GLOBAL HIV CLINICAL FORUM: INTEGRASE INHIBITORS
DURBAN, SOUTH AFRICA • 16 JULY 2016

PROGRAM BOOK

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DEAR COLLEAGUE,

It is our pleasure to welcome you to the Global HIV Clinical Forum: Integrase Inhibitors meeting.

The Global HIV Clinical Forum is an abstract-driven educational program dedicated to the integration of science and clinical practice focusing on Integrase Inhibitors. This newer class of drugs promises to impact greatly the daily management of HIV. Already Integrase is identified as first line treatment in several countries and many other countries will follow in the [near] future. It is essential to prepare the medical community extensively on how to best integrate this class of drugs into daily clinical management in order to ensure best treatment for their patients.

The Global HIV Clinical Forum will provide an independent scientific program involving Key Opinion Leaders, for HIV clinicians and allied healthcare professionals. Forum participants will receive updates on the latest developments related to Integrase, will be able to share their clinical experience and will be encouraged to present the results from their ongoing and completed cohorts / research programs on Integrase. Furthermore, the program provides an educational setting where HIV medical professionals acquire specific skills that will enhance their capabilities to interpret research results and even develop new research projects.

This state-of-the-art scientific program will offer translational plenary lectures followed by ample time for Q&A and debate, stimulating interaction in order to bridge the knowledge gap between experts and the HIV treating community. Furthermore the program includes skills building sessions and clinical case discussions.

The Global HIV Clinical Forum is part of the HIV FORA platform that aims at enhancing the clinical knowledge and research capabilities of Healthcare Professionals working in the field of HIV therapy.

We wish you a fruitful meeting.

On behalf of the Forum Chairs,

CHARLES BOUCHER, MD, PHD
Erasmus Medical Center, The Netherlands

ANDREW KAMBUGU, MBCHB, MMED
Infectious Diseases Institute, Uganda
ACKNOWLEDGEMENTS

CONFERENECE SUPPORTER

The Global HIV Clinical Forum is supported by an unrestricted educational grant from Viiv Healthcare.

CONTRIBUTORS

HETERO LABS LTD.

CONFERENCE ORGANISER

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FORUM WEBSITE

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Virology Education is accredited by the South African Medical Association (SAMA) and the Health Professions Council of South Africa to provide the following CPD activity for medical specialists.

The SAMA is a non-statutory, professional association for public and private sector medical practitioners. It is a voluntary membership association, existing to serve the best interests and needs of its members in any and all healthcare-related matters.

The HPCSA guides and regulates the health professions in the country in aspects pertaining to registration, education and training, professional conduct and ethical behaviour, ensuring continuing professional development, and fostering compliance with healthcare standards.

The Global HIV Clinical Forum: Integrase Inhibitors is designated for a maximum of 7 clinical CPD points. Each medical specialist should claim only those hours of credit that he/she actually spent in the educational activity.
GENERAL INFORMATION

BADGE POLICY
All registered delegates are provided with an identity badge. Please wear it at all times to ensure admission to the meeting.

CERTIFICATE OF ATTENDANCE
A digital certificate of attendance will be sent to you by e-mail in the week following the meeting.

CONFERENCE MATERIALS
Presentations will be posted on www.hiv-clinical-forum.com shortly after the meeting and only upon approval of the speakers.

EVALUATION FORM
Evaluation sheets can be found in the back of this program book. At the end of each session, you are kindly requested to complete the evaluation form of the session, after which our hostesses will be collecting them. It is highly important that you fill out this form. Your feedback is very valuable to us and will enable us to further improve this meeting. Our assistants will be collecting the forms or you can simply hand them in during breaks.

GROUP PICTURE
The group picture will be taken during the start of the lunch break in the Global Village Session Room 2 (GV2).

MEETING SECRETARIAT
The meeting secretariat is situated at the Hospitality desk area of the Global Village Session Room 1 (GV1). The conference organizers can be addressed for all questions concerning the logistics of the meeting during conference hours.

MEETING ROOMS
Plenary sessions - Global Village Session Room 1 (GV1)
Breaks - Global Village Session Room 2 (GV2)

SOCIAL PROGRAM
There will be a network dinner starting at 19.00h. The location of this dinner will be the Outer Rainbow Terrace at the Hilton Hotel located next to the International Convention Centre.

SPEAKERS
Presenters are requested to submit their presentation on USB stick as early as possible, but latest in the break prior to their session. Presenters will be asked to sign an agreement letter in order to allow us to post the presentation on the website.

VIDEO REGISTRATION
During the plenary sessions, video registrations of invited lectures and discussions will take place. Filmed presentations will be placed online shortly after the meeting and only upon approval of the presenter.

WIFI
Wifi is available during the entire meeting. Access codes will be provided on the slides.

