Abstracts presented at the
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ABSTRACT CONTENTS

Table 1. (*Abstract P06*)

	Week 26	Week 52
VAT (%)	-27.4 (14.0) vs 9.8 (14.9)[1]	-31.1 (16.8) vs 8.1 (13.8)[1]
WC (cm)	-4.2 (5.7) vs -0.4 (4.4)*	-4.7 (6.4) vs -1.0 (4.9)*
TG (mg/dl)	-50 (147) vs -12 (105)*	-68 (159) vs 3 (102)*
IGF-I (ng/ml)	136 (106) vs 85 (104)*	91 (100) vs 76 (138)
FBG (mg/dl)	1 (16) vs 5 (14)*	-1 (14) vs 8 (17)*
Insulin (μIU/ml)	-1.0 (24.7) vs 5.6 (13.2)*	-2.5 (18.7) vs 4.8 (17.5)*
HbA1c (%)	0.07 (0.34) vs 0.27 (0.41)*	0.03 (0.32) vs 0.18 (0.46)*

Data are mean (SD).*P<0.05. [1]Analysis not done.

Method: Two Phase III multicenter, randomized, double-blind, trials, consisting of 26-week, placebo-controlled primary intervention phase followed by 26-week extension phase were conducted. Data from the two studies were pooled. In the per-protocol population, 402 HIV patients with excess abdominal fat were treated with tesamorelin for the main phase (26 weeks) and 176 patients for both phases (52 weeks). Statistical analyses were performed on combined results from the two trials using ANCOVA models for efficacy and some safety parameters.
Results: Dropout rates were similar in treatment and placebo groups. At week 26, 68.8% (n=232) of tesamorelin-treated patients vs 32.6% (n=56) of placebo-treated patients were categorized as responders (P<0.001). 72.4% of patients treated with tesamorelin for 52 weeks were categorized as responders. Changes from baseline (mean [standard deviation]) in tesamorelin-treated responders versus non-responders are shown in Table 1 for the main and the extension phases.
Distress due to belly image as assessed by patients was also improved in VAT responders at week 26 (score change: 15.53 vs 3.40 [P<0.001]). FBG and insulin were unchanged in responders and deteriorated in non-responders.
Conclusion: This analysis revealed a significantly greater responder rate in tesamorelin-treated patients compared to placebo. FBG and insulin were unchanged in the responders but deteriorated in non-responders. These data show that no clinically significant changes in glucose parameters occurred in the large majority of HIV patients with excess abdominal fat responding to tesamorelin, with significant reductions in VAT. Moreover, significant benefits in metabolic risk factors accrued. These data provide important new evidence for the clinical utility and metabolic benefits of strategies to reduce VAT by augmenting the biological secretion of GH.

ABSTRACT P07

Antiviral Therapy 2011; **16 Suppl 2:**A30

Coronary artery calcification is associated with femoral but not with lumbar spine mineral density

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Background: Vascular calcification (VC) of the coronaries (CAC) is associated with a high risk of cardiovascular (CV) events and poor survival. A large body of evidence suggests the existence of a link between bone demineralization and VC. We aimed at testing the association between CAC and bone mineral density (BMD) in a large cohort of HIV-infected patients.
Materials: We assessed simultaneously CAC as well as lumbar and femoral BMD in a large cohort of 681 consecutive HIV-infected patients by means of cardiac CT and DEXA. Logistic regression analysis was used to determine the association between low femoral and lumbar spine BMD (defined as BMD below the 25th percentile of the study cohort distribution) and extensive CAC (defined as CAC greater than 100 Agatston Unit)
Results: Patients with CAC>100 were older, more likely to be male, diabetic and overweight. In contrast, a better renal function and a lower CV risk profile was note among patients without extensive CAC<100. At univariable analyses, a trend toward low femoral (14.26 vs 22.6, P=0.10) but not lumbar spine BMD (15 vs 16, P=0.95) was noted. Adjustments for factors associated with either

CAC or BMD revealed a significant association between CAC and femoral but not lumbar spine BMD. Indeed, patients with extensive CAC had a twofold higher risk of having a low femoral BMD (OR: 2.24; 95% CI: 1.08–4.65; *P*=0.03) after adjustment for age, sex, diabetes, BMI, Framingham risk score, estimated glomerular filtration rate (by EPI equation), protease inhibitor exposure and CD4 nadir.
Conclusion: Current results show that CAC is independently associated with low BMD in HIV infected patients. Further studies are needed to elucidate the mechanisms that link bone demineralization and VC deposition and whether therapies that impact BMD might also attenuate VC progression in HIV-infected patients.

