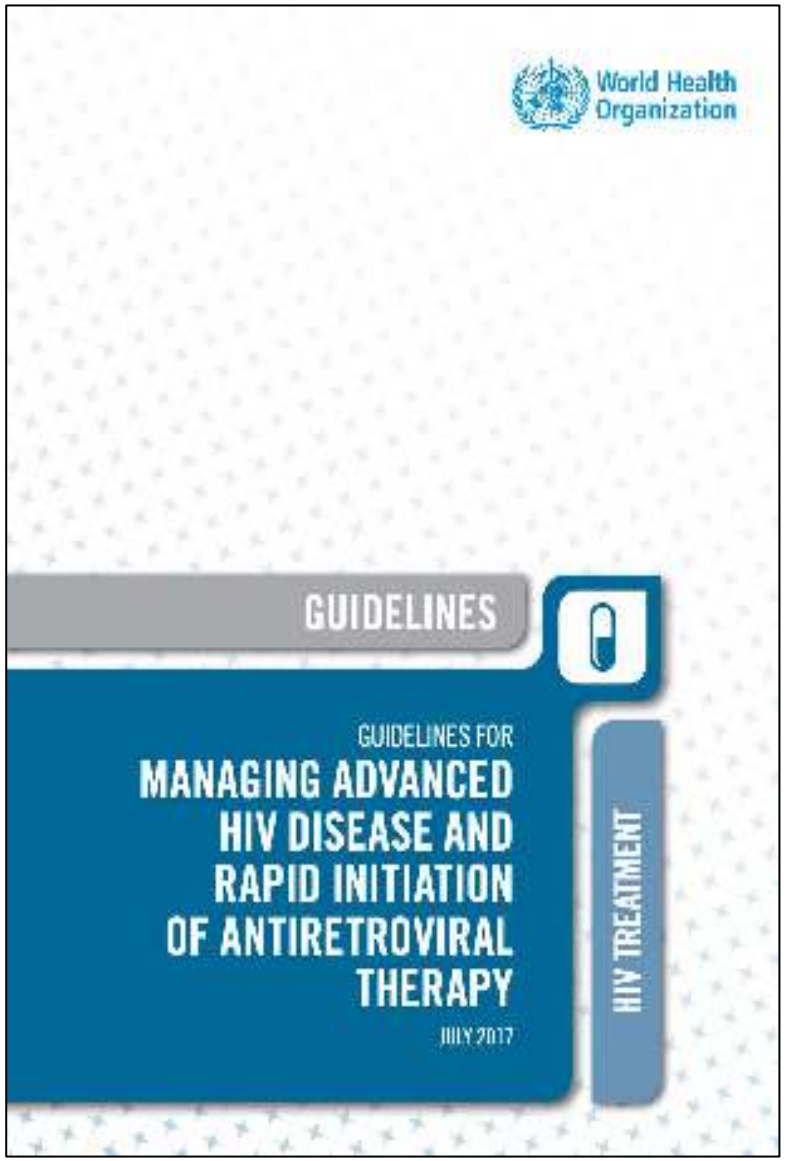

Hızlı Tedavi Başlangıcı

- Enflamasyonların, komorbiditelerin (kardiyovasküler, nörokognitif, malignensiler vb) riskini azaltarak hasta için yarar sağlamaktadır

Hospitalization Rates and Reasons Among HIV Elite Controllers and Persons With Medically Controlled HIV Infection

Trevor A. Crowell,[1] Kelly A. Gebo,[1] Joel N. Blankson,[1] P. Todd Korthuis,[2] Baligh R. Yehia,[3] Richard M. Rutstein,[4] Richard D. Moore,[1] Victoria Sharp,[6] Ank E. Nijhawan,[10] W. Christopher Mathews,[11] Lawrence H. Hanau,[7] Roberto B. Corales,[9] Robert Beil,[8] Charurut Somboonwit,[13] Howard Edelstein,[12] Sara L. Allen,[5] and Stephen A. Berry[1]; for the HIV Research Network

[1]Department of Medicine, Johns Hopkins University School of Medicine, Baltimore, Maryland; [2]Department of Public Health/Preventive Medicine, Oregon Health and Science University, Portland; [3]Department of Medicine, University of Pennsylvania Perelman School of Medicine, [4]Division of General Pediatrics, Children's Hospital of Philadelphia, and [5]Department of Medicine, Drexel University College of Medicine, Pennsylvania; [6]Center for Comprehensive Care, St Luke's Roosevelt Hospital Center, [7]Department of Medicine, Montefiore Medical Center, [8]Montefiore Medical Group, Bronx, and [9]Trillium Health, Rochester, New York; [10]Department of Internal Medicine, University of Texas Southwestern Medical Center, Dallas; [11]Department of Medicine, University of California, San Diego, and [12]Department of Internal Medicine, Alameda County Medical Center, Oakland, California; and [13]Tampa General Health Care, Florida

(See the editorial commentary by Karris and Haubrich on pages 1689–91.)

