ISSN 1472-4863

hiv treatment bulletin (e)

HTB: 2019 vol 20 no 6

20 May 2019: no 6

Conference reports and PARTNER 2 published

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Published by HIV i-Base

h-tb

HIV TREATMENT BULLETIN

HTB is published in electronic format by HIV i-Base. As with all i-Base publications, subscriptions are free and can be ordered using the form on the back page or directly online:

http://www.i-Base.info

or by sending an email to: subscriptions@i-Base.org.uk

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HTB is a not-for-profit community publication. It reviews the most important medical advances related to clinical management of HIV including access to treatment. We compile comments to articles from consultant, author and editorial responses.

HIV i-Base receives educational grants from charitable trusts, individual donors and pharmaceutical companies. All editorial policies are strictly independent of funding sources.

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HIV i-Base is a registered charity no 1081905 and company reg no 3962064. HTB was formerly known as DrFax.

EDITORIAL

This issue of HTB includes reports from three conferences: an early report from INTEREST, additional reports from BHIVA 2019 and final reports from CROI.

The INTEREST report includes further data from women using dolutegravir during conception - without complications in this cohort.

Several of the BHIVA reports are notable for highlighting aspects of routine HIV care that are not meeting UK guidelines. The management examples we have included - diabetes and blood pressure, testosterone and the menopause - are likely to be relevant to many other UK clinics.

And we conclude our coverage from CROI 2019, with a review of the various studies looking at whether integrase inhibitors are associated with weight gain - individually, or as a class - and the answer unfortunately still calls for more and better data.

Finally, though the news is already widely distributed, we report that the full results from the PARTNER 2 study have been published as an open access paper in The Lancet. HTB readers will have already known these results last year when the study was presented at IAS in Amsterdam. But the publicity generated by The Lancet, meant that this important HIV story was covered on every TV news channel and both national and local press - and not just in the UK, but globally.

SUPPLEMENTS

U=U resources for UK clinics: free posters, postcards and factsheets

Please continue to order these free resources.

Customise U=U posters for your clinic

i-Base can customise U=U posters to include pictures of your doctors, nurses, pharmacists, peer advocates or any other staff that would like to help publicise U=U.

For further information please contact Roy Trevelion at i-Base: roy.trevelion@i-base.org.uk

i-Base 2019 appeal

This year we are continuing a funding appeal to help i-Base continue to provide free publications and services.

Your help has been inspiring – and we hope this support will continue during 2019. If 1000 people support us with £5 a month we will be on course to meet our funding shortfall. All help is appreciated.

http://i-base.info/i-base-appeal-we-need-your-help

CONFERENCE REPORTS

13th INTEREST Workshop

14–17 May 2019, Accra, Ghana

Introduction

The INTEREST Workshop shows findings from African HIV treatment and prevention research and is largely attended by delegates from the across the continent.

The abstract book and some oral presentations will be posted online soon after the meeting at:

http://interestworkshop.org

The meeting has limited information currently online other than the conference programme.

The article in this issue of HTB is:

- No increased adverse outcomes among women starting dolutegravir before conception in the ADVANCE study.

No increased adverse outcomes among women starting dolutegravir before conception in the ADVANCE study

Polly Clayden, HIV i-Base

Women who started dolutegravir (DTG)-based ART before conception did not have higher rates of adverse pregnancy outcomes compared with those starting efavirenz (EFV) in a South African study comparing three first-line regimens – according to data presented at 13th INTEREST workshop.

The ongoing, 96-week, phase 3, randomised ADVANCE study (n=1053) is evaluating the safety and efficacy of DTG + tenofovir alafenamide (TAF) + emtricitabine (FTC) vs DTG + tenofovir disoproxil fumarate (TDF) + FTC vs EFV + TDF + FTC.

The pregnancy sub study included all women who completed week 48, receiving ART before conception, had gestational age assessment (early ultrasound) and congenital foetal anomaly screening.

Women in the DTG arms were switched to alternative regimens if pregnancy was less than 8 weeks' gestation.

Adverse outcomes included: spontaneous abortion, elective termination, preterm delivery, small for gestational age, still birth and neonatal death. The sub study also evaluated neonate HIV status and birth defects.

There were 78 pregnancies among 625 women participating in ADVANCE (12.5%). Of these 15 (19.2%) were spontaneous abortion, 19 (24.4%) elective abortion, 1 (1.3%) stillbirth, 1 (1.3%) neonatal death, 34 (43.6%) live births and 8 (10.3%) pregnancies were ongoing at the time of analysis.

Approximately two thirds of pregnancies were among women in the DTG arms: 29 DTG + TAF + FTC and 21 in DTG + TDF + FTC.

Median birth weight was similar across treatment arms: 3.1 kg (IQR 2.9 to 3.3). A slightly higher proportion of infants exposed to EFV + TDF + FTC were small for gestational age: 22.2% vs 12.5% with DTG + TAF + FTC and 16.7% with DTG + TDF + FTC arms, p=0.768. All subgroup comparisons for all adverse pregnancy outcomes were p >0.10.

There were no vertical transmissions in this sub study. Two infants in the DTG arms had minor birth defects: naevus flammeus and umbilical hernia.

Polly Clayden is on the scientific advisory committee of the ADVANCE study.

C O M M E N T

Presenting author Dr Chandiwana reminded us of the importance of pooling data across similar trials and of prospective birth surveillance studies in African countries.

She noted that these data will also be submitted to the Antiretroviral Pregnancy Registry.

More data from the Botswana Tsepamo study is expected at IAS 2019.

Reference

Chandiwana N et al. Pregnancy and infant outcomes among HIV positive women on dolutegravir versus efavirenz-based antiretroviral therapy: week 48 analysis of the ADVANCE trial. 13th INTEREST. Accra, Ghana. 14–17 May 2019. Mini oral abstract 15.

CONFERENCE REPORTS

25th Annual BHIVA Conference (BHIVA 2019)

2 – 5 April 2019, Bournemouth

Introduction

The 25th Annual BHIVA Conference was held this year in Bournemouth and included an impressive programme that covered the diversity of the UK healthcare response to HIV.

