

Results: Patient characteristics: Mean age: 70±9.8 SD years, Gender: 98% were females, 2% Males. 75% had RA, 10% SLE, 15% had other rheumatic diseases. 70% on TNF inhibitors, 30% on other biologics. Before Denosumab (over 2 years): cumulative infection rate 17.5%, which is 8.75 cases per 100 person-years. 9% hospitalization rate. Post Denosumab: After 12 months: No infections within the first year. After 60 months: incidence rate of infections=12.5 cases/100 person-years. After 66 months, incidence rate of infections=15.9 cases/100 person-years. Urinary tract infection (UTI) accounted for the most common infection (17.5%). No opportunistic infections, and no reactivation of latent TB found in our patients.

Conclusions: No infections developed within the first year, suggesting a cumulative effect of increased infection risk, if any. We cannot attribute the overall infection rate solely to the combination of denosumab and biologics as patients who developed infections either had Diabetes Mellitus, urinary incontinence, recent surgery, underlying pulmonary disease. Patients did not develop infections beyond what would be expected for their comorbidities and medications. Whether prophylactic antibiotics are indicated in patients with recurrent infections PRIOR to denosumab is uncertain, but may be a consideration in certain patients.

References:

[1] Cummings SR, San Martin J, et al. Denosumab for prevention of fractures in postmenopausal women with osteoporosis. *N Engl J Med.* 2009;361:756–765. doi: 10.1056/NEJMoa0809493.

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AB0853 DENOSUMAB: CLINICAL PERSPECTIVE AND DRUG SURVIVAL IN A SECONDARY CARE SET UP IN UK

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Background: Denosumab has become a useful parental therapy for the treatment of osteoporosis. FREEDOM extension study has shown safety and effectiveness of denosumab beyond 8 years. Real life data on the efficacy and safety of denosumab is lacking. There are no studies looking at the drug survival in the osteoporosis population either. Observational data from clinical practice can provide unique clinical perspective for novel therapies like denosumab.

Objectives: 1. To look at the baseline characters of patients receiving denosumab in a secondary care unit in UK.

2. To study the drug survival rate, analyse the reasons for discontinuation of therapy.

3. To assess fractures during the course of denosumab therapy.

Methods: We looked at the case records retrospectively of all the patients receiving denosumab therapy from 01/01/2011 to 31/12/2016. A database to record baseline characters, indications and previous fracture was prepared. Renal function, calcium, alkaline phosphatase (ALP), vitamin D levels at baseline and renal function, calcium and ALP levels for each injection visit were noted. Vitamin D status was assessed at least once a year. Reasons to stop therapy were recorded.

Results: 237 patients were offered the treatment. One patient declined the treatment at the beginning.

5 (2.1%) patients had fracture on treatment. 2 had a hip fracture and one of them had a previous fracture (humerus). Other fracture sites were ankle, humerus and metatarsal. None of them had any further fractures during the follow up period.

61 patients discontinued therapy during the course of treatment over 3 years. 8 (4.2%) had infections, 7 (3.6%) due to declining eGFR and 9 (4.7%) were lost to follow up. 1 patient had jaw necrosis after the first injection. 1 developed hepatitis after the first injection which resolved on withdrawal of therapy. 6 (3.1%) patients withdrew consent for therapy. 19 (8%) patients died causes unrelated to denosumab therapy. 23 (9.7%) patients moved away. Treatment was stopped due to other side effects in 3 patients (2 had rash and 1 headache). There were no episodes of hypocalcaemia.

Conclusions: 1. Majority patients were elderly and female. Majority were high risk and had received osteoporosis treatments previously.

2. Denosumab therapy was well tolerated and nearly 2/3rd were still receiving therapy at 3 years. Treatment was withdrawn due to an adverse event in only 14 (6%) patients.

3. Fracture rate was very low and there were no repeat or multiple fractures.

References:

[1] Pappapoulos S et al. The effect of 8 or 5 years of denosumab treatment in postmenopausal women with osteoporosis: results from the FREEDOM Extension study. *Osteoporosis Int.* 2015 Dec;26(12):2773–83.

