

OSTEOPOROSIS & INJURIES— Patient-Reported Outcomes

WOMEN TREATED WITH MONTHLY IBANDRONATE DEMONSTRATE IMPROVED PERSISTENCE VERSUS WEEKLY BISPHOSPHONATES

Cramer JA¹, Sunyecz JA², Derman R³, Harley C⁴, Poston S⁵,
Barr CE⁶

¹Yale University School of Medicine, West Haven, CT, USA, ²Laurel Highlands Ob/Gyn, P.C., Hopwood, PA, USA, ³University of Missouri-Kansas City, Kansas City, MO, USA, ⁴i3 Innovus, Eden Prairie, MN, USA, ⁵GlaxoSmithKline, Research Triangle Park, NC, USA, ⁶Roche Pharmaceuticals, Nutley, NJ, USA

OBJECTIVES: The objective of this early postlaunch analysis was to examine medication persistence among women ≥ 45 years and newly prescribed monthly or weekly bisphosphonate (BP) therapy at 9 months. **METHODS:** The i3 Innovus administrative claims database was used to retrospectively identify female patients who filled a new prescription for a weekly BP (risedronate or alendronate) or monthly ibandronate starting in April 2005. Medication persistence was defined as having no refill gaps exceeding grace periods of 30 (weekly BPs) and 45 days (monthly BPs). Cox proportional hazard analysis was used to control for the effects of potential confounding factors including age, co-pay, and co-morbidities. **RESULTS:** This analysis included 967 women prescribed monthly ibandronate and 8662 women prescribed weekly BPs. At 9-months, the median number of days until discontinuation was 236 days for monthly and 141 days for weekly ($p < 0.0001$). Significantly more patients receiving monthly ibandronate were persistent compared to patients receiving weekly BPs (48% vs 35%, $P < 0.0001$). After adjusting for potential confounding factors, monthly users overall were 38.0% more likely to persist with therapy versus weekly users (hazard ratio = 0.620, 95% CI 0.563–0.683, $P < 0.0001$). **CONCLUSION:** The 9-month results of this analysis indicate that more women on monthly therapy are persistent than women on weekly bisphosphonates. This early finding suggests enhanced long-term persistence with ibandronate monthly therapy, with the potential for improved clinical outcomes. Follow-up of this cohort is ongoing.

PO16

WOMEN ARE MORE PERSISTENT WITH MONTHLY IBANDRONATE VS. WEEKLY BISPHOSPHONATES: RESULTS FROM A RETROSPECTIVE DATABASE

Cramer JA¹, Silverman S², Cziraky MJ³, Barr CE⁴, Poston S⁵

¹Yale University School of Medicine, West Haven, CT, USA, ²Cedars-Sinai Medical Center/UCLA, Beverly Hills, CA, USA, ³HealthCore, Inc, Wilmington, DE, USA, ⁴Roche Pharmaceuticals, Nutley, NJ, USA, ⁵GlaxoSmithKline, Research Triangle Park, NC, USA

PO17

OBJECTIVES: Data from health care databases are used to determine patient persistence with bisphosphonates in a real-world setting. The observational nature of retrospective database studies removes a source of potential influence on patient behavior. The objective of this analysis is to evaluate 9-month persistence among patients receiving monthly ibandronate versus weekly bisphosphonates. **METHODS:** De-identified patient data were collected from the HealthCore managed care claims database, which represents over 17.5 million covered lives. Eligible women were ≥ 45 years and filled a new prescription for monthly ibandronate or weekly alendronate or risedronate starting April 1, 2005. Persistence was evaluated based on a gap in coverage of 30 days for weekly bisphosphonates; a 45-day gap was analyzed for monthly ibandronate due to its 3-week dosing window. Cox proportional hazard models were used to analyze persistence and controlled for potential confounders such as age, patient co-pay, and comorbidities. **RESULTS:** A total of 4548 women were included (213 receiving monthly ibandronate and 4335 receiving weekly therapy). The median number of days until discontinuation for monthly was 145 days and for weekly was 115 days ($p = 0.0032$). At 9 months, significantly more patients receiving monthly ibandronate (41%) were persistent compared to patients receiving weekly BPs (33%) ($P = 0.003$). After adjusting for age, co-pay, comorbidities, and prescriptions with greater than a 30-day supply, monthly users were 31% less likely to discontinue therapy compared with weekly users at 9 months ($P < 0.0001$). **CONCLUSION:** Persistence during the initial 9 months after launch of ibandronate was higher for ibandronate monthly BP therapy than weekly BP therapy. Longer follow-up of this cohort is ongoing.