There were 486 delegates registered for the conference and this number included 12 BHIVA Scholarship winners and 40 Community Registration places.

Webcasts are already online for all talks from the main programme, including abstract presentations.

This year it is also really helpful that most posters are also available to download as PDF files.

https://www.bhiva.org/AnnualConference2019

https://www.bhiva.org/file/5ca469a56b895/AbstractBook2019.pdf (PDF abstract book)

https://www.bhiva.org/AnnualConference2019Posters (posters)

Articles in this issue include:

- Fifty new HIV diagnoses at Dean Street linked to cap on IMPACT study
- Management of testosterone deficiency in HIV positive people
- Menopause and bone health in management of HIV positive women
- Type 2 diabetes is often undermanaged in HIV positive people
- Adopting new US blood pressure targets for HIV positive people could reduce cardiovascular-related deaths
- Selected webcasts from BHIVA 2019

Fifty new HIV diagnoses at Dean Street linked to cap on IMPACT study

Simon Collins, HIV i-Base

One of the most sobering posters at BHIVA 2019 was able to directly link recent HIV infections to the NHS block on access to PrEP.

This was a retrospective case notes review of all new HIV diagnoses during 2018 (n=177) at 56 Dean Street. Of these, 28% (50/177) had visited the clinic during the previous year.

These were almost exclusively gay men (one women, one MSW). Median age was 33 years (IQR: 27 to 37) with median of three partners in the previous three months (IQR: 2 to 11) and median of two HIV tests (IQR: 1 to 4) during the previous year.

Many of these men were engaged with healthcare and at high risk of HIV. They easily fulfilled criteria to access PrEP if it was available: one-third had previously used PEP, 38% disclosed chemsex with 10% injecting, 50% had had rectal gonorrhoea or chlamydia and 30% had early syphilis.

Only 12% had previously used PrEP, but 56% had a documented PrEP discussion.

The poster noted that although PrEP was discussed with more than half of the people who later became HIV positive, there were no places on the IMPACT study for the majority of the study period.

C O M M E N T

These cases – in a context when PrEP was clearly indicated, but also blocked given the limited places on the unnecessary PrEP IMPACT study – warrant a public interest legal case against the NHS, and questions in parliament, similar to the legal challenge many years ago that generated access to PEP.

THE UK PROUD study unquestionably proved PrEP efficacy in the UK in 2014 after the study was rapidly unblinded to offer immediate PrEP to all study participants in 2014 and with full results published in The Lancet in September 2015. [2, 3]

The IMPACT study itself - too little, too late - is controversial for limiting access to PrEP once clear data supporting efficacy and safety were established. This should have been an open access service based on demand, without caps on enrollment.

Even when expanded places were announced for the IMPACT study in January 2019, these have still not been made available to London clinics.

Reference

1. Woolham D et al. New HIV diagnoses in a London sexual health clinic: missed opportunities? BHIVA 2019. Poster abstract P99. https://www.bhiva.org/file/5ca73250e7009/P099.pdf (PDF)
2. UK PROUD study to provide PrEP to all participants earlier than expected: planned follow-up to continue to two years. HTB, December 2014. http://i-base.info/htb/27593
3. McCormack S et al. Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomised trial. The Lancet. Sept 9 2015. Open access. http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(15)00056-2/fulltext (full text)
4. NHS England doubles places on IMPACT PrEP study to 26,000. HTB: 21 January 2019. http://i-base.info/htb/35568

Management of testosterone deficiency in HIV positive people

Simon Collins, HIV i-Base

Two posters at BHIVA 2019 reported on under diagnosis and treatment of testosterone deficiency in HIV positive people.

Although low testosterone levels are more common in HIV positive people than the general population, this is often not included in routine HIV care, even when general symptoms warrant screening (erectile dysfunction, low desire, fatigue, low mood and/or reduced muscle mass).

V Kopanitsa from UCL Medical School and colleagues used a retrospective case note review to audit current practice in order to develop new local guidelines and to then audit practice before and after the guidelines had been implemented. The guidelines were developed by a multidisciplinary team of HIV, sexual dysfunction and endocrinology specialists. [1]

Key points that were highlighted in the guidelines included:

- Repeat testing of asymptomatic individuals which is not recommended.
- Poor accuracy of timing of the samples (these need to be taken before 10.30 am).
- Failure to calculate free (rather than total) testosterone.

While total testosterone (free plus protein bound) is commonly measured, HIV positive people should be monitored by free testosterone levels, because HIV is associated with increased sex hormone binding globulin (SHBG) which complicates the interpretation of test results.

Free testosterone can be calculated online using albumin, testosterone and SHBG results taken at the same time:

http://www.issam.ch/freetesto.htm

Unfortunately, although the local guidelines clearly identified best practice, they failed to improve local practice, showing that more work is still needed.

Although patient numbers were apparently low and were not included in the review the percentages of people with samples taken before 10.30 am dropped from approximately 46% to 13% and measuring free testosterone dropped from approximately 17% to only 5% of tests.

The poster did note that overall the study was small and that the guidelines would be republicised and the results reaudited.

In the second poster, Celia Simpson and colleagues from the Lawson Unit in Brighton, reviewed the management of patients in Brighton who had been diagnosed with low free testosterone (<160 bmol/L) over the previous five years. [2]

Of the 69 patients identified, approximately half had abnormal SHBG that were too high indicating the risk of under diagnosis from relying on total testosterone and showing the importance of testing free rather than total testosterone.

Median age in this group was 58 years (range: 31 to 88) with CD4 nadir 375 (range 15 to 1037) copies/mm^3. All people had undetectable viral load. Average time on ART was 15 years (range 1 to 32). Eight patients had type 2 diabetes and one person had diabetes mellitus. Although median BMI was 26.5 this ranged from 17.1 to 39.0). 32/69 patients have started testosterone therapy with a further five still awaiting treatment.