MOBILE PHONES
As a courtesy to speakers and other delegates, we request that all mobile phones and pagers are turned off.
before entering the meeting.

**INSURANCE & LIABILITY**

It is highly recommended that all participants carry proper individual travel and health insurance, as the meeting secretariat cannot accept liability for accidents, illness or injuries that may occur at or during the meeting. We advise you to not leave any valuable possessions unattended at the meeting. The organization cannot liable for any lost items during or at the meeting.

**DISCLAIMER**

This conference aims to offer participants the opportunity to share information. The conference organiser of this conference cannot accept any liability for the scientific content of the sessions or for any claims that may result from the use of information or publications from this conference. Virology Education disclaims all liability for injuries or losses of whatever nature incurred by individuals attending the conference.
PROGRAM
PROGRAM

SATURDAY 16 JULY

8.30 h  Check in & Welcome Coffee/Tea

9.00 h  Welcome and Introduction by the Workshop Chairs

Session 1

Chairs  Andrew Kambugu, Mauro Schechter

9.15 h  Basic Science of Integrase Inhibitors
        Mark A. Wainberg, MD, PhD, McGill University AIDS Centre, Canada

9.45 h  Q&A

10.00 h Resistance Characteristics of Integrase inhibitors
        Charles Boucher, MD, PhD, Erasmus Medical Center, The Netherlands

10.30 h  Q&A

10.45 h  Evaluation form

10.50 h  Coffee break

Session 2

Chairs  Pedro Cahn, Flavia Mugala-Mukungu

11.15 h  Pharmacological Considerations
         Anna Maria Geretti, MD, PhD, University of Liverpool, United Kingdom

11.45 h  Q&A

12.00 h  Integrating Science Into The Clinic: Current and Future Use of Integrase Inhibitors
         Anton Pozniak, MD, FRCP, Chelsea and Westminster Hospital, UK

12.30 h  Q&A

12.45 h  Evaluation form

12.50 h  Group picture (GV2)

13.00 h  Lunch break

Session 3

Chairs  Loice Achieng, Praphan Phanuphak

14.00 h  Optimizing HIV Therapy in Resource Limited Settings
         Francois Venter, MD, University of the Witwatersrand, South Africa
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<td><strong>Only the Best in Botswana - Optimizing the ART Response</strong></td>
<td><strong>Ava Avalos, MD</strong>, Careena Medical Center, Botswana</td>
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<td><strong>Integrase strand-transfer inhibitors primary resistance in patients with acute/recent HIV infection</strong></td>
<td>J. Ambrosioni O_01</td>
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<td><strong>Dolutegravir plus two nucleoside reverse transcriptase inhibitors versus efavirenz plus two nucleoside reverse transcriptase inhibitors as initial antiretroviral therapy for people with HIV: a systematic review</strong></td>
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<td><strong>Response to Raltegravir based third-line antiretroviral therapy among Ugandan children: A Case series from an urban HIV clinic</strong></td>
<td>E. Kaudha O_04</td>
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<td><strong>Cross-resistance to integrase strand transfer inhibitors (INSTIs) in 23 multiexperienced Mexican patients failing to raltegravir</strong></td>
<td>A. Orta-Reséndiz O_05</td>
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<td><strong>Future Challenges of HIV treatment</strong></td>
<td><strong>Stefano Vella, MD</strong>, Istituto Superiore di Sanità, Rome, Italy</td>
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INVITED SPEAKERS

AVA AVALOS

AVA AVALOS, MD is an HIV specialist physician who has been living and working in Botswana for the past 15 years. She has extensive clinical, research, policy, and programmatic experience, serving as the Clinical Advisor to the Department of HIV/AIDS Prevention and Care in the Botswana Ministry of Health.

Her area of clinical research and expertise focuses on HIV & TB drug resistance and treatment failure. She also serves as the Chair of the University of Botswana Institutional Review Board, and as a member of the Health Research and Development Committee at the Ministry of Health. She is a leading member of the Botswana TB and HIV Clinical Care Guidelines Committee and technical advisor for costing and drug forecasting within the Ministry.

In 2016 she was named to coordinate the National Task Force on "Treat All" implementation. Dr. Avalos directs her own medical research and consultancy business in Gaborone. Completing her undergraduate and graduate education in dance and physiological science before studying medicine in California, she continues to teach dance and yoga to both children and adults.

CHARLES BOUCHER

CHARLES A. B. BOUCHER, MD, PHD received his MD cum laude at the Academic Medical Center in 1987. In 1993 he finished his PhD in Virology at the University of Amsterdam. He published over 250 peer reviewed papers, that have appeared in Science, New England Journal of Medicine, The Lancet, Nature Medicine, Journal of Infectious Diseases and AIDS He coordinated several success European funded programs. He is the coordinator of a large network (33 countries) in Europe that studies the transmission of drug resistant HIV and chairs the European Society for Antiviral Research (ESAR). His current position is professor in Virology at the Erasmus Medical Center in Rotterdam, clinical microbiologist at the Erasmus Medical Center, coordinator of the Honours Class with the medical curriculum and scientific director at Virology Education, Utrecht, Netherlands.

