evolutionary course, the loss of BMI only showed a tendency to correlate with the decrease in bone mass in the femoral neck (p -value 0.089), but not in the other locations.

Conclusion: In our sample of morbidly obese patients undergoing bariatric surgery, there is a significant and widespread loss of bone mineral density one year after the procedure, all this despite the supplementation and the increase in 25OHD levels. This loss only seems to be directly related to the decrease in weight at the femoral neck, just probably by a mechanism to reduce mechanical load.

Disclosure of Interests: I Vázquez-Gómez: None declared, Ramón Trullenque Juan: None declared, Carlos Morillas Ariño: None declared, L Montolio-Chiva: None declared, Ana V Orenes Vera: None declared, Eduardo Flores: None declared, Elia Valls-Pascual Grant/research support from: Roche, Novartis, and AbbVie, Speakers bureau: AbbVie, Lilly, Pfizer, MSD, Novartis, Janssen, Bristol Myers Squibb, UCB Pharma, Desamparados Ybañez: None declared, À Martínez-Ferrer: None declared, Inmaculada Torner Hernández: None declared, V Núñez-Monje: None declared, A Sendra-García: None declared, Juanjo J Alegre-Sancho Consultant of: UCB, Roche, Sanofi, Boehringer, Celltrion, Paid instructor for: GSK, Speakers bureau: MSD, GSK, Lilly, Sanofi, Roche, UCB, Actelion, Pfizer, Abbvie, Novartis

DOI: 10.1136/annrheumdis-2020-eular.6258

FRIDAY, 05 JUNE 2020

Osteoarthritis

FRI0378

GENERAL SAFETY AND TOLERABILITY OF SUBCUTANEOUS TANEZUMAB FOR THE TREATMENT OF OSTEOARTHRITIS: A POOLED ANALYSIS OF RANDOMIZED, PLACEBO-CONTROLLED TRIALS

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Background: Tanezumab, a monoclonal antibody against nerve growth factor, is in development for the treatment of signs and symptoms of osteoarthritis (OA).

Objectives: To assess the safety and tolerability of subcutaneous (SC) tanezumab in patients with OA.

Methods: Data were derived from 3 randomized placebo-controlled OA trials. SC treatment (every 8 weeks for 16–24 weeks with 8–24 week follow-up) included placebo, tanezumab 2.5mg, tanezumab 2.5/5mg (2.5mg at day 1 and 5mg at week 8), and tanezumab 5mg. Overall treatment-emergent adverse events (TEAEs) and TEAEs of abnormal peripheral sensation were pooled from all 3 trials (placebo N = 586; tanezumab: 2.5mg N = 602, 2.5/5mg N = 219, 5mg N = 347). Pre-specified TEAEs potentially associated with sympathetic neuropathy (anhidrosis, bradycardia, hypohidrosis, orthostatic hypotension, or syncope) and pre-specified joint events (primary osteonecrosis, rapidly progressive OA [RPOA] type 1 or type 2, subchondral insufficiency fracture, or pathological fracture; adjudicated by an independent committee of experts) were pooled from the 2 trials that included prospective evaluation of sympathetic and joint safety (placebo N = 514; tanezumab: 2.5mg N = 528, 2.5/5mg N = 219, 5mg N = 284). TEAEs are presented for the treatment period; joint safety is presented for the full study (treatment plus follow up) period.

Results: Patient demographics (80.7% white, 66.8% female, mean age $\approx$ 63 years) and clinical characteristics were similar across groups. TEAE rates were: placebo = 51.7%, tanezumab 2.5mg = 52.3%, tanezumab 2.5/5mg = 47.0%, and tanezumab 5mg = 54.8%. Of TEAEs occurring in $\geq 2\%$ of patients in any group, only oedema peripheral, joint stiffness, and paraesthesia had a higher incidence (95% confidence interval excluded 0) in any tanezumab group relative to placebo. Serious TEAE rates were: placebo = 1.5%, tanezumab 2.5mg = 2.2%, tanezumab 2.5/5mg = 1.4%, and tanezumab 5mg = 2.6%. Rates of treatment and/or study discontinuation due to TEAEs were: placebo = 2.2%, tanezumab 2.5mg = 1.8%, tanezumab 2.5/5mg = 0.5%, and tanezumab 5mg = 1.4%. Only arthralgia and OA led to discontinuation in >1 patient in any group. TEAEs of abnormal peripheral sensation rates were: placebo = 2.2%, tanezumab 2.5mg = 5.1%, tanezumab 2.5/5mg = 3.2%, and tanezumab 5mg = 6.1%. Paraesthesia and hypoaesthesia were the most common events. Potential sympathetic neuropathy TEAE rates were: placebo = 0.8%, tanezumab 2.5mg = 1.5%, tanezumab 2.5/5mg = 0.5%, and tanezumab 5mg = 2.8%; exposure-adjusted rates were not statistically different between any tanezumab group and placebo. Bradycardia and orthostatic hypotension were the most common events. No patient was considered to have a sympathetic neuropathy. TEAEs of abnormal peripheral sensation and potential sympathetic neuropathy were mostly mild and resolved. Joint safety event rates

were statistically different for tanezumab 5mg (3.2%), but not 2.5mg (1.9%) or 2.5/5mg (0.5%), compared to placebo (0%). RPOA type-1 was the most common event. Total joint replacement rates were: placebo = 4.5%, tanezumab 2.5mg = 5.9%, tanezumab 2.5/5mg = 6.8%, and tanezumab 5mg = 7.0%; rates were not statistically different between any tanezumab group and placebo.