References

1. Simpson C et al. A review of hypogonadism in an HIV cohort. 25th Annual BHIVA, 2–5 April 2019, Bournemouth (BHIVA 2019). Poster abstract P137.
   https://www.bhiva.org/file/5ca7325113af9/P147.pdf
2. Kopanitsa V et al. Improving testosterone testing in people living with HIV. 25th Annual BHIVA, 2–5 April 2019, Bournemouth (BHIVA 2019). Poster abstract P137.
   https://www.bhiva.org/file/5ca732510ca0d/P137.pdf

Menopause and bone health in management of HIV positive women

Simon Collins, HIV i-Base

At least three posters at BHIVA 2019 looked at aspects of women's health in relation to the menopause.

Importance of annual menopause review

Munatsi and colleagues from Nottingham University Hospitals presented results from a questionnaire looking at contraception, menopausal symptoms, comorbidities, medications and lifestyle risk factors in 31 HIV positive women aged 45-56. Overall, 13% (152/1200) of this clinic's population are women of this age. [1]

A case note review was then used to compare to clinical management, including FRAX score and cardiovascular risk.

Most women (90%) were on ART with undetectable viral load. Ethnicity included 61% black African, 13% white British and 6% Asian.

None of the women had had a menopause review - even though 40% had menopause symptoms. Awareness of HRT was low (only 20%) with only half of women having information from a healthcare professional. The remaining 60% were still having regular periods but were likely to be reaching the menopause in the near future.

The results have been used to change practice in Nottingham by emphasising an annual review and including more information about HRT and guidance about how to deal with the menopause. The study also suggested the importance for women to be able to access specialist services.

Given that BHIVA guidelines state that all HIV positive women aged 45-56 should have an annual menopause review with the option for hormone replacement therapy (HRT), the review from Munatsi and colleagues should be an immediate prompt for other clinics to review their services.

Low age at osteoporosis - signal to review guidelines?

Yvonne Gilleece and colleagues from Brighton presented DEXA results on bone health from 40 HIV positive women seen at their specialist women's HIV service. [2]

Results were available to 37/40 women and mean age was 51 years (range 36 to 84).

DEXA results were normal in 38% (14/37), osteopenia in 41% (15/37) and osteoporosis in 21% (8/37) and most of the women with osteoporosis (7/8) were post-menopausal. The median age for each category was 51 years (42–58), 48 years (36–60) and 53 years (46–84) respectively.

Although the study had small numbers, the authors highlighted the low median age for osteoporosis and that this was twice as common in HIV positive women than HIV positive men. Also that the low ages for osteoporosis in this population and the related increased risk of fragility fractures warrants a review in current BHIVA monitoring guidelines.

Current BHIVA guidelines recommend BMD risk factor assessment: at first HIV diagnosis, before ART and then every 3 years in individuals on ART who are ≥ 50 years of age. Bone mineral density assessment is advised initially using FRAX and also with DEXA scanning in all women aged ≥65 years and women >50 years old if they have an intermediate to high FRAX score and/or additional risk factors.

These guidelines may not identify all women at risk of low BMD.

Under-use of current guidelines

A third poster presented complimentary results to both these studies.

F Hirst and colleagues from Solent NHS Trust presented result from a retrospective case note review of 44 women older than 50 years to see how closely their hospital followed BHIVA guidelines for bone health. [3]

Only 10/44 women (23%) had a documented discussion on HRT with 3/44 (7%) receiving HRT. 2/44 (4.5%) women had a history of a low-trauma fracture and 1/44 (2.3%) reported parental hip fracture.

Only 29/44 (66%) had a documented FRAX score. The score for the remaining patients was calculated for the study and overall, based on the FRAX score, 27/44 (61%) were categorised as intermediate risk, with 21 of those (78%) included solely through inputting HIV as a secondary cause of osteoporosis in the FRAX tool. Of the 27 women at intermediate risk, 7 (27%) had been referred for a DEXA scan.

The study concluded that BHIVA guidelines were only being followed to a moderate degree, and that suboptimal menstrual questions and missing FRAX scores were underestimating bone mineral density risk in this cohort.

C O M M E N T

These studies highlight aspects of HIV positive women's health that should prompt other doctors and clinics to review the management of this patient group.

More than 10,000 HIV positive women aged 45-56 attend UK HIV clinics.

References

Unless stated otherwise, all references are to the programme and abstracts of the 25th Annual BHIVA Conference, 2–5 April 2019, Bournemouth (BHIVA 2019).

1. Munatsi S et al. The menopause experience: a quality improvement project. BHIVA 2019. Poster abstract P151. https://www.bhiva.org/file/5ca732511644f/P151.pdf (PDF)
2. Gilleece Y et al. No bones about it: high rates of osteoporosis in women living with HIV. BHIVA 2019. Poster abstract P68. https://www.bhiva.org/file/5ca73250cf798/P068.pdf (PDF)
3. Hirst F et al. Assessment of bone health of women living with HIV aged>50 years in clinical practice: are we doing enough? BHIVA 2019. Poster abstract P52. https://www.bhiva.org/file/5ca73250c2b47/P052.pdf (PDF)

Type 2 diabetes is often undermanaged in HIV positive people

Simon Collins, HIV i-Base

A retrospective review of patient notes (up to December 2015) from a large London HIV clinic reported prevalence of type 2 diabetes mellitus (T2DM) of 3% (256/9131 patients) and that approximately half were not achieving NICE-recommended blood pressure targets.

This poster was presented by Qingwei Zhang from Imperial College and colleagues from the Chelsea and Westminster Hospital, London.

Of these 256 patients, 88% were men and 47% were white British.

HIV characteristics included median CD4 count 637 cells/mm^3 and 85% had viral load <20 copies/mL.

Current ART (in 2015) included commonly used combinations including darunavir/r (35%), efavirenz (23%) and raltegravir (20%). NRTI backbone was TDF/FTC in 33% and abacavir/3TC in 15%.