Prof. Boucher is an organizer of international workshops, meetings and conferences, a consultant throughout Europe and the United States, a reviewer for scientific journals and co-chairman of several international committees. He is the author of numerous publications.
ANNA MARIA GERETTI

ANNA MARIA GERETTI, MD, PHD, FRCPATH is Professor of Virology & Infectious Diseases at the Institute of Infection & Global Health of the University of Liverpool, and Honorary Consultant at the Royal Liverpool University Hospital, where she consults on virus infections, sees patients with HIV or chronic viral hepatitis, teaches and conducts research.

She trained in Italy, the Netherlands, and the UK and has a special interest in HIV, hepatitis B and hepatitis C infection. In these areas she contributes to the educational, scientific, and guideline-formulation activities of national and international specialist societies and advisory bodies including the British HIV Association, the British Association for HIV and Sexual Health, and the European AIDS Clinical Society (EACS). She was elected to the EACS Governing Board in 2009 and in 2012 was elected EACS Secretary. She is also a founding member of the recently formed British Society for NanoMedicine.

Her research interests focus on antiviral therapy and drug-resistance, virus genetic variability, viral co-infections and molecular diagnostics. She has published over 100 peer-reviewed articles, editorials, reviews and book-chapters, runs capacity building programmes for resource-limited countries and enthusiastically shares her expertise to train doctors and scientists.

VICTOR MUSIIME

VICTOR MUSIIME, MBCHB, MMED, PHD is a Senior Lecturer at Makerere University, College of Health Sciences, Department of Paediatrics and Child Health, in Kampala, Uganda and an Investigator at Joint Clinical Research Centre (JCRC), Kampala, Uganda. He has worked as a Paediatrician at JCRC in HIV research, clinical care and treatment since 2004.

He was part and led a team of personnel that initiated and followed up a cohort of over 2000 HIV-infected children on antiretroviral therapy, provided treatment for opportunistic infections, as well as other forms of comprehensive Paediatric HIV care and treatment. He has also been an investigator on several research protocols, including the ARROW clinical trial, the CHAPAS 3 clinical trial and the PENTA 16 clinical trial.

His clinical and research interests are in Paediatric HIV-infection, antiretroviral therapy, child nutrition and infectious diseases.
ANTON POZNIAK

ANTON POZNIAK, MD, FRCP studied at the University of Bristol UK, qualifying in medicine in 1979. He began caring for patients with HIV in 1983 at Middlesex Hospital, London UK and worked as a Consultant Physician in Zimbabwe while researching for his doctorate in TB/HIV. From 1991, he ran the HIV research unit at King’s College, London. He became a fellow of the Royal College of Physicians in 1996 and in 1998 moved to his current position as Consultant Physician/Senior Lecturer, Chelsea and Westminster Hospital.

He is Director, HIV Services and Lead TB Physician. He is a Life member of the British HIV Association (BHIVA), helped write the BHIVA anti-viral HIV guidelines, and chairs the TB/HIV guidelines committee. He was an HIV advisor for the UK Government Health Select Committee and sits on the Expert advisory group on AIDS, UK Department of Health.

He is a DSMB member for numerous trials. An executive member of the European AIDS Clinical Society, he is IAS Treasurer and President, European AIDS Trial Network Foundation NEAT-ID. A member of the 2013 WHO HIV guidelines committee, he is on the Scientific Advisory Board and executive committee of the St Stephens AIDS Trust. He has published widely on clinical aspects of HIV treatment and care.

STEFANO VELLA

STEFANO VELLA, MD is a medical doctor specialized in infectious diseases and internal medicine, and a re-searcher in pathogenesis and therapy of viral infections. He is the Head of the “Pharmacology” De-partment at The Italian National Health Institute (ISS) and his research group has published exten-sively on various aspects of HIV pathogenesis, treatment and prevention in both the Northern and Southern hemispheres.

He served as President of the International Aids Society (IAS) from 2000 to 2002 and was instrumental in the organization of the conference in Durban (2000) which is considered to be a milestone event in the fight against health inequalities. Dr. Vella has been a member of the Technical Review Panel (TRP) of the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) and is currently the Italian member of the EDCTP General Assembly.

Dr. Vella is Vice President with Francoise Barrè Sinoussi, of the Scientific Council, ANRS (Agence Nationale de Recherche sur le Sida), Paris, France and also Special Scientific Advisor to the UNAIDS and Chair of the 2013 WHO HIV TREATMENT GUIDELINES PANEL.
FRANÇOIS VENTER

FRANÇOIS VENTER, MD, FCP (SA), MMED, DTM&H, DIP HIV is the Deputy Executive Director of the Wits Reproductive Health and HIV Institute at the University of the Witwatersrand. He leads multiple antiretroviral treatment optimisation studies, and has an active interest in public sector access to HIV services.