Conclusion: Tanezumab was generally safe and well tolerated in most patients, with rates of overall TEAEs and treatment/study discontinuations similar to placebo and no evidence of a sympathetic safety signal. TEAEs of abnormal peripheral sensation and joint safety events were infrequent but more common with tanezumab than placebo.

Disclosure of Interests: Francis Berenbaum Grant/research support from: TRB Chemedica (through institution), MSD (through institution), Pfizer (through institution), Consultant of: Novartis, MSD, Pfizer, Lilly, UCB, Abbvie, Roche, Servier, Sanofi-Aventis, Flexion Therapeutics, Expanscience, GSK, Biogen, Nordic, Sandoz, Regeneron, Gilead, Bone Therapeutics, Regulaxis, Peptinov, 4P Pharma, Paid instructor for: Sandoz, Speakers bureau: Novartis, MSD, Pfizer, Lilly, UCB, Abbvie, Roche, Servier, Sanofi-Aventis, Flexion Therapeutics, Expanscience, GSK, Biogen, Nordic, Sandoz, Regeneron, Gilead, Sandoz, Thomas Schnitzer Consultant of: Pfizer, Lilly, AstraZeneca, GSK, Alan Kivitz Shareholder of: AbbVie, Amgen, Gilead, GSK, Pfizer Inc, Sanofi, Consultant of: AbbVie, Boehringer Ingelheim, Flexion, Genzyme, Gilead, Janssen, Novartis, Pfizer Inc, Regeneron, Sanofi, SUN Pharma Advanced Research, UCB, Paid instructor for: Celgene, Genzyme, Horizon, Merck, Novartis, Pfizer, Regeneron, Sanofi, Speakers bureau: AbbVie, Celgene, Flexion, Genzyme, Horizon, Merck, Novartis, Pfizer Inc, Regeneron, Sanofi, Lars Viktrup Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, Anne Hickman Shareholder of: Pfizer Inc, Employee of: Pfizer Inc, Glenn Pixton Shareholder of: Pfizer Inc, Employee of: Pfizer Inc, Mark Brown Shareholder of: Pfizer Inc, Employee of: Pfizer Inc, Isabelle Davignon Shareholder of: Pfizer, Employee of: Pfizer, Christine West Shareholder of: Pfizer Inc, Employee of: Pfizer Inc

DOI: 10.1136/annrheumdis-2020-eular.268

FRI0379

VARIATIONS IN THE UTILIZATION OF BILATERAL TOTAL KNEE ARTHROPLASTY IN THE MANAGEMENT OF OSTEOARTHRITIS

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Background: A third of knee osteoarthritis presents with bilateral symptomatic arthritis. In these patients, treatment options include either a staged Unilateral Total knee arthroplasty (UTKA) procedure, or a simultaneous Bilateral TKA (BTkA) procedure. Even though literature regarding outcomes in BTkA procedure has not consistently been favorable, it remains popular in select patients due to use of a single anesthetic, shorter overall surgical time, lower cost and lower overall use of narcotics. African Americans (AAs) have lower utilization and worse outcomes in UTKA literature. It is unclear whether these racial variations extend to BTkA.

Objectives: We sought to examine BTkA vs UTKA utilization rates and outcomes comparing AA and White patients.

Methods: National Inpatient Sample (NIS) - Healthcare Cost and Utilization Project (HCUP) database (2007-2016) was used. We identified all patients $\geq$ 50 years who underwent elective primary TKA using ICD-9-CM code 81.54 for UTKA and BTkA from January 1, 2012 to September 30, 2015, and ICD-10-CM codes 0SR00x and 0SRD0x thereafter. Patients with inflammatory arthritis, pathologic fractures, metastatic disease and avascular necrosis were excluded. Major in-hospital complications included post-operative myocardial infarction, prosthetic device complication, surgical wound infection, and venous thromboembolism. Differences in temporal trends in utilization and major in-hospital complications of BTkA vs UTKA were compared between AAs and Whites. Multivariable logistic regression models were used to assess differences in both these trends between AAs and Whites after adjusting for individual (age, sex, Elixhauser comorbidity index, and morbid obesity), hospital level (hospital volume, bed size, region and teaching status) and community level (median household income) variables. Discharge weights were used to enable nationwide estimates. Multiple imputation was performed for missing race variable (11.9%).

Results: From 2007 to 2016, an estimated 276,194 BTkA (unweighted observations 56,675) and 5,528,429 UTKA (unweighted observations 1,131,329) were identified (Table 1). Females had a higher proportion of TKAs performed (62.1% UTKA vs 55.9% BTkA). Patients had fewer comorbidities (measured by the Elixhauser Index) when undergoing BTkA compared to UTKA. The proportion of BTkA amongst all TKAs declined from 5.53% in 2007-08 to 4.03% in 2015-16. AAs continued to have significantly lower proportion of BTkA utilization compared to Whites (4.68% in AAs vs 6.08% in Whites in 2007-08, whereas 3.28% in AAs vs 4.19% in Whites in 2015-16, adjusted $p < 0.001$) (Figure 1a). In-hospital complication rates for UTKA and BTkA were significantly higher in Whites compared to AAs throughout the study period (0.77% in AAs vs 0.9% in Whites in 2007-08, whereas 0.69% in AAs vs 0.83% in Whites in 2015-16,