Many of these people had been HIV positive for many years and historical ART included AZT (38%), d4T (33%), ddI (29%), saquinavir (13%) and indinavir (7%).

Comorbidities were very common including cardiovascular disease (54%), dyslipidaemia (17%) and chronic kidney disease (17%).

Diabetic medication included multiple treatments for many patients: metformin (62%), sulphonyureas (31%), insulin (25%) peptide analogues (17%) and 15% were on diet-control only.

However, almost half this cohort (48%) were not meeting NICE blood pressure targets.

- 70% did not have LDL-cholesterol within range
- Only 23% were having HbA1c levels checked every 6 months.
- Less than half (48%) had protein:creatinine ratio (uPCR) checked annually
- Only 4% had albumin:creatinine (uACR) checked annually.

This study concluded that access to updated treatment (SGLT-2 inhibitors) and better communication with GPs was needed.

As a result of the audit, the hospital also established a specialist metabolic HIV clinic.

C O M M E N T

The new HIV metabolic outpatient service is a cross directorate outpatient clinic once a month for all patients with HIV and complex metabolic comorbidities.

A live well pathway also links to dietician and physiotherapy services as part of a holistic approach to care that includes support for lifestyle modifications in order to prevent and reduce the long term cardiovascular risks.

The prevalence of both diabetes and dyslipidaemia is likely to be underestimated due to limitations of electronic patient records in this database.

Reference

Zhang Q et al. Audit of type 2 diabetes in people living with HIV: performance against NICE guidelines targets. BHIVA 2019. Poster abstract P053. https://www.bhiva.org/file/5ca73250c5137/P053.pdf (PDF)

Adopting new US blood pressure targets for HIV positive people could reduce cardiovascular-related deaths

Simon Collins, HIV i-Base

A review of management of HIV positive people with high blood pressure (BP) in a large London hospital showed 42% were not well controlled but care was improved after move to new US guidelines.

This prospective audit was presented at BHIVA 2019 as a poster by G Manmathan and colleagues from the Royal Free Hospital. The audit results on 111 HIV positive patients were initially presented to staff at the clinic and 125 patients were later reaudited.

As background, hypertension is the leading risk for cardiovascular disease and in 2018 US guidelines lowered the threshold for treatment from 140/90 mmHg to 130/80 mmHg.

Mean age of 111 patients in the initial audit was 49 years (+/– 11) and 77% were men. Current ART was not linked to higher PB.

Approximately 1 in 4 (23%) were on BP treatment but only 58% were well controlled: 38% had BP >140 mmHg and 56% had > 130 mmHg. Although only 21% had a diastolic BP >90mmHg, this increased significantly to 63% when using new US guideline threshold of >80 mmHg.

The authors reported that using new guidelines resulted in more patients achieving current UK targets, although some post-audit outcomes were only slightly improved with changes unlikely to be statistically significant (26% vs 23% on medication and 36% vs 42% poorly controlled).

The authors still strongly recommended moving to new guidelines to more aggressively manage BP in HIV positive people given higher rates of hypertension and cardiaovascular risk in this younger cohort compared to the general UK population. They also concluded: “Many cardiovascular related deaths could be averted by the simple application of basic knowledge about blood pressure for which there has been broad consensus for decades”.

Reference

Manmathan G et al. Impact of application of new American hypertension guidelines to a UK HIV cohort. BHIVA 2019. Poster abstract P65.

https://www.bhiva.org/file/5ca73250cdc10/P065.pdf (PDF)

Selected webcasts from BHIVA 2019

Simon Collins, HIV i-Base

Most of the key presentations from BHIVA 2019, including oral abstracts and invited lectures, are available online.

Webcasts are for the whole session (rather than being separate for each talk) but these can be advanced until the right position is found. Please refer to the main programmed to estimate how far to advance these times.

A selection of talks is included below.

New hepatitis data: hepatitis C in people with and without HIV, lessons learned from the hepatitis A outbreak

Andrew Ustianowski, North Manchester General Hospital

https://www.bhiva.org/190403-1 (at 28 mins)

Declining HIV incidence: is it all good news?

Valerie Delpech, Public Health England

https://www.bhiva.org/190403-1 (at 56 mins)

Smoking: are e-cigarettes the solution?

Lion Shahab, University College London

https://www.bhiva.org/190403-4

Immune reconstitution inflammatory syndrome (IRIS)

Sarah Pett, MRC Clinical Trials Unit at UCL

https://www.bhiva.org/190405-3 (at 13 mins)

Pregnancy and breastfeeding

Catriona Waitt, University of Liverpool

https://www.bhiva.org/190405-3 (at 42 mins)

Is rapid ART right for all?

Simon Collins, HIV i-Base

https://www.bhiva.org/190405-3 (at 1h:02 mins)

CONFERENCE REPORTS

Conference on Retroviruses and Opportunistic Infections (CROI 2019)

4–7 March, 2019

Introduction

This year the Conference on Retroviruses and Opportunistic Infections (CROI 2019) was held in Seattle from 4–7 March.

CROI is notable for providing same-day or next-day webcasts for most talks and comprehensive online access to abstracts and PDF files for posters.

This year HTB will include summary highlights for each day of the conference, with links to key studies.
http://www.croiconference.org

Reports from CROI have been included in the three previous issues of HTB.

Articles in this issue are.

- INSTI and weight gain: reports from CROI 2019
- B/F/TAF suitable for children from six years of age

INSTI and weight gain: reports from CROI 2019

Polly Clayden, HIV i-Base

Several presentations at CROI 2019 showed data from analyses of INSTI-associated weight gain from mostly US cohorts (and one prevention study).

Although topical and a potential cause for concern – particularly with the accelerating roll out of dolutegravir worldwide – no clear conclusions emerged from what was presented.

ACTG A5001 and A5322

Annual within-person weight gain increased following switch to INSTI-based ART among AIDS Clinical Trials Group (ACTG) participants in protocols A5001 and A5322. The increase was particularly significant for women, black people and people aged 60 and above. [1]

This assessment included A5001 and A5322 participants, in follow-up from 1997–2017, who switched to INSTI. Participants were their own controls for estimation of background/age-related weight gain (before vs after switch).

