

platinum therapy are largely unknown. In light of emerging therapies, a retrospective chart review was conducted in France to characterize the experiences of patients with R/M SCCHN who have been previously treated with a platinum-based regimen. **METHODS:** Real-world data were collected through a chart review. Included were patients randomly selected from all adults aged ≥ 18 years diagnosed with SCCHN at treating sites between January 1, 2013 and June 30, 2014 to meet an a priori sample-size calculation. Patients were followed through August 20, 2016 or until death. Clinical trial participants were excluded. Demographics and treatment data were analyzed descriptively. Overall survival (OS) was quantified using Kaplan-Meier analysis censoring for date of chart abstraction in surviving patients. **RESULTS:** Twenty-three oncologists contributed data for a random selection of 204 patients; 86% were men and 97% were current or former tobacco users. The mean (SD) age was 63 (10.5) years at initial R/M SCCHN diagnosis. Most patients (89%) were treated first-line with a platinum-based regimen, and 117 (65%) of these patients progressed to second-line treatment. Second-line treatment among these 117 patients consisted largely of monotherapy with a taxane (33%), cetuximab (21%), or methotrexate (12%) irrespective of disease stage (ie, IVC vs non-IVC), and 98 (84%) patients were identified as being second-line platinum-refractory (ie, did not receive second-line platinum). Among those receiving second-line treatment, median OS from first-line initiation was 14.6 (95% CI: 13.0, 16.3) months. **CONCLUSIONS:** More than half of the patients in this chart review received second-line treatment following first-line platinum-based therapy, but median survival remained well under 1.5 years. This study highlights the need for more effective treatments for a patient population with a significant level of unmet need.

PCN286

RETROSPECTIVE ANALYSIS OF PATIENTS WITH OVARIAN CANCER RECEIVING TREATMENT AT A TERTIARY CARE HOSPITAL IN INDIA

Abraham PS, Greene M

MCPSH University, Boston, MA, USA

OBJECTIVES: To review the patient characteristics and treatment methods of ovarian cancer patients at a tertiary hospital in India. **METHODS:** This study was a retrospective review of electronic medical records from a tertiary care hospital in Mumbai, India. Patients ≥ 18 years of age hospitalized for ovarian cancer treatment between Jan 2014 and May 2015 were included in the study. Descriptive and inferential statistics were used to analyze and compare differences between patients. **RESULTS:** A total of 45 patients met the study criteria. Of these, 38 patients were in the age group of 18 to 64 years. The mean age for all the ovarian cancer patients was 52.17 \pm 13.0 years. The mean age was lowest for patients with CGHS while highest for patients with RGJAY (RGJAY=56.50 \pm 11.57 years, PI=55.8 \pm 9.50 years, NI=43.36 \pm 12.33 years, CGHS=35.0 \pm 18.38 years.). The majority of the patients (n=33, 73.3%) underwent a surgical procedure during their stay at the hospital. The majority of the patients were subscribed to RGJAY payer scheme (RGJAY=22, 48.9%; NI=11, 24.4%; PI=10, 22.2%; CGHS=2, 4.4%). Pain was the most common reason for admission into the hospital (n=22, 48.9%). 11 (24.4%) patients with hypertension and 10 (22.2%) patients with diabetes were reported as major comorbidities during hospitalization. The majority of the patients had stage 2 or 3 ovarian cancer (16, 48.5%), while 11 (33.3%) patients had stage 1 ovarian cancer and 6 (18.2%) patients had stage 4 ovarian cancer. Of the total 33 patients that had surgery, majority of them underwent a total abdominal hysterectomy bilateral salpingo oophorectomy (TAHBSO) (n=14). **CONCLUSIONS:** Majority of the ovarian cancer patients were diagnosed during the advanced stages of the disease and were subscribed to RGJAY scheme. The common reason for hospital admission was pain and the common procedure patients underwent was the TAHBSO.