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AB0854 THE BMD CHANGE AFTER IBANDRONATE (BONVIVA®) TREATMENT IN OSTEOPENIC POSTMENOPAUSAL WOMEN

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Background: Ibandronate (Bonviva®) is effective in the treatment of postmenopausal women with osteoporosis. But, there were few datas about Ibandronate (Bonviva®) treatment in Korea. We evaluated the effect of Ibandronate (Bonviva®) therapy on bone mass and compared the effectivity on bone mineral density (BMD) in 1-year treatment group

Objectives: The aim of the study is to assess the effect of 1-year treatment with Ibandronate (Bonviva®) on bone mineral density (BMD) in postmenopausal women with osteopenia or osteoporosis.

Methods: The BMD was assessed in 118 postmenopausal women with osteopenia or osteoporosis from March 2007 to January 2011, 42 patients who treated with 2.5 mg per day of Ibandronate (Bonviva®) were enrolled to study. BMD of lumbar spine (L2-L4) and femur was assessed by dual energy absorptiometry at baseline, 12 months after treatment.

Results: The annual BMD of the lumbar spine showed a 9.11% increase, while also positive changes were noted in the proximal femur as a 1.89% increase. The BMD changes were 11% (L: Lumbar spine) and 1.1% (F: Femur) for the T-scores <-4.0, 6.3% (L) and 0.9% (F) for the T-scores -3.0~-4.0, and 3.8% (L) and 0.5% (F) for the T-scores >-3.0 respectively.

Conclusions: This study suggests that Ibandronate (Bonviva®) treatment in postmenopausal women with osteopenia or osteoporosis is effective in terms of improving BMD.

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AB0855 THE DISPARITIES BETWEEN FRACTURE RISK ASSESSMENT (FRAX) WITH BMD AND WITHOUT BMD IN KOREAN PATIENTS WITH ANKYLOSING SPONDYLITIS- MULTICENTER TRIAL

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Objectives: The aims of this study are to determine the proportion of patients with ankylosing spondylitis (AS) at high risk for major osteoporotic and hip fractures of Fracture risk assessment (FRAX) in Korean and to determine if a care gap exists for high risk.

Methods: This study is a multicenter study including 163 AS patients in 5. All of the AS patients fulfilled the modified New York criteria. The classification of osteoporosis according to WHO criteria was based on T-score ≤ -2.5. The FRAX criteria for high risk of osteoporotic fracture, which is 10-year probability of ≥20% for major osteoporotic fracture or ≥3% for hip fracture, were calculated by the FRAX tool including the bone mineral density (BMD) values. We assessed various demographic factors, clinical and laboratory findings of AS, and medication use for AS and osteoporosis, and then evaluated the risk factors for osteoporotic fracture.

Results: The mean age of AS patients was 44.3 years, and 42 patients were female (25.2%) with 23 postmenopausal women 56.1%. Osteoporotic fracture was detected in 16 (9.8%) patients with AS. Among the 16 patients ≥65 years of age, 2 (12.5%) and 8 (50%) were at high risk for a major osteoporotic fracture (10-year probability ≥20%) and hip fracture (>3%), respectively.

Among patients with BMD measurements (n=106), the 10-year risk of a major osteoporotic fracture and hip fracture calculated with BMD was significantly higher than in those without BMD measurements (P=0.001, P=0.002) respectively. The 10-year risk of a major osteoporotic and hip fracture fracture calculated with BMD was significantly higher than in those without BMD measurements (P<0.001, P=0.003) respectively among male patients with BMD measurements (n=74). There is no statistic difference of the 10-year risk of a major osteoporotic fracture

Abstract AB0853 – Table 1. Baseline characters

Total no of patients	Gender F (%) / M (%)	Age (in years) Mean (range)	eGFR Mean (range)	Prior fracture (%)	Baseline bone density (data for 99 patients)	
236	210 (89%) / 26 (11%)	76 (45–95)	37.9 (17.7–90)	93 (39.4%)		
		>75	<30	Vertebral	Osteoporosis	61 (61.6%)
		65–74	30–59.9	Wrist	Osteopenia	30 (30.3%)
		55–64	>60	Hip	Normal	8 (8.1%)
		<55		Multiple		