A total of 972 adults switched to INSTI at a median of 7.8 years after enrolling in the parent trial. The evaluation included 691 with undetectable viral load at switch: 82% men, 45% non-white, median age 51 years, CD4 610 cells/mm^3 and BMI 26 kg/m^2; 289 switched to raltegravir, 204 to elvitegravir and 198 to dolutegravir.

Median follow up was 1.8 years – although this was up to 10 years for people receiving raltegravir. Approximately two thirds switched from a PI and the remainder from an NNRTI.

In adjusted models (for age, sex, race/ethnicity, parent study baseline BMI and their interactions, nadir CD4, smoking, diabetes and percent follow-up time with suppressed viral load <200 copies/mL), white or black race, age ≥60 and BMI ≥30 kg/m^2 were associated with greater annual weight gain following switch for women, and age ≥60 was the greatest risk factor for men.

Dolutegravir was associated with the greatest annual weight gain with pre-post difference of 1 kg more per year p=0.0009. Pre-post differences in kg/year for elvitegravir and raltegravir were not statistically significant in this cohort.

Although subset analyses of NRTI back bone in this cohort were limited by sample size, switch to any INSTI with abacavir and switch to elvitegravir with tenofovir alafenamide were statistically significant, p<0.05.

NA-ACCORD

Treatment-naive adults starting INSTI, especially dolutegravir and raltegravir, were at higher risk of weight gain compared to those starting older NNRTI-based regimens in the North American AIDS Cohort Collaboration on Research and Design (NA-ACCORD). [2]

Participants in NA-ACCORD starting INSTI, protease PI, and NNRTI-based ART regimens after 1 January 2007 were included and followed through 31 December 2016.

Predicted weights by ART class were reported at years 2 and 5. Because of shorter follow-up for newer INSTI, predicted weights for raltegravir, elvitegravir, and dolutegravir were reported at years 1 and 2.

Of 24,001 participants, 4,720 started INSTI-based regimens: 1681 (35%) raltegravir, 2124 (45%) elvitegravir and 936 (20%) dolutegravir. A further 11,825 started NNRTI-based and 7436 started PI-based ART. The vast majority, 87% were men, and 41% were white.

At baseline, median age was approximately 42 years, BMI was 25 kg/m^2 and CD4 approximately 300 cells/mm^3.

Predicted weight gain for participants receiving INSTI at 2 and 5 years, was 4.9 and 6.0 kg, respectively, compared to 3.3 and 4.3 kg for NNRTI and 4.4 and 5.1 kg for PI.

Of those starting INSTI, predicted weight gain at year 2 was 6.0 kg for dolutegravir, 4.9 kg for raltegravir, and 3.8 kg for elvitegravir.

Weight gain associated with INSTI-based regimens did not vary by sex in this cohort (although this comparison is limited by few women vs men) or race (white vs non-white).

US ART-experienced cohort

Only psychiatric disorders were associated with weight gain in a treatment-experienced US cohort including 3468 virologically suppressed people with HIV – according to a retrospective analysis. [3]

Hypogonadism, obese or overweight at baseline and PI use were negatively associated with weight gain.

Although the association between INSTI-based ART and weight gain reached significance in bivariate analyses, this did not remain significant in multivariate analysis.

Participants were from 21 US states and Washington DC. The majority, 81% were men; 14% were women and the remaining 5% unspecified; 61% were white, 28% African-American and 11% unknown. Of these, 64% had received an INSTI, 28% an NNRTI and 20% a PI.

Between August 2013 and August 2018, 30% of participants had annualised weight gain ≥3%, 16% had weight loss ≥3%, and 54% had weight change <3%.

In multivariate analysis, psychiatric disorders were associated with weight gain ≥ 3%: OR 1.28 (95% CI: 1.0 to 1.6), p=0.020. Factors negatively associated with ≥3% weight gain were: hypogonadism OR 0.81 (95% CI 0.6 to 1.0), p=0.050; overweight at baseline OR 0.69 (95% CI 0.6 to 0.8); obese at baseline OR 0.62 (95% CI 0.5 to 0.8), and PI use OR 0.58 (95% CI 0.4 to 0.7), all p<0.001.

The proportion with ≥3% weight gain was significantly lower among participants receiving a PI vs no PI. And the proportion with ≥3% weight gain was higher among those receiving INSTI vs no INSTI. There was no statistically significant difference between the NNRTI and no NNRTI groups.

Analysis was by drug class, analysis by individual drug was not presented.

WIHS

In the Women's Interagency Health Study (WIHS) a switch to INSTI was associated with significant increases in body weight and measurements, body fat, and blood pressure vs no INSTI. [4]

Women who switched to or added an INSTI to ART were compared to women who remained on non-INSTI ART. The study examined changes in body weight; body mass index (BMI); percentage body fat; circumference of waist, hip, arm, and thigh; blood pressure; and incident diabetes mellitus, between 2008 and 2017.

There were 1118 WIHS participants included, of which 234 switched to or added an INSTI. The mean follow up was 2 years and there were no differences in baseline characteristics between groups: mean age 48.8 years; 61% African American; and mean CD4 669 cells/mm^3. Baseline weight and BMI were 80.8 kg and 31 respectively.

Women receiving an INSTI had 2.14 kg greater increase in weight, 0.78 kg/m^2 greater increase in BMI, 1.35% greater increase in percentage body fat, and 2.05, 1.87, 0.58, and 0.98 cm greater increases in waist, hip, arm, and thigh circumference, respectively.

HOPS

Greater BMI increases among people who switched to INSTI-based ART than those who switched to non-INSTI-based ART found in the HIV Outpatient Study (HOPS). The association was most pronounced in women and people of Latino/a ethnicity. [5]

This study was an analysis medical record data of participants from nine US clinics who were INSTI-naive and virally suppressed for >1 year on non-INSTI ART, and who switched to INSTI-based ART and remained suppressed. They received INSTI-based ART for >6 months, had >2 weights recorded in the year before switch and >1 after.