He is currently working on new first and second line antiretroviral options, patient linkage to care interventions, and self-testing projects. Previously, he lead large PEPFAR-funded HIV programmes in South Africa, including one that focused on truckers and sex workers. He has been represented on South African and regional guidelines for over a decade, having done almost all his training within South Africa.

His major research currently focus on low dose stavudine, low dose darunavir in second line treatment, and combinations of newer drugs to improve the resistance and potency of first line, as well as using patient information to drive improved linkage to care after diagnosis.

MARK WAINBERG

MARK A. WAINBERG, MD, PHD is Professor of Medicine and Microbiology and Immunology at McGill University in Montreal, Canada, and Director of the McGill University AIDS Centre. He served as President of the International AIDS Society between 1998-2000 with responsibilities that included organization of the XIIIth International Congress on AIDS in Durban, South Africa, 2000. He was also co-Chair of the XVth International AIDS Conference that took place in Toronto in August, 2006.

He is well-known for his initial identification of 3TC as an anti-viral drug, in collaboration with BioChem Pharma Inc. in 1989, as well as for multiple contributions to the field of HIV drug resistance. Dr. Wainberg now works on efforts to achieve a cure for HIV infection. Among other honours, Dr. Wainberg is an Officer of the Order of Canada and a Chevalier in the Legion d’Honneur of France as well as the recipient of a number of honorary doctorates.

Dr. Wainberg is an author of over 500 research papers and 100 reviews and commentary articles that have appeared in the scientific literature. He is co-Editor-in-Chief of Retrovirology, co-Editor-in-Chief of Journal of the International AIDS Society, and is a member of the editorial committees of multiple other journals. More than 30 students have obtained their Ph.D. degrees under his tutelage.
ABSTRACTS
Abstract: O_01

Integrase strand-transfer inhibitors primary resistance in patients with acute/recent HIV infection

Juan Ambrosioni1, David Nicolás1, Christian Manzano1, Fernando Agüero1, José Luis Blanco1, María del Mar Mosquera2, Judit Peñafiel1, José María Gatell1, María Angeles Marcos2 and José María Miró1

1. Infectious Diseases Service, Hospital Clinic-IDIBAPS, University of Barcelona, Barcelona, Spain. 2. Laboratory of Virology, Microbiology Service, Hospital Clinic-IDIBAPS, University of Barcelona, Barcelona, Spain.

Background: Acute/recent HIV infection represents approximately 20 to 25% of new HIV-diagnosed patients in many European countries. However, these cases contribute disproportionately to HIV transmission due to the high viral load (VL) and frequent unawareness of HIV infection. Most recent international guidelines suggest integrase strand-transfer inhibitors (InSTIs) as preferred antiretroviral regimens for naïve HIV-infected individuals. However, primary resistance to InSTIs is still not monitored in many centers. The aim of our study was to evaluate the prevalence of resistance mutations to InSTIs in newly-diagnosed patients with acute/recent HIV infection.

Methods: Genotypic drug resistance test were performed in all consecutive patients prospectively enrolled in the Acute/recent HIV infection cohort of Hospital Clinic (documented infection of less than 6 months), from May 12th 2015 to May 12th 2016. Sequences were obtained by high-throughput sequencing. Mutations present in any proportion were reported; mutations present in more than 20% of sequences were considered as clinically relevant. Cases with InSTIs mutations were described and compared with the rest of the patients included in the cohort in this 1-year period. Categorical variables were expressed as a frequency (percentage). Continuous variables were expressed as median (interquartile range). To compare categorical variables between the two groups the Fisher exact test was used. To compare continuous variables between the two groups the Mann-Whitney test was performed. Data were analyzed with R software.

Results: Five out of 36 consecutive patients (13.89%, IC95% [4.67-29.5]) with acute/recent HIV infection included in our cohort in a 1-year period were detected to have strains carrying InSTIs mutations conferring low level resistance to raltegravir and elvitegravir. Four patients had the 157Q mutation and one patient the Q95K mutation. All cases were men-who-have-sex-with-men patients with a median age of 37 y.o and infected with subtype B strains. All were HLA-B5701 negative. Three out of four cases had X4 tropism. Median VL was 5.33 log copies/mL (range 2.92-6.95 log/mL). The InSTI mutation was present in a high proportion of RNA copies (mutational load >95% of viral load in all cases). There were no major epidemiological or viral differences compared to the 31 patients without InSTIs mutations included in our cohort in the same period (age, route of transmission, geographical origin, CD4 cell count, transmission of drug resistance to other ARV families, subtype distribution; Fiebig stage; p>0.05 for all variables).