PO18

CAN THE SF-36 PHYSICAL FUNCTION SCALE CAPTURE FUNCTIONAL OUTCOMES DURING RECOVERY FROM TRAUMATIC INJURY? A REVIEW OF THE LITERATURE

Vernon MK¹, Murray L¹, Mannix S¹, Leidy NK¹, Kelly KM², Mody S²

¹United BioSource Corporation, Bethesda, MD, USA, ²Ortho-Biotech Clinical Affairs, LLC, Bridgewater, NJ, USA

OBJECTIVES: For survivors of traumatic injury, critical care services are often required, followed by long-term recovery as patients overcome or adapt to the effects of their injury on physical function (Holtzlag, 2006). Recently, increased attention has been focused on the use of patient reported outcome (PRO) assessments to evaluate functional outcomes in this population. In order to appraise current validation evidence for the use of a simple-to-administer PRO (Physical Function (PF) Scale of the Medical Outcomes Study Short-Form (SF-36) health survey), a literature review was completed. **METHODS:** Comprehensive literature review (including a review of articles identified from previous work with trauma patient populations and with the SF-36 as well as a comprehensive search of PUBMED & EMBASE, 2000–2006 for articles that used PRO measures to assess recovery in trauma patients); 92 articles were reviewed. **RESULTS:** Ten studies presented psychometric data for the SF-36 in trauma patients (number of trauma patients included in these studies ranged from 64–1197). PF Scale properties were as follows: Internal consistency reliability: Alpha = 0.93 (multiple trauma patients; Statz, 2002). Discriminant validity: The PF Scale discriminated between patients with different injury types (Michaels, 2001). Trauma patients had significantly lower PF scores ($p < 0.001$) than control patients with no disability (Fidler, 2001) and US norms at various time points (up to 27 months) post-trauma (Brennenman, 1995; Holtzlag, 2006; Hoogendoorn, 2001). Concurrent validity: PF scores were significantly related to those on the Sickness Impact Profile (Holt-

slag, 2006), neurocognitive functioning (COG scale) (Mackenzie, 2002), and Beck Depression Inventory (Findler, 2001). **CONCLUSION:** There is evidence to suggest that the PF Scale of the SF-36 is reliable, as measured by internal consistency, and valid, as measured by discriminant and concurrent validity.

SKIN—Cost Studies

PSK1

COST EFFECTIVENESS OF THE USE OF INFLIXIMAB COMPARED TO OTHER BIOLOGICAL AGENTS (BA) IN THE SYSTEMIC TREATMENT OF MODERATE TO SEVERE PSORIASIS

Fonseca M, Araujo G

Axia.Bio Consulting, São Paulo, Brazil

OBJECTIVES: New BA offer more therapeutic options to control psoriasis symptoms but add to the already considerable cost of managing psoriasis. Expert panels have published guidelines for the use of BA although few of them considered the treatment options cost-effectiveness. The Brazilian expert guidelines, however, considered. We present a Brazilian cost effectiveness model based on micro-simulation. **METHODS:** Our cost effectiveness model simulates the real-life Brazilian treatment sequence (acitretin, methotrexate, cyclosporine, BA) for 1000 patients based on the average time of use of each drug (10.74, 6.56, 24.00, and 30.00 months, respectively). Three different BA, adalimumab, etanercept and infliximab, were analyzed. Cost effectiveness was calculated in terms of the number of patients that achieve PASI 75 response with each BA. The base case was a moderate-to-severe psoriasis patient, with at least 10% BSA affected, PASI score of at least 12, without infection in the lesions and eligible for systemic therapy. Time of use of each drug in Brazil came from a previous Brazilian study and the PASI score from major studies with each drug from the medical literature. The local disease management and costs were based on a Delphi panel according to the private health care perspective. Outcomes were discounted at 3% annually. **RESULTS:** In order that all patients pass all the four treatment lines it took an average time of 71.3 months; the Brazilian treatment sequence added to fortnightly adalimumab, weekly adalimumab, infliximab and etanercept, respectively, generated 529, 799, 879 and 490 patients achieving PASI 75 and also, respectively, generated R\$ 129,071,880.38, R\$ 257,708,724.48, R\$ 132,251,142.76, R\$ 342,274,532.45 total costs. **CONCLUSION:** The Brazilian treatment sequence added to infliximab is a dominant alternative in relation to that added to weekly adalimumab and etanercept. It also has an acceptable cost-effectiveness ratio in Brazil in relation to fortnightly adalimumab (R\$9092.70).