Of 653 participants, 368 (56.4%) switched to an INSTI-based regimen and 285 (43.6%) switched to a non-INSTI- based regimen.

Of the participants receiving INSTI, median age was 51 years and 17.7% were women. INSTI regimens included raltegravir (48.6%), elvitegravir (21.7%), or dolutegravir (29.6%). Mean duration of INSTI use after switch was 2.4 years

Mean change in weight on INSTI-based regimens was greater than that on non-INSTI-based regimen: 1.2 kg vs 0.3 kg, p=0.05.

In multivariate analysis women and people of Latino/a ethnicity had greater BMI, and people who inject drugs had lower BMI than MSM, all p=<0.01.

BMI trajectory slopes post-ART switch were greater for dolutegravir-based ART than for regimens with other INSTIs, p=0.03 vs raltegravir and p=0.003 vs elvitegravir.

Only elvitegravir-based ART was not associated with increases in BMI, p=0.67.

Parkland Health and Hospital System in Dallas, Texas

Elvitegravir was associated with greater BMI gains overall; dolutegravir and raltegravir were associated with greater BMI gains in women; and dolutegravir with greater gains in black and Latino/a people in a large urban clinic in Dallas. [6]

All patients starting ART at the Parkland Health and Hospital System in Dallas, Texas from 2009 to 2017 were included in this analysis.

Of 4,048 participants, 69% were men, 53% black, 28% Latino/a, and 16% white. Mean age was 46.3 years (SD +/– 11.9). Mean baseline BMI was 27.0 kg/m^2 (SD +/– 6.4). Median duration of ART was 6.7 years (IQR: 2.8 to 11.2).

There was no significant interaction between sex and race/ethnicity on BMI gains. Proportion of overweight /obese participants (BMI ≥ 25) increased from 51% at ART initiation to 65% at year 3, p<0.001.

The BMI slope per year on NNRTI, PI and INSTI were 0.22, 0.24 and 0.32 kg/m^2, respectively.

Among INSTIs, elvitegravir appeared to be associated with greater BMI gains overall (0.39/year), but the effect did not vary or by sex or race/ethnicity.

Dolutegravir and raltegravir were associated with greater BMI gains in women than men: 0.44 vs 0.12/year, p<0.01; and 0.3 vs 0.08/year, p=0.03, respectively. Dolutegravir was also associated with greater BMI gains in black and Latino/a people vs white.

Cabotegravir

There was no difference in weight gain among HIV negative people receiving cabotegravir compared with placebo in HPTN 077. [7]

This is a phase 2a randomised placebo-controlled prevention study of two dose/dose-interval regimens of cabotegravir,

Table 1: Weight changes on ART: studies at CROI 2019

Abstract no.	Design	Details	Findings	Higher risk
Abs 669. Lake JE et al. USA.	ACTG switch study (US). Prospective cohort: 2007–2017 - within <2 years of switch during follow-up. BUT weight changes were modelled, adjusted for age, sex, BMI, CD4, smoking, diabetes etc.	n=961 VL <200 c/mL 18% women. 55% white, 26% black, 19% Latino/a	Generated weight trajectories before and after switch. Weight inc with DTG, only when switch from PI and with EVG and DTG from NNRTI.	Women Black race Older >60 y
Abs 670. Bourgi K et al. USA.	NA-ACCORD cohorts (US). Naive (<45 d), 2007-2016. Modelled weight gain by class: NNRTI vs PI vs INSTI.	n-24,000 (n=4740 INSTI) 90% male. 42% black. BMI 25 (IQR: 23 to 29)	Predicted weight increase (kg) at 2 yr: +3.3 (NNRTI), +4.4 (PI), +4.9 (INSTI). DTG (+6.0) > RAL (+4.9) > EVG (+3.9).	No differences by gender or race.
Abs 671. McComsey G et al. USA.	Retrospective US observational switch study 2013–2017. VL<200 c/mL and 2 x BMI. compared risk factors for weight gain (>3%) vs no weight gain.	n=3468 19% women. 62% white 28% black	Overall. 30% weight gain, 54% minimal change and 16% weight loss. INSTI > no INSTI (32% vs 28%). No PI > PI (32% vs 22%).	No INSTI effect in multivariate analysis BUT not by ART. Lower BMI (NS) but high BMI significantly reduced risk. No differences by gender or race. Psychiatric illness increased risk.
Abs 672. Kerchberger AM et al. USA.	Retrospective analysis WIHS cohort (US) 2008-2017 switch analysis.	n=1118 (n=234 switch) VL <1000 c/mL. 100% women. ~2 yrs follow up. Only difference between arms was higher PI use in switch group (69% vs 46%m p<0.0001).	Significant increases in INSTI switch group for weight (difference +2.14 kg) BMI (0.78 kg/m^2), percentage body fat (+1.35%), and waist, hip, arm, and thigh circumference (2.05, 1.87, 0.58, and 0.98 cm respectively). Also greater change in systolic and diastolic BP (2.24 and 1.17 mmHg, p<0.05) and new-onset DM (4.5% and 2.2%) in STAY, p=0.11.	No significant differences by INSTI.
Abs 674. Palella FJ et al. USA.	Retrospective analysis HOPS cohort (US) 2007–2017. All switch analysis with >2 x BMI.	n=653 (n=363 INSTI switch vs 285 non-INSTI switch). VL <200 c/mL. Approx 20% women. 60% white, 25% black, 12% Latino/a.	Greater mean weight increase on INSTI-based switch (1.2 kg vs 0.3 kg, p=0.05). Increases with both DTG and RAL but not with ELV.	Women and Latino/a associated with greater BMI increases.
Abs 675. Bedimo R et al. USA.	Retrospective analysis of treatment naive pts 2009 - 2017.	n=4,048. 29% women. 53% black, 28% latino, and 16% non-Hispanic Whites. Mean baseline BMI 27.0 kg/m2 (SD 6.4). Median follow-up on ART 6.7 years (IQR 2.8 – 11.2).	BMI, ≥ 25 increased from 51% to 65% at year 3 (p<0.001). BMI slope per year was 0.22, 0.24 and 0.32 on NNRTI, PI and INSTI, respectively.	All PIs >BMI women > men, but no difference by race/ethnicity. EVG >BMI vs DTG/RSL. No difference by sex or race/ethnicity. DTG and RAL are associated with greater BMI gains in women, and DTG with greater gains in black & Latino/a.
Oral Abs 30. Landovitz R et al. USA, Brazil and sub-Saharan Africa.	Phase 2a randomised placebo-controlled study of two dose regimens of cabotegravir vs placebo in HIV negative.	n=199 (n=134 active CAB). 66% women. 26% white, 40% black, 25% Latino/a.	Median weight change over 41 weeks was +1.1 kg (IQR -0.9, 3.0) in the CAB arm and +1.0 kg (IQR -1.2, 3.2) in the PBO arm (p=0.66).	