MUSCULAR-SKELETAL DISORDERS – Clinical Outcomes Studies

PMS1

PREVALENCE OF BISPHOSPHONATE-ASSOCIATED OSTEONECROSIS OF THE JAW USING TRUVEN HEALTH ANALYTICS MARKETSCAN® 2008-2014

Alqhtani H, Hartzema A

University of Florida, Gainesville, FL, USA

OBJECTIVES: To determine the prevalence of Osteonecrosis of the jaw (ONJ) cases among adult users of Bisphosphonates (BPs) and identify the potential risk factors that contribute to ONJ among BPs users. **METHODS:** In a retrospective cohort study, we used Truven Health Analytics MarketScan® databases from 2008 to 2014 to identify cohort members. The cohort included patients aged ≥ 18 years who received at least one prescription of bisphosphonates (oral or IV) for underlying bone or malignant disorders. We included BPs that were approved in the US for human use. The outcome variable is having ONJ, (ICD 733.45), and the independent variables included BPs types (Alendronate, Risedronate, Ibandronate, Zoledronic acid, Pamidronate and Etidronate), route of administration of BPs (oral Vs. IV), demographic characteristics (age and gender), and comorbidities (diabetes, hypertension, hypercholesterolemia). Multivariate logistic regression analysis was used to examine the association between risk factors and ONJ outcomes. **RESULTS:** We identified a study population of 837867 men and women who aged ≥ 18 years and had at least one prescription of BPs. We found only 66 patients with ONJ, so the prevalence of ONJ among the BPs users is less than 0.01%. We found that there was no statistically significant association between the outcome (ONJ) and BPs' characteristics (BPs type OR=0.751 95% CI 0.419-1.359). Furthermore, there was no statistically significant association between the outcome (ONJ) and patients' characteristics (age OR=1.01 95% CI 0.914-1.104 and gender OR=0.1228 95% CI 0.440-3.43). Moreover, there was no statistically significant association between the outcome (ONJ) and comorbidities (diabetes OR=1.23 95% CI 0.69-5.37, hypertension OR=0.797 95% CI 0.47-1.36 and hypercholesterolemia OR=0.69 95% CI 0.418-1.141). **CONCLUSIONS:** The prevalence of ONJ among the BPs users is less than 0.01% and there is no statistically significance

association between ONJ and BPs type, route of administration, age, gender, diabetes mellitus, hypertension and hypercholesterolemia.

PMS2

BISPHOSPHONATES AND OSTEONECROSIS: ANALYSIS OF THE KOREA ADVERSE EVENT REPORTING SYSTEM

Kim NH, Je S, Song SM, Shin AN, Suh D

Chung-Ang University, Seoul, South Korea

OBJECTIVES: To examine if bisphosphonate (BP) use is associated with drug related osteonecrosis (osteonecrosis) using adverse drug reaction (ADR) data reported in the Korea Adverse Event Reporting System (KAERS) from 2013 to 2015. **METHODS:** The KAERS database contained a total of 754,231 ADR reports from 38,974 patients, resulting in an average of 1.99 reports per patient; the ADR reports include patient demographics, concomitant drugs, patients' outcomes, reaction severity, reporting centers, and the results of causality assessments. The reporting odds ratio (ROR) was calculated to estimate the association between osteonecrosis and implicated medications. Chi-square tests were also conducted to compare the sociodemographic characteristics of osteonecrosis patients who reported BP use to those using other drugs. **RESULTS:** 230 ADR reports involving osteonecrosis cases were identified from the total 754,231 ADR reports. Among the 230 osteonecrosis reports, 201 reports (87.4%) were attributed to BP use, while 27 reports (11.7%) were attributed to other drug use; 2 reports lacked drug information. The ROR for osteonecrosis and BP use was 82.57 (95%CI, 55.06-123.82), with a majority of cases (n=105) associated to alendronate use among the six different classes of BP. Among the 228 reports of osteonecrosis, females (n=167, 87.6%) were more likely to report BP-related osteonecrosis than males (n=24, 12.6%) (p<0.001). Concomitant medications that were used with BP were rare and included Amlodipine, Calcitriol, Risedronate and Tiotropium bromide (each, n=3, 7.5%). **CONCLUSIONS:** The risk of BP use for drug related osteonecrosis in ADR reports in South Korea were examined. The results imply that BP use needs to be carefully monitored for patients with susceptibility for osteonecrosis.