Conclusions: Although signature InSTI mutations (such Y143R/C, N155H or Q148K/R/H) were not detected, other polymorphic accessory mutations conferring low level resistance to raltegravir and elvitegravir were frequently found in baseline genotypic test during this one-year study. All cases were infected with subtype B, the most frequent in Europe. In the context of primary HIV infection, virological response to the different InSTI-based regimens should be carefully monitored to evaluate the impact of these InSTI mutations.
Abstract: O_02

Dolutegravir plus two nucleoside reverse transcriptase inhibitors versus efavirenz plus two nucleoside reverse transcriptase inhibitors as initial antiretroviral therapy for people with HIV: a systematic review

George W. Rutherford, Hacsi Horvath, Global Health Sciences, University of California, San Francisco, USA

Background: Dolutegravir (DTG) is a once-daily unboosted second-generation integrase-inhibitor that along with two nucleoside reverse transcriptase inhibitors is one of several regimens recommended by the United States, United Kingdom and European Union for first-line antiretroviral treatment of people with HIV infection. Our objective was to review the evidence for the efficacy and safety of DTG-based first-line regimens compared to efavirenz (EFV)-based regimens.

Methods: We conducted a systematic review. We comprehensively searched a range of databases as well as conference abstracts and a trials registry. We used Cochrane methods in screening and data collection and assessed each study’s risk of bias with the Cochrane tool. We meta-analyzed data using a fixed-effects model. We used GRADE to assess evidence quality.

Results: From 492 search results, we identified two randomized controlled trials, reported in five peer-reviewed articles and one conference abstract. One trial tested two DTG-based regimens (DTG + abacavir (ABC) + lamivudine (3TC) or DTG + tenofovir + emtricitabine) against an EFV-based regimen (EFV+ABC+3TC). The other trial tested DTG+ABC+3TC against EFV+ABC+3TC. In meta-analysis, DTG-containing regimens were superior to EFV-containing regimens at 48 weeks and at 96 weeks (RR=1.10, 95% CI 1.04-1.16; and RR=1.12, 95% CI 1.04-1.21, respectively). In one trial, the DTG-containing regimen was superior at 144 weeks (RR=1.13, 95% CI 1.02-1.24). DTG-containing regimens were superior in reducing treatment discontinuation compared to those containing EFV at 96 weeks and at 144 weeks (RR=0.27, 95% CI 0.15-0.50; and RR=0.28, 95% CI 0.16-0.48, respectively). Risk of serious adverse events was similar in each regimen at 96 weeks (RR=1.15, 95% CI 0.80-1.63) and 144 weeks (RR=0.93, 95% CI 0.68-1.29). Risk of bias was moderate overall, as was GRADE evidence quality.

Conclusions: DTG-based regimens should be considered in future World Health Organization guidelines for initial HIV treatment.
Abstract: O_03

Dolutegravir Monotherapy In A Small Cohort Of HIV-Infected Naive Patients With <100.000 Copies/Ml HIV RNA Load

Stefano Nicolè¹, Massimiliano Lanzafame², Emanuela Lattuada¹, Romualdo Mazzi¹, Fabio Rigo³, Giulia Cucchetto¹, Davide Gibellini³, Ercole Concia¹, Sandro Vento³

¹ Infectious Diseases Unit, G.B. Rossi University Hospital, Verona, Italy; 2 "Diagnosis and Therapy of HIV Infection" Unit, G.B. Rossi University Hospital, Verona, Italy; 3 Microbiology Unit, G.B. Rossi University Hospital, Verona, Italy; 4 Department of Medicine, School of Medicine, Nazarbayev University, Astana, Kazakhstan

Dolutegravir is an HIV integrase inhibitor with a potent antiviral activity, distinct resistance profile and favorable pharmacokinetic profile recently approved for use in naive and HAART-experienced patients. In dose-ranging study, dolutegravir monotherapy has shown a potent antiviral activity, with a significant reduction in plasma HIV-RNA levels from baseline to day 11 for various doses¹.

We report our experience in sixteen antiretroviral naive HIV-1 infected patients followed at the Infectious Diseases Outpatient Department of G.B. Rossi Hospital in Verona, Italy, who started dolutegravir monotherapy after refusing nucleoside reverse transcriptase inhibitors. They all gave written informed consent to the use of dolutegravir as only antiretroviral drug. The 12 men and 2 women were all HIV monoinfected, with a mean age of 43.5 years (range 28 –76). Pre-treatment characteristics of the patients, HIV RNA level and number of CD4 cells at baseline, HIV RNA level and number of CD4 lymphocytes at the last control, and duration of dolutegravir monotherapy are indicated in Table 1 (see next page, ed note).

The second table shows total cholesterol, low-density lipoprotein and high-density lipoprotein cholesterol, and triglycerides levels before starting dolutegravir and at the last control.