conducted at sites in the US, Brazil and sub-Saharan Africa. A total of 199 participants were enrolled and randomised 3:1 to cabotegravir or placebo.

Median weight change over 41 weeks was +1.1 kg (IQR: –0.9 to +3.0) in the cabotegravir arm and +1.0 kg (IQR: –1.2 to +3.2) in the placebo arm (p=0.66). There were no differences by sex, dose, age, race/ethnicity, smoking, or BMI.

C O M M E N T

A systematic review, conducted earlier this year, concluded that it is currently unclear whether INSTI cause clinically significant changes in body weight or whether these changes are statistically significant but small. [8]

Data shown at CROI 2019 showed no distinct patterns.

RCT data, expected at IAS 2019 from the ADVANCE and NAMSAL studies (comparing dolutegravir-based regimens to efavirenz-based ones in two African countries) where weight was looked at systematically will be important.

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B/F/TAF suitable for children from six years of age

Polly Clayden, HIV i-Base

The adult fixed dose combination formulation of bictegravir, emtricitabine, and tenofovir alafenamide (B/F/TAF) is appropriate for the treatment of adolescents and children 6 to 18 years of age and weighing 25 kg and above.

Week 48-week efficacy, safety, acceptability, and palatability data presented at CROI 2019 (combined with previously reported PK data), support the use of adult strength B/F/TAF (50/200/25 mg) in this paediatric population.

The study was sequential in age descending cohorts. Virologically suppressed adolescents (12 to <18 years) weighing ≥35 kg (cohort 1) and children (6 to <12 years) weighing ≥ 25 kg (cohort 2) with viral load <50 copies/mL for ≥6 months and CD4 ≥200 cells/mm^3 were switched to B/F/TAF once daily.

Fifty adolescents and 50 children were enrolled. Sites were in South Africa, Thailand, Uganda and US.

For cohort 1, at baseline, median age was 15 years (range: 12 to 17), weight 45 kg (IQR: 40 to 56), 64% girls, 65% black, and median CD4 count 751 cells/mm^3.

For cohort 2, median age was 10 years (range: 6 to 11), median weight 29 kg (IQR: 27 to 33), 54% girls, 72% black, and median CD4 count 930 cells/mm^3.

Population pharmacokinetics showed bictegravir exposure to be similar to adults in both children and adolescents. Bictegravir trough levels was lower in adolescents than adults but remained >11-fold above paEC50; but similar to adults in children. Exposures of FTC and TAF were in the range of historical adult data and for children/adolescents treated with elvitegravir/cobicistat/F/TAF.

All 100 participants had viral load <50 copies/mL at week 24 and 98% (74/75) at week 48 (US FDA snapshot). No participant had treatment-emergent resistance.

One child discontinued after week 16 due to an adverse event (grade 2 insomnia and anxiety).

All participants reported B/F/TAF size (15 x 8 mm) and shape as acceptable and taste as palatable. Median percent adherence (pill counts) to study drug was high at 98.9% (range: 80% to 100%).

C O M M E N T S

Further investigations (by the originator manufacturer Gilead)

with reduced strength, paediatric B/F/TAF 30/120/15 mg FDC in 2 years of age and above and weight 14 to <25 kg are ongoing.

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HIV PREVENTION

PARTNER 2 study published in the Lancet

Simon Collins, HIV i-Base

On 2 May 2019, the final results from the PARTNER study, including the full results in gay men, was published as an open access article in the Lancet. [1]

Although these data were widely reported when they were presented at the IAS conference in Amsterdam last year [2], the high profile of the Lancet, which also included an accompanying editorial commentary and its own press release, meant that this research was picked up by mainstream news media.

Radio 4 news reported that "for many years evidence has been building that drug treatments for HIV reduce the virus to such low levels in the body that passing it on through sex is no longer a risk". [3]

Alison Rodger, Professor of Infectious Diseases at the Institute for Global Health at UCL London and lead author on the paper explained in the interview how the study "provides conclusive evidence that if you are on effective HIV treatment that you cannot pass on the virus. This should normalise HIV. It supports the message of the U=U campaign, that having an undetectable viral load makes HIV untransmissable."

The Guardian made this a front page story, although somewhat prematurely heralding "an end to AIDS". [4]

Actually, the level of news coverage was unprecedented, even compared to the "AIDS cure" coverage from CROI 2019 earlier in 2019. This was a study in viral news.

Every major media outlet in terms of national press and television covered this story often with interviews with members of the study team or other HIV organisations. [5]

The story was quickly picked up by smaller regional media and social media. The coverage in English was mirrored by similarly wide coverage in other languages. The PARTNER study made global news.

C O M M E N T

This is all good news and the high level of interest across mainsteam media show its immediate importance.

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FUTURE MEETINGS

Conference listing 2019

The following listing covers some of the most important upcoming HIV-related meetings and workshops.