PSK2

THE HEALTH CARE AND WORK LOSS COSTS ASSOCIATED WITH ATOPIC DERMATITIS

Duh MS¹, Fowler JF², Rovba L¹, Buteau S¹, Pinheiro L¹, Lobo F³, Sung J³, Doyle JJ³, Mallett D⁴, Kosicki G¹

¹Analysis Group, Inc, Boston, MA, USA, ²University of Louisville, Louisville, KY, USA, ³Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA, ⁴Ingenix Employer Solutions, New Haven, CT, USA

OBJECTIVES: To determine the incremental direct health care and indirect work loss costs associated with patients diagnosed with atopic dermatitis (AD) from an employer-payer perspective. **METHODS:** A de-identified claims database consisting of 5.1 million covered lives from 31 Fortune 500 self-insured employers over the period 1998–2005 was used. Each AD patient was matched with three controls based on age and gender. The average monthly direct health care costs (i.e., medical & phar-

maceutical costs) were computed for the respective groups. For the subset of patients who were active employees, the indirect costs of lost work time were calculated for each group, as measured by employer disability payments and sick leave time multiplied by the employee's wage. In addition, a multivariate two-part regression was used to isolate the cost increase attributable to AD by controlling for age, gender, year, comorbidities, and organ transplantation. **RESULTS:** The univariate analysis showed that the AD patients (N = 13,749) were associated with higher medical and pharmacy costs than the control group (N = 41,247) by an average of \$47 and \$42 per person per month, respectively (medical: \$270 vs. \$223, p < 0.003; pharmacy: \$80 vs. \$38, p < 0.0001), bringing the total increase in health care costs to \$88 per person per month (\$349 vs. \$261, p < 0.0001). In the subset of active employees, the AD group (N = 1588) was associated with higher indirect work loss costs of \$64 per person per month (\$148 vs. \$85, p < 0.0001) than the control group (N = 3900). For each cost category, a statistically significant cost increase for AD patients was confirmed through the multivariate analysis (adjusted incremental direct cost = \$52, p < 0.0001; adjusted incremental indirect cost = \$31, p < 0.0001). **CONCLUSION:** AD was associated with a statistically significant increase in health care and work loss costs. The multivariate analysis indicated that the total direct and indirect cost increase was approximately \$83 per person per month.

PSK3

THE DIRECT AND INDIRECT COST BURDEN ASSOCIATED WITH SEBORRHEIC DERMATITIS

Duh MS¹, Fowler JF², Rovba L¹, Buteau S¹, Pinheiro L¹, Lobo F³, Sung J³, Doyle JJ³, Mallett D⁴, Kosicki G¹

¹Analysis Group, Inc, Boston, MA, USA, ²University of Louisville, Louisville, KY, USA, ³Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA, ⁴Ingenix Employer Solutions, New Haven, CT, USA

OBJECTIVES: To determine the incremental direct health care and indirect work loss costs experienced by employer-payers for patients diagnosed with seborrheic dermatitis (SD). **METHODS:** A de-identified claims database consisting of 5.1 million covered lives from 31 Fortune 500 self-insured employers over the period 1998–2005 was used. Each SD patient was matched with three controls based on age and gender. The average monthly direct health care costs (i.e., medical & pharmaceutical costs) were computed for the respective groups. For the subset of patients who were active employees, the indirect costs of lost work time were calculated for each group, as measured by employer disability payments and sick leave time multiplied by the employee's wage. In addition, a multivariate two-part regression was used to isolate the cost increase attributable to SD by controlling for age, gender, year, comorbidities, and organ transplantation. **RESULTS:** The univariate analysis showed that the SD patients (N = 6860) were associated with higher medical and pharmacy costs than the control group (N = 20,580) by an average of \$136 and \$62 per person per month, respectively (medical: \$412 vs. \$277, p < 0.0001; pharmacy: \$139 vs. \$76, p < 0.0001), bringing the total increase in health care costs to \$198 per person per month (\$551 vs. \$353, p < 0.0001). In the subset of active employees, the SD group (N = 1666) was associated with a higher indirect work loss cost of \$50 per person per month (\$132 vs. \$82, p < 0.0001) than the control group (N = 4103). For each cost category, a statistically significant cost increase for SD patients was confirmed through the multivariate analysis (adjusted incremental direct cost = \$62, p = 0.005; adjusted incremental indirect cost = \$44, p = 0.042). **CONCLUSIONS:** SD was associated with a statistically significant increase in health care and work loss costs. The multivariate analysis indi-