Background. Elite controllers spontaneously suppress human immunodeficiency virus (HIV) viremia but also demonstrate chronic inflammation that may increase risk of comorbid conditions. We compared hospitalization rates and causes among elite controllers to those of immunologically intact persons with medically controlled HIV.

Methods. For adults in care at 11 sites from 2005 to 2011, person-years with CD4 T-cell counts ≥350 cells/mm^2 were categorized as medical control, elite control, low viremia, or high viremia. All-cause and diagnostic category-specific hospitalization rates were compared between groups using negative binomial regression.

Results. We identified 149 elite controllers (0.4%) among 34 354 persons in care. Unadjusted hospitalization rates among the medical control, elite control, low-viremia, and high-viremia groups were 10.5, 23.3, 12.6, and 16.9 per 100 person-years, respectively. After adjustment for demographic and clinical factors, elite control was

Hızlı Tedavi Başlangıcı

- HIV bulaşma riskini azaltmaya yönelik bir yaklaşım (partnere ve anneden bebeğe)
- Özellikle seronegatif partneri olanlar için önemli
- Akut retroviral hastalık döneminde hızlıca ART başlanması bulaşma riskini daha belirgin olarak azaltır
- Latent HIV rezervuarını azaltarak gelecekteki HIV eradikasyon stratejileri için hastayı tedaviye uygun hale getirebilir. İmmün sistem korunur

- Tedavi edilmesi zor olan hasta popülasyonları (ileri evre hastalar, evsizler, uyuşturucu kullanıcıları, cinsel aktif daha genç bireyler) için tedaviye bağlılık-uyum açısından yararlı

Benefits and risks of rapid initiation of antiretroviral therapy

Nathan Ford[a,b], Chantal Migone[a], Alexandra Calmy[c], Bernhard Kerschberger[d], Steve Kanters[e], Sabin Nsanzimana[f,g], Edward J. Mills[h], Graeme Meintjes[i], Marco Vitoria[a], Meg Doherty[a] and Zara Shubber[j]

Background: Recent attention has focused on the question of how quickly antiretroviral therapy (ART) should be started once HIV diagnosis is confirmed. We assessed whether rapid ART initiation improves patient outcomes.

Methods: We searched five databases from inception up to August 2017. Rapid ART initiation was defined as initiation within 14 days of HIV diagnosis. Data were pooled using random effects meta-analysis.

Results: Across the randomized trials, ART start on the same day increased viral suppression at 12 months [three trials: relative risk (RR) 1.17, 95% confidence interval (CI) 1.07–1.27], retention in care at 12 months (RR 1.11, 95% CI 0.99–1.26), and the likelihood of starting ART within 90 days (four trials: RR 1.35, 95% CI 1.13–1.62) and 12 months after eligibility was established (three trials: RR 1.17, 95% CI 1.07–1.27). There was a nonsignificant trend toward reduced mortality (three trials: RR 0.53, 95% CI 0.24–1.08), as well as reduced loss to follow-up at 12 months (2 trials: RR 0.66, 95% CI 0.42–1.04). In the observational studies, offering accelerated ART initiation resulted in a greater likelihood of having started ART within 3 months (two studies: RR 1.53, 95% CI 1.11–2.10). There was a trend toward an increased risk of being lost to follow-up at 6 months (three studies: RR 1.85, 95% CI 0.96–3.55).

Conclusion: Accelerated ART initiation can lead to improved clinical outcomes and is likely to be of particular benefit in those settings where extensive patient preparation prior to starting ART results in long delays. These findings informed a WHO recommendation supporting accelerated ART initiation, including same day ART start.