17th European Meeting on HIV & Hepatitis

22 – 24 May 2019, Rome

www.virology-education.com

Viruses, vaccines and eradication conference 2019

Thursday 6 June 2019, London

http://www.vveconference.com

11th International Workshop on HIV Pediatrics

20 – 21 July 2019, Mexico City

www.virology-education.com

HIV & HBV Cure Forum

20 – 21 July 2019, Mexico City

https://www.iasociety.org/HIV-Programmes/Programmes/Towards-an-HIV-Cure/Events/2019-HIV-HBV-Cure-Forum?

International Workshop on HIV & Transgender People

July 2019, Mexico City, date TBC

www.virology-education.com

10th IAS Conference on HIV Science

21 – 24 July 2019, Mexico City

www.ias2019.org

4th European Workshop on Healthy Living with HIV

13 – 14 September 2019. Barcelona

www.virology-education.com

21st Intl Workshop on Comorbidities and Adverse Drug Reactions in HIV

5 – 6 November 2019, Basel, Switzerland

https://www.intmedpress.com

10th International Workshop on HIV & Aging

10 - 11 October 2019 | New York, NY, USA

www.virology-education.com

17th European AIDS Conference

6 – 9 November 2019, Basel

www.eacsociety.org

PUBLICATIONS & SERVICES FROM i-BASE

i-Base website

All i-Base publications are available online, including editions of the treatment guides.

http://www.i-Base.info

The site gives details about services including the UK Community Advisory Board (UK-CAB), our phone service and Q&A service, access to our archives and an extensive range of translated resources and links.

Publications and regular subscriptions can be ordered online.

The Q&A web pages enable people to ask questions about their own treatment:

http://www.i-base.info/qa

i-Base treatment guides

i-Base produces six booklets that comprehensively cover important aspects of treatment. Each guide is written in clear non-technical language. All guides are free to order individually or in bulk for use in clinics and are available online in web-page and PDF format.

http://www.i-base.info/guides

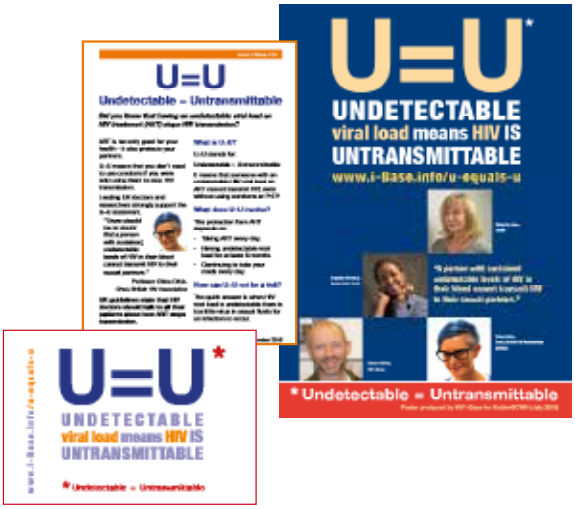
- Introduction to ART (May 2018)
- HIV & quality of life: side effects & long-term health (Sept 2016)
- Guide to PrEP in the UK (March 2019)
- HIV testing and risks of sexual transmission (June 2016)
- Guide to changing treatment and drug resistance (Jan 2018)
- Guide to HIV, pregnancy & women's health (April 2019)

Pocket guides

A series of pocket-size concertina folding leaflets that is designed to be a very simple and direct introduction to HIV treatment.

The five pocket leaflets are: Introduction to ART, HIV and pregnancy, ART and quality of life, UK guide to PrEP and HCV/HIV coinfection.

The leaflets use simple statements and quotes about ART, with short URL links to web pages that have additional information in a similar easy format.



U=U resources for UK clinics: free posters, postcards and factsheets

i-Base have produced a new series of posters, postcards and leaflets to help raise awareness about U=U in clincs.

This project was developed with the Kobler Centre in London.

As with all i-Base material, these resources are all free to UK clinics.

Until our online order form is updated to include the U=U resources, more copies can be orded by email or fax.

email: subscriptions@i-base.org.uk

Fax: 0208 616 1250

Other i-Base resources can still be ordered online as usual.

http://i-base.info/forms/order.php

Customise U=U posters for your clinic

i-Base can customise U=U posters to include pictures of doctors. nurses, pharmacists, peer advocates or any other staff that would like to help publicise U=U.

Personalising these for your clinic is cheap and easy and might be an especially nice way to highlight the good news.

For further information please contact Roy Trevelion at i-Base:

roy.trevelion@i-Base.org.uk

Order publications and subscribe online

All publications can be ordered online for individual or bulk copies. All publications are free. Unfortunately bulk orders are only available free in the UK.

http://i-base.info/order

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- **HIV Treatment Bulletin (HTB) every two weeks** ☐ **by e-mail**
- **Pocket leaflets** - *A7 small concertina-folded leaflets (2017)*

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Pocket ART	**quantity** _____	**Pocket pregnancy**	**quantity** _____
Pocket side effects	**quantity** _____	**PrEP for women**	**quantity** _____

- **Booklets about HIV treatment**

ART in pictures: HIV treatment explained *(August 2018): 32-page A4 booklet* **quantity** _____

Guide to hepatitis C coinfection *(April 2017): 52-page A5 booklet* **quantity** _____

UK Guide To PrEP *(March 2019): 24-page A5 booklet* **quantity** _____

Introduction to ART *(May 2018): 48-page A5 booklet* **quantity** _____

HIV and quality of life: guide to side effects and long-term health *(Sept 2016): 96-page A5* **quantity** _____

Guide to HIV testing and risks of sexual transmission *(July 2016): 52-page A5 booklet* **quantity** _____

Guide to HIV, pregnancy and women's health *(April 2019): 52-page A5 booklet* **quantity** _____

Guide to changing treatment: what if viral load rebounds *(Jan 2018): 24-page A5 booklet* **quantity** _____

- **Other resources**

U=U resources:

A3 posters quantity _____ **A5 leaflets quantity** _____ **A6 postcards quantity** _____

HIV Treatment 'Passports' - Booklets for patients to record their own medical history **quantity** _____

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