No patients had baseline HIV resistance mutations for NRTI, NNRTI, PI or INSTI. For CD4 cell count the mean increase was of 585 cells/ µL.

The mean duration of effective DGT monotherapy was 7,9 months (range 2-13) and all fourteen patients achieved a viral load less than 20 copies/ml at this time. Serum lipids increased importantly only in 1 patient (n. 1, Table 2), who had also an increase in her body weight. The treatment of HIV infection continue to be based on the combination of three antiretroviral drugs. Monotherapy with protease inhibitors in antiretroviral naive patients is inferior to standard antiretroviral regimens in clinical studies².

Dolutegravir in association with two nucleosides is superior to efavirenz and darunavir in naive patients. Dolutegravir 50 mg daily showed a high antiviral potency with a reduction of viral load of 2.5 log10 after ten days of monotherapy.

Recently a combination of dolutegravir and lamivudine was virologically effective in 20 treatment-naïve patients in a pilot study³. The results of our small and time limited study suggest the feasibility of a dolutegravir monotherapy in patients with a viral load lower than 100,000 copies/mL. Should well powered clinical trials with long follow-up confirm our results, a dolutegravir monotherapy strategy could be used to preserve future antiretroviral drug options, reducing side-effects and healthcare costs.

REFERENCES


(This presenter was not present at the meeting, ed. note)
### Table 1: Baseline characteristics of the patients, HIV-RNA level and number of CD4 cells at baseline, HIV RNA level* and number of CD4 lymphocytes at last control, and months on dolutegravir monotherapy.

<table>
<thead>
<tr>
<th>Patient number</th>
<th>Age/Gender/sexual orientation</th>
<th>CDC stage</th>
<th>CD4/µL at baseline</th>
<th>HIV-RNA copies/mL at baseline</th>
<th>HIV-RNA copies/mL at last visit</th>
<th>CD4/µL at last visit</th>
<th>Months on Dolutegravir</th>
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<td>1</td>
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<td>A2</td>
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*The blood samples were collected from HIV-1 seropositive patients by venipuncture. All plasma were extracted and quantified by the COBAS AmpliPrep/COBAS TaqMan HIV-1 test, version 2.0 (Roche, Mannheim, Germany), following the manufacturers’ instructions. The amount of HIV-1 RNA is shown as the number of copies per milliliter of plasma. The lower quantitative detection limit is determined at 20 copies/ml (HIV RNA < 20 copies/ml or not detectable."

### Table 2: Serum levels of total cholesterol, LDL and HDL cholesterol and triglycerides before starting dolutegravir and at last control.

| Patient number | Pretreatment total cholesterol/LDL/HDL (Total C. n.v.:<200 mg/dL) (LDL n.v. <130 mg/dL) (HDL d.v. >40 mg/dL) | Total cholesterol/LDL/HDL at last visit (Total C. n.v.:<200 mg/dL) (LDL n.v. <130 mg/dL) (HDL d.v. >40 mg/dL) | Pretreatment Triglycerides (n.v. <150 mg/dL) | Triglycerides at last visit (n.v. <150 mg/dL) |
|----------------|----------------------------------------------------------------|
| 1              | 194 / 111 / 52                                                  | 236 / 141 / 71                                                  | 153                                               | 114                                               |
| 2              | 107 / 72 / 42                                                   | 118 / miss / 59                                                  | 43                                                | 36                                                |
| 3              | 173 / 107 / 51                                                  | 189 / 107 / 60                                                  | 75                                                | 103                                               |
| 4              | 138 / 112 / 26                                                  | 168 / 106 / 33                                                  | 157                                               | 145                                               |
| 5              | 132 / 95 / 36                                                   | 180 / 116 / 41                                                  | 76                                                | 112                                               |
| 6              | 170 / 118 / 34                                                  | 206 / 148 / 41                                                  | 92                                                | 79                                                |
| 7              | 160 / 104 / 42                                                  | 193 / 126 / 49                                                  | 68                                                | 90                                                |
| 8              | 221 / 144 / 59                                                  | 192 / 117 / 51                                                  | 90                                                | 119                                               |
| 10             | 175 / 109 / 49                                                  | 183 / 106 / 52                                                  | 82                                                | 120                                               |
| 11             | 208 / 142 / 42                                                  | 206 / 123 / 33                                                  | 115                                               | 246                                               |
| 12             | 225 / 129 / 76                                                  | 210 / 114 / 80                                                  | 92                                                | 78                                                |
| 13             | 123 / miss / 40                                                 | 128 / miss / 41                                                  | 59                                                | 63                                                |
| 14             | 150 / 81 / 43                                                   | 139 / miss / 47                                                  | 126                                               | 54                                                |
Abstract: O_04

Response to Raltegravir based third-line antiretroviral therapy among Ugandan children: A Case series from an urban HIV clinic

Elizabeth Kaudha, Eva Natukunda, Grace Mirembe, Immaculate Nankya, Jonathan Mwesigwa, David Williams Eram, Francis Saali, Victor Musimwe

Joint Clinical Research Centre, Kampala, Uganda

Background: There is an increasing number of HIV-positive children failing second-line antiretroviral therapy (ART) and those who develop resistance to Protease inhibitors (PI); these require third-line/salvage therapy. There is limited data regarding response to raltegravir based third-line ART among children in resource limited clinical settings. Here we describe the response to raltegravir based third-line ART among 5 children at Joint Clinical Research Centre (JCRC), in Kampala, Uganda.