AIDS 2018, **32**:17–23

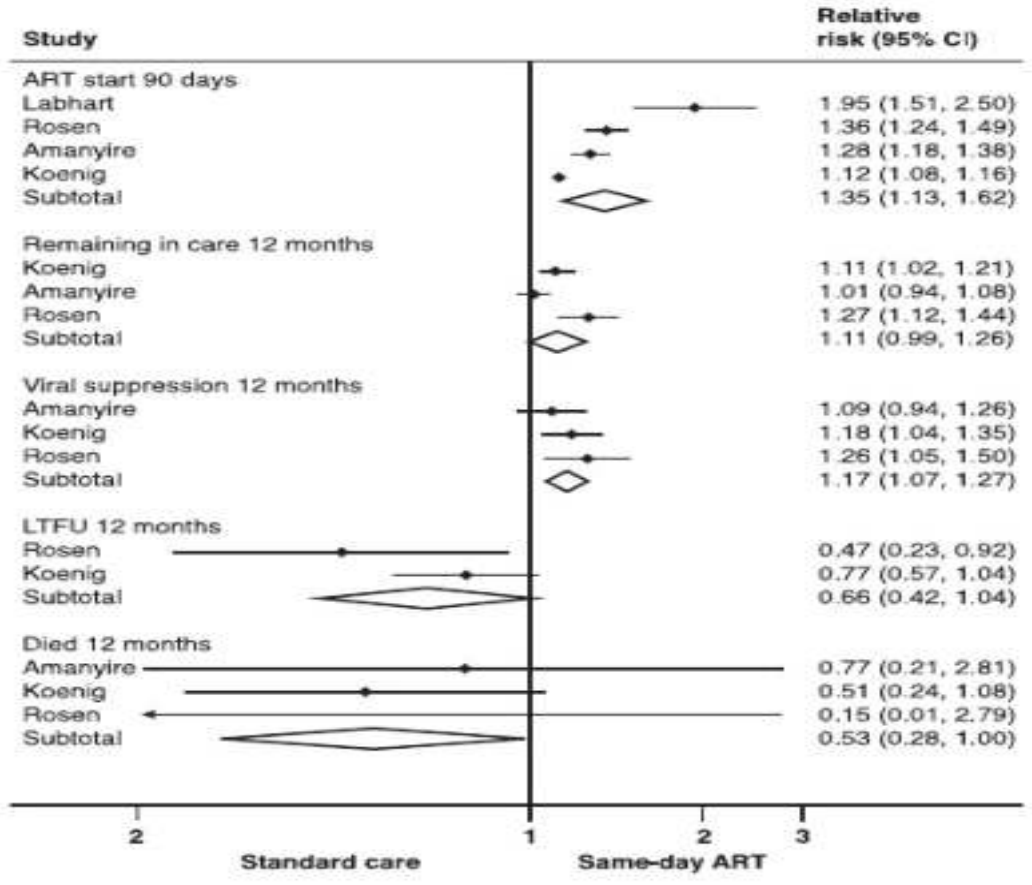

Fig. 1 Outcomes from randomized trials that compare same-day ART initiation *vs.* standard of care [4,7,8,13]. Reproduced with permission [3]. ART, antiretroviral therapy; CI, confidence interval; LTFU

Hızlı ART Uygulamasının Önündeki Potansiyel Engeller

Minimal laboratuvar değerleri ile ART başlamak konusunda çekince

Bir çok aşamada düzenlemeye ihtiyaç var

- klinik çalışma düzeni (zaman, personel)
- klinik çalışanları (hasta bilgilendirme, tetkiklerin planlaması)
- sağlık sistemi (randevu, ilaç raporlama)
- Hemşireler, laboratuvar (kan alma, radyoloji, raporlama süresi)
- Eczacılar (ilaç temini)

Fırsatçı enfeksiyonlar (TB, kriptokok) o kadar yaygın mı?

ART direnci ??

Hızlı Tedavi Başlangıcı Potansiyel Faydalar ve Limitasyonlar

Potansiyel Faydalar

- Daha az tedavisiz dönem, daha iyi klinik sonuçlar
- Hastanın sağlık bakımına uyumunun artırılması
- Daha az direnç gelişim riski
- İmmün yetersizlikte azalma, progresyondan koruma
- Azalmış anksiyete ve artmış güven hissi
- Azalmış bulaş
- Akut HIV enf döneminde başlanırsa rezervuarda azalma

Potansiyel Limitasyonlar

- ART seçeneklerinde limitasyon (HLA testi, HBV taraması, renal yetmezlik)
- ART öncesi hastaya daha fazla zaman ayrılması gerek
- Fırsatçı enfeksiyonlar her zaman dışlanamayabilir
- Tedavi ve tedavi uyumu bilgilendirmesi için daha kısa zaman, daha fazla efor
- Düşük direnç bariyeri olan rejimlerde direnç riski
- Hızlı tedavi başlangıcı için gerekli olabilecek iş akışındaki değişiklikler

Sonuç olarak

- Tanı konulduğu gün ART başlanması rehberlerde önerilmektedir
- Hemen ART başlanması
  - Daha erken viral baskılama
  - Viral baskılanma oranında artış, bulaşta azalma
  - Tedavide kalma oranında artış
  - Mortalitede azalma sağlar

- Hızlı ART başlanması
  - Birçok klinik durumda ve eşlik eden hastalığı olan olgularda da uygulanabilir
  - Ekip işidir, hasta ve tedavi/bakım verenlerin uyumu önemlidir