PMS3

A NETWORK META-ANALYSIS OF THE EFFICACY OF TREATMENTS IN BIOLOGIC NAÏVE PATIENTS WITH MODERATE TO SEVERE RHEUMATOID ARTHRITIS AFTER INADEQUATE RESPONSE TO CONVENTIONAL DISEASE MODIFYING ANTIRHEUMATIC DRUGS

Tongbram V¹, Mutebi A², Hawkins N³, Ndirangu K¹, McGovern A¹, Gharaibeh M², Kaur P², Collier D², Stolshek B²

¹ICON, New York, NY, USA, ²Amgen Inc, Thousand Oaks, CA, USA, ³University of Glasgow, Glasgow, UK

OBJECTIVES: To compare the efficacy of treatments in moderate-to-severe rheumatoid arthritis (RA) in biologic-naïve patients with inadequate response to conventional disease modifying antirheumatic drugs (cDMARDs). **METHODS:** MEDLINE, Embase, and Cochrane Central Register were searched for RCTs published in 01/1990 to 08/2016. Treatments included were tumor necrosis factor inhibitors (TNFis; etanercept, adalimumab, infliximab, certolizumab pegol, golimumab), rituximab, abatacept, Interleukin 6 inhibitors (tocilizumab, sarilumab), and Janus kinase inhibitors (tofacitinib and baricitinib), each combined with cDMARDs. Outcomes were difference in mean change in modified Total Sharp Scores (mTSS) between each regimen and cDMARDs, and probabilities of $\geq 20\%$ improvement in the American College of Rheumatology response criteria (ACR20), at 6-months and 12-months. A Bayesian network meta-analysis using random-effects models estimated the comparative efficacy for these regimens. **RESULTS:** Up to 72 studies were included in this analysis. At 6-months, the difference in mean change in mTSS (95%CrI) versus cDMARDs ranged from -1.01(-3.70;1.69) for adalimumab to -3.74(-8.07;0.62) for infliximab in TNFis; and from -0.36(-2.80;2.04) for tofacitinib to -1.08 (-3.21;1.01) for tocilizumab in non-TNFis. At 6-months only the etanercept regimen had statistically significant difference in mean mTSS change -2.08(-3.67;-0.52) vs. cDMARDs. At 6-months, ACR20 (95%CrI) in TNFis ranged from 58.8% (47.8%;69.8%) for infliximab to 74.3%(66.2%;81.1%) for certolizumab pegol; and from 52.8%(33.5%;71.7%) for baricitinib to 63.3%(45.1%;80.0%) for sarilumab in non-TNFis. At 12-months, differences in mean change in mTSS ranged from -2.15(-5.41;1.10) for adalimumab to -7.03(-10.34;-3.83) for infliximab in TNFis; and from -1.08(-5.56;3.35) for rituximab to -2.52(-6.36;1.43) for sarilumab in non-TNFis. At 12-months, ACR20 ranged from 62.7%(48.0%;75.9%) for infliximab to 82.5% (56.9%;95.3%) for certolizumab pegol in TNFis; and from 63.6%(41.0%;85.5%) for sarilumab to 73.0%(56.1%;88.3%) for tocilizumab in non-TNFis. **CONCLUSIONS:** Targeted immune modulator in general showed reduced radiographic progression as measured by mTSS compared with cDMARDs. TNFis appear to be the most effective class as measured by the ACR20.

PMS4

COMPARATIVE EFFICACY OF TARGETED IMMUNE MODULATORS AS MONOTHERAPY AND IN COMBINATION WITH CONVENTIONAL DMARDS IN RHEUMATOID ARTHRITIS

Synnott PG, Liu S, Agboola FO, Ollendorf D

Institute for Clinical and Economic Review, Boston, MA, USA

OBJECTIVES: To evaluate the comparative effectiveness of targeted immune modulators (TIMs) in patients with moderately-to-severely active rheumatoid arthritis (RA) who have had an inadequate response to prior conventional disease modifying antirheumatic drugs (cDMARDs) and are TIM-naïve. **METHODS:** Two investigators conducted a systematic literature review of RCTs that evaluated the efficacy of 11 TIMs relative to cDMARDs and to each other: rituximab, abatacept, tocilizumab, sarilumab, tofacitinib, baricitinib, adalimumab, certolizumab pegol, etanercept, golimumab, and infliximab. Outcomes of interest included measures of disease activity, ACR response, and radiographic progression. Bayesian network