Methods: We searched the patient care database for children attending JCRC who failed second-line ART; had triple class antiretroviral drug resistance (Nucleoside-Reverse-Transcriptase-inhibitor (NRTI), Non-nucleoside-Reverse-Transcriptase-Inhibitor (NNRTI) and PI resistance); and were on raltegravir based third-line ART for a minimum of 6months. Five patients fulfilled the selection criteria and for these we conducted a retrospective chart review. We assessed weight, CD4 count, viral load and World Health Organization (WHO) clinical stage at baseline and after switch to raltegravir based therapy. ART history and genotypic resistance test results prior to switch were also reviewed.

Results: Of the 5 children, 4 were male and 1 was female. The children at switch to third-line ART were mean age, 10(range 5 to 12) years. The children were followed up on raltegravir based third-line ART for 6 to 54months; all were still on their initial third-line regimens at the last visit. The children's third-line regimens were: darunavir/ritonavir (DRV/r) +raltegravir (RAL) (N=3); etravirine (ETR)+DRV/r+RAL (N=1); tenofovir (TDF)+lamivudine (3TC)+DRV/r+RAL (N=1). All had been on 2NRTIs+1NNRTI for their first-line ART, and lopinavir/ritonavir based second-line ART, and each had developed: 5 or more NRTI resistance associated mutations (RAMs); 2 or 3 NNRTI RAMs (N=4) and 1 NNRTI RAM (N=1); and 3 or 4 PI RAMs.

At the two time points, baseline/switch to third-line ART (Visit A) and the most recent laboratory visit (Visit B), the patient's reviewed parameters were as follows:


In summary, all the 5 children achieved viral suppression, they had increased weights and CD4 counts, and none developed new WHO stage III/IV events.

Conclusion: These children responded favourably - clinically, immunologically and virologically, to Raltegravir based third-line ART.
Abstract: O_05

**Cross-resistance to integrase strand transfer inhibitors (INSTIs) in 23 multiexperienced Mexican patients failing to raltegravir.**

Orta-Reséndiz A\(^1\), Rodríguez-Díaz RA\(^1\), Hernández-Flores M\(^1\), Angulo-Medina Luis\(^2\), Soto-Ramírez LE\(^1\).

\(^1\) Instituto Nacional de Ciencias Médicas y Nutrición "Salvador Zubiran", Mexico City, Mexico, 2 Complejo Hemato Oncológico y Radiocirugía/Instituto Venezolano de los Seguros Sociales IVSS, Caracas, Venezuela.

**Background:** The use of integrase inhibitors in Mexico is mainly limited to raltegravir in multiexperienced patients. With the increased use of raltegravir, some failures have been detected. The objective of this study was to determine the frequency of cross-resistance between INSTIs in patients failing to raltegravir as salvage regimen.

**Materials & Methods:** Data were collected from 23 multiexperienced patients failing a raltegravir containing regimen from different centers in Mexico from 2010 to 2016. Genotyping test at raltegravir failure was performed by RT-PCR amplification and sequencing for the integrase, reverse transcriptase and protease genes. All viral loads were determined by COBAS AmpliPrep/COBAS TaqMan HIV-1 Test, v2.0 Resistance-associated mutations (RAMs) and clinical resistance degree were determined with the Stanford HIVdb algorithm (v7.0).

**Results:** From patient’s available data, the mean/median viral load were 4.08/3.83 log10 copies/ml respectively. All samples were subtype B. The most frequent mutations detected were Y143C/R/H (30.4%), Q148H/K (13%), N155H (13%) and G140A/S (13%). At failure, viruses were considered as fully susceptible to raltegravir in 52.2%, with intermediate resistance in 4.3% and 43.4% with high level resistance. All raltegravir susceptible cases were susceptible to other INSTIs (n=12). Of those resistant to raltegravir (n=11), all were also resistant to elvitegravir and 45.5% (n=5) were resistant to dolutegravir. 3/5 resistant cases to dolutegravir (60%) had the K/H substitution at position 148 plus the 140S/A and the 138K in one case. The other two cases had low level resistance including important primary or accessory mutations (92Q, 138K, 74M). We found a high prevalence of the combination of L101I/T124A polymorphic mutations (26.1%).