ABSTRACT P08

Antiviral Therapy 2011; **16 Suppl 2:**A31

The Metabolic Abnormalities, Telmisartan, and HIV Infection (MATH) Trial

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Background: Visceral adipose tissue (VAT) accumulation in the setting of HIV infection and ART is not fully understood, and treatment options remain limited. Telmisartan, an angiotensin receptor blocker and PPAR-γ agonist, has been shown to decrease VAT in HIV-uninfected subjects. This study examines the effects of standard-dose telmisartan on adipose tissue (AT) volumes and metabolic parameters in HIV-infected patients with lipohypertrophy.
Methods: 35 HIV-infected men and women with HIV-1 viral loads <48 copies/ml on ART and central fat accumulation (defined for women/men as: waist circumference >94/95 cm or a waist-to-hip ratio >0.88/0.94) received open-label telmisartan 40 mg daily for 24 weeks. AT volumes were quantified at 0 and 24 weeks by L4-L5 single slice CT scans. Waist circumference and waist:hip ratios were performed by a single operator using standardized technique. Fasting serum lipids, glucose and hs-CRP were obtained. 35 subjects provided 80% power to detect a 10% decrease in VAT over 24 weeks (two-sided alpha 0.05).
Results: 15 women and 20 men were enrolled and completed the 24-week protocol. At entry (mean or %): age 49; 43% Hispanic, 34% Black, 23% White; 91% non-smokers; CD4 635 cells/mm^3; BMI 34.6; 51% PI, 20% NNRTI, 26% RAL, 74% TDF, 66% FTC. After 24 weeks, no significant improvement in VAT was observed, although participants lost a mean of 3.3% (95% CI -11.9%, 5.42%; *P*=0.45). A significant loss of both total (TAT; 4.2%; 95% CI -8.6, -0.21; *P*=0.04) and subcutaneous (SAT; 3.4%; 95% CI -6.41%, -0.46%; *P*=0.03) AT was observed. A concomitant decrease in both waist and hip circumference accompanied SAT loss without an overall change in waist: hip ratio, VAT:TAT ratio, weight or BMI.
This study was not powered to detect differences between subgroups, however women lost 5.2% VAT (*P*=0.48), while men lost 1.9% (*P*=0.73). SAT and VAT loss was greater for subjects with BMI≥30 at baseline (SAT: 5.6% vs 1.0%, *P*=0.12; VAT: 6.2% vs 0.02%, *P*=0.49).
No significant change in lipids, glucose or hs-CRP was observed. The average decrement in systolic/diastolic BP over 24 weeks was 7/5 mmHg, similar to that seen in HIV-negative subjects. No related Grade 3 or 4 adverse events occurred.
Conclusions: Telmisartan was extremely well-tolerated. No significant loss of VAT was demonstrated. However, an overall loss of VAT was observed, and greater losses may have been seen with continued follow-up. SAT loss has not been observed with telmisartan in the HIV-negative population. These findings warrant continued investigation of telmisartan's effects on AT depots in HIV-infected patients with lipodystrophy, including the potential for differential responses to treatment by sex.

ABSTRACT P09

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Peripheral intermuscular adipose tissue and intramyocellular lipids: other fat compartments implicated in HIV-associated lipodystrophy changes seen on switching from thymidine analogues to tenofovir

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Background: Subcutaneous adipose tissue (SAT) decreases and that visceral abdominal fat (VAT) increases in HIV-associated lipodistrophy, measured by DEXA and CT scan. Decreased intermuscular adipose tissue (IMAT) and an elevation of intramyocellular lipid (IMCL) accumulation measured by magnetic resonance (MR) have also been described. No longitudinal studies have been reported evaluating any correlation between adipose tissue compartments, their association with metabolic parameters and the effects of switching from thymidine analogues (TA) to tenofovir disoproxil fumarate (TDF)-containing regimens.
Methods: 28 HIV-infected patients, 22 men and 6 women with moderate to severe lipoatrophy receiving