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Background

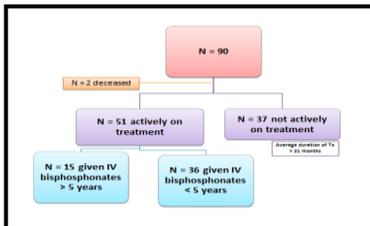
- PLWH are at increased risk of osteoporosis/ osteopenia/ fragility fractures;
- Risk factors for osteoporosis and fragility fracture s are older age, low body weight, low muscle mass, corticosteroid use, and hypogonadism, smoking and high alcohol intake;
- With the initiation of ART there is an overall decrease in bone mineral density (BMD) over the first 48 to 96 weeks; tenofovir disoproxil fumarate (TDF) and protease inhibitors (PIs) have been associated with a decrease in BMD;
- **BHIVA guidelines** recommend clinicians to perform a FRAX score in PLWH > 50 years, BMD in patients at increased risk of fracture, their vitamin D/parathyroid hormone status assessed, and their ARVs reviewed¹;
- IV bisphosphonate treatment is indicated for patients with FRAX score > 20%, who have had baseline renal function tests, and serum corrected calcium, vitamin D and phosphate levels measured. Its important that patients are aware that dietary calcium intake should be more than 700mg/day;
- It is known that administration of IV bisphosphonates is superior to switching TDF to TAF in PLWH ²;
- Zoledronic acid at 5 mg intravenously once yearly is approved for the treatment of osteoporosis in PLWH at increased risk of fracture, including those with a recent low trauma fracture;
- IV Bisphosphonate therapy has also been associated with jaw necrosis and atypical fracture in 0.01% of patients ³;
- However, a clear prescribing policy for use of IV bisphosphonates in the setting of HIV has not yet been established.

Methods

- Retrospective data collection was carried out on PLWH receiving IV bisphosphonate therapy on the Gazzard Day Unit at Chelsea & Westminster Hospital to evaluate safety outcomes and duration of treatment;
- Search included all patients who had received at least one dose of IV ibandronic or zoledronic acid between Jan 2015 and Dec 2017;
- Each patient's notes were reviewed for: FRAX score documentation, BMD and reason for treatment initiation; ARVs at time of diagnosis of osteoporosis/ bisphosphonate initiation; vitamin D & calcium serum levels and renal function; ARV regimen changes; duration of IV bisphosphonate therapy ; follow/up BMD ; any adverse events secondary to IV bisphosphonate treatment.

Results

Overall Audit Results



Safety Parameters measured prior to IV bisphosphonate administration

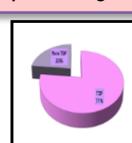
Safety Parameters measured prior to IV bisphosphonate administration	% Patients meeting safety parameters
Renal function (CrCl > 60ml/min)	100%
Serum corrected calcium (2.20 - 2.60mmol/L)	100%
Serum phosphate (0.8 - 1.5mmol/L)	100%

No patients were found to have experienced adverse effects secondary to IV bisphosphonate therapy.

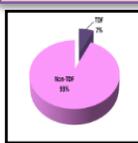
Patient Demographics at Baseline

Patient Demographics at Baseline	% patients
Sex	78.9% M; 21.1% F
Age	17.7% <50; 82.3% >50
Ethnicity	
Viral Load <50	94.4%; 5.6% detectable
FRAX score documentation	2.20%
BMD spine < -2.5	52.20%
BMD femur < -2.5	11.10%
BMD < -2.5 (spine & femur)	7.80%

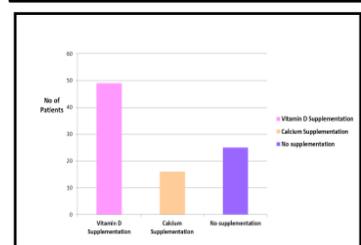
ARVs at time of Osteoporosis Diagnosis



Current ARVs



Calcium & Vitamin D supplementation



Conclusions

- PLWH are at higher risk of osteoporosis due to a combination of traditional risk factors, including lifestyle, and continuous antiretroviral treatment;
- There were no reported AE secondary to IV bisphosphonates in our patients
- As a result of this audit and to ensure better management and monitoring of patient receiving IV bisphosphonates, a multidisciplinary approach was taken including the creation of a policy, forms, PILs and patient reminder cards (in accordance with NICE).
- Use of IV bisphosphonates in PLWH will be re-audited in 12 months to review strategies put into place.

Strategies to Improve Practice

Bisphosphonate Policy



Referral & Follow-up Forms



Patient Reminder Card



Patient Information Leaflet



References

- ¹ BHIVA guidelines on the routine investigation and monitoring of HIV-1 positive adults. (2016).
- ² Brown T, Yin M, Gupta S, Short W, et al. Combined effects of bisphosphonates & TDF→TAF switch in HIV positive adults with low BMD. (2018).
- ³ Summary of Product Characteristics, Zoledronic acid 4mg/5ml concentrate for solution for infusion (Intrapharm Laboratories Limited). Updated 2017.