**Conclusions:** This is the first study to explore the integrase inhibitors resistance profile in Mexican patients. Our frequencies of INSTIs RAMs in salvage combination with raltegravir at failure were lower than those reported in BENCHMRK. Also, our frequencies of cross-resistance to dolutegravir were also lower than those reported in VIKING-3. We found a high frequency of polymorphic combination 101I/124A than that reported for subtype B and that is related to development of dolutegravir resistance. Minority variants should be investigated.
Abstract: O_06

Drug-induced hypersensitivity syndrome (DIHS/DRESS) after initiation of darunavir and raltegravir: report of a fatal case

Walter A. Eyer-Silva¹, Guilherme Almeida Rosa da Silva¹, Maria Alessandra Leite Freire²

¹ Hospital Universitário Gaffrée e Guinle, Universidade Federal do Estado do Rio de Janeiro, Rio de Janeiro, Brazil. ² Setor de Epidemiologia, Secretaria Municipal de Saúde de Miracema, Rio de Janeiro State, Brazil.

Background: DIHS is a severe, idiosyncratic, multiorgan disorder that arises 2 weeks to 3 months after initiation of a drug and is characterized by fever, cutaneous eruption, and involvement of one or more internal organs. It is also known as DRESS (drug reaction with eosinophilia and systemic symptoms), but eosinophilia is absent in around 50% of cases. The diagnosis may be challenging due to the broad clinical and laboratory presentation. Aromatic anticonvulsants are prominent culprits.

Case Report: In early May 2016, a 38-year-old HIV-infected African-Brazilian female patient presented with an acute onset of fever and a cutaneous eruption that started on the face. The eruption was first noted 5 days previously. Since some households had had a recent diagnosis of Zika virus infection, the patient attributed her signs and symptoms to this arbovirus infection. She complained of malaise and was icteric. The patient was under regular follow up at the municipal HIV/AIDS program of a small city in inner Rio de Janeiro State since July 2004 and had a 12-year experience to multiple antiretroviral agents, including the 3 HIV protease inhibitors. Her most recent CD4 cell count was 521/mm³ and the plasma HIV viral load was log10=4,7. She had significant visual and auditory deficits as a result of 2 previous life-threatening episodes of cryptococcal meningitis. Five weeks previously, she had started a novel, genotypic-guided antiretroviral combination composed of the HIV integrase inhibitor raltegravir and the protease inhibitor darunavir (with a booster dose of ritonavir). She was taking no other medications. The rash was highly suggestive of DIHS. There was facial edema, mainly periorbital, with follicular accentuation. The patient was admitted to the hospital and all antiretroviral agents were interrupted. Supportive care, intravenous fluids, corticosteroids, and prophylaxis with sulfamethoxazole-trimethoprim and fluconazole were given. Laboratory evaluations showed an increased activity of liver transaminases (ALT 131 U/L; AST 251 U/L), conjugated (3,8mg/dl) and total bilirubin (4,2mg/dl), and leukocytosis (12,500/μL) without eosinophilia. Renal function was normal, as well as alkaline phosphatase and γ-glutamyl transferase levels. She had no evidence of previous liver disease and tested negative for hepatitis B and hepatitis C. Scaling, cheilitis and caudal progression to shoulder level and distal extremities followed. An ocular secretion gave the face a yellowish-crusted appearance. The patient died of respiratory failure in the intensive care unit 9 days after admission. No cutaneous biopsy or necropsy studies were performed.

Discussion: Raltegravir, the first HIV integrase inhibitor, is considered a drug of low adverse effect profile. At least 5 previous reports of DIHS/DRESS after its initiation have been published since 2011. This is the first fatal case ever reported. It is noteworthy that 5 out of 6 reported cases occurred in female patients and 5 out of 5 occurred in patients of African ancestry (ethnic information is lacking in one report).

Conclusions: Patients starting raltegravir-including regimens should be advised on early recognition of signs and symptoms of drug hypersensitivity since early discontinuation of the culprit drug is of utmost importance in the management of DIHS/DRESS.

(This presenter was not present at the meeting, ed. note)
**DISCLOSURE STATEMENTS**

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In order to ensure independence and objectivity of this workshop and to meet with the regulations of CPD issuing agencies, it is required that faculty members and invited speakers disclose relationships with a commercial interest if both:

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- the individual has the opportunity to affect the content of CPD about the products or services of that commercial interest.

This policy pertains to relationships with pharmaceutical companies, biomedical device manufacturers, or other corporations whose products or services are related to the subject matter of the presentation topic.

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**HIV FORA: INTEGRATING SCIENCE AND CLINICAL PRACTICE**
- **EUROPEAN HIV CLINICAL FORUM: INTEGRASE INHIBITORS**
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- **INTERNATIONAL WORKSHOP ON**
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