**A102**


**NEWLY DIAGNOSED FLT3-MUTATED AML PATIENTS**

Title: A Phase II, Open-Label Study of the Addition of a Novel Oral INK4i (DOX6) to Standard-Intensity Idarubicin and Cytosine Arabinoside in Patients with Newly Diagnosed Acute Myeloid Leukemia with FLT3 Internal Rearrangement

**OBJECTIVES:**

- To evaluate the safety and tolerability of DOX6 in combination with standard-intensity Idarubicin and Cytosine Arabinoside (IDAC) in patients with newly diagnosed FLT3-internal rearrangement (IR) AML.
- To evaluate the clinical activity of the combination of DOX6 + IDAC.
- To assess the potential for improvement in hematologic and cytogenetic response rates with the addition of DOX6.

**METHODS:**

- A Phase II, open-label, single-arm, multicenter study of DOX6 in combination with IDAC.
- Eligible patients were those with newly diagnosed FLT3-IR AML who were not eligible for or did not qualify for clinical trials.
- The study included a total of 58 patients, with a median age of 61 years (range 22-77).

**RESULTS:**

- The major adverse events were neutropenia, thrombocytopenia, and anemia.
- The most common grade 3 or 4 laboratory abnormalities were neutropenia, thrombocytopenia, and anemia.
- Hematologic responses were achieved in 71% of patients, with 31% achieving a complete remission.
- Cytogenetic responses were achieved in 48% of patients, with 31% achieving a complete remission.

**CONCLUSIONS:**

- The addition of DOX6 to standard-intensity IDAC in patients with newly diagnosed FLT3-IR AML is feasible and well-tolerated.
- The combination demonstrated clinical activity with responses achieved in both hematologic and cytogenetic parameters.

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**REFERENCES:**


**AUTHORS:**

utilization, lower QoL and greater work impairment. Additional research is warranted to further characterize the impact of cost and reimbursement on patient outcomes.

**PSY25**

**HEALTH CARE RESOURCE UTILIZATION (HRU) AND COSTS ASSOCIATED WITH FRAILTY IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) IN A MEDICAID POPULATION IN THE UNITED STATES**

Em H1, Song X2, Rechel B1, Johnson BH1, O’Sullivan D3, Molia CT6
1University of Southern California, Los Angeles, CA, USA
2Villacorta R, Hay J, Messali A
3University of Buenos Aires, Buenos Aires, Argentina
4University of Southern California, Los Angeles, CA, USA
5AUP Health Solutions, Englewood, CO, USA
6IMS Heatlh México, Ciudad de México, Mexico

**OBJECTIVES:** Limited data exist on the economic impact of SLE frailty. This study estimated HRU and costs of SLE frailty in a U.S. Medicaid population. **METHODS:** SLE Patients <18 years old were extracted from a large Medicaid database 2002-2009. Index date was the date of the first SLE diagnosis. All patients were continuously enrolled for at least 12 months prior to index date and fulfilled the earliest of inpatient death, end of enrollment, or study end. Mild, moderate, and severe frailty were identified in the follow-up period. Costs attributable to frailty were measured during 30 days following a flare. If a flare of higher severity occurred within 30 days, the length was limited to the period up to the start of the new flare.

**RESULTS:** 14,262 patients met the study criteria and 97% experienced at least one flare during an average follow-up of 39 months (3,540 had severe, 9,597 had moderate, and 669 had mild flares as their most severe flares). Mean costs per flare were $11,716, $562, and $129 for severe, moderate, and mild flares, respectively. Patients with ≥2 severe flares during follow-up had 1.7 inpatient (IP) admissions, 3.5 emergency room (ER) visits, and 16.0 outpatient (OP) visits with a total medical cost of $49,754/per year. Patients with ≥1 moderate flares but no severe flares had 0.9 IP admissions, 2.4 ER visits, and 12.8 OP visits with a cost of $21,941. Patients with only mild flares had 0.1 IP admission, 1.5 ER visits, and 7.0 OP visits with a cost of $17,574. Patients with severe and moderate but no mild flares and patients with severe flares only incurred the highest annual cost ($66,412 and $74,491, respectively).

**CONCLUSIONS:** Flares occurred in almost all SLE patients and were associated with a significant economic burden.

**PSY26**

**COSTS AND OUTCOMES OF PATIENTS WITH HEMOPHILIA A (HA) AND FACTOR VIII INHIBITORS TREATMENT: THE IMMUNE TOLERANCE AND ECONOMICS RETROSPECTIVE REGISTRY (ITER) RESULTS**

Gingerich A1, Scalone K2, Crespo PA1, Rocino A3, Mantovani LO4
1Onofrio Ferrari Hospital, University of Genova Clinical Center, Genova, Italy
2University of Milano-Bicocca, Monza (MB), Italy
3North Mississippi Medical Center, Tupelo, MS, USA
4University of Bari, Bari, Italy

**OBJECTIVES:** Immune tolerance induction (ITI) is generally accepted as first choice treatment to eradicate inhibitors in hemophilia A patients. Little is known about the outcomes and cost consequences of this treatment option. **METHODS:** The Immune Tolerance and Economics Retrospective (ITER) study is an observational, retrospective, multicenter, multinational study aiming to estimate cost of treatment in hemophilia A patients, undergoing ITI. Data on hemostatic treatment given in the following time periods were collected: up to 12 months before the diagnosis of Inhibitors, between Inhibitors diagnosis and ITI start, during ITI, and 12 months after ITI. Costs of treatment were calculated in the perspective of the third party payer and expressed as mean €/patient-month.

**RESULTS:** Seventy-one valid patients, with median age at ITI start 3.8 (0.4-41) years, were enrolled. Before ITI the median Inhibitors peak titre was 18.5 (0.80-704) BU. ITI was started 6 months before and 6 months after the Inhibitors diagnosis and ITI start (92% for bypassing agents), and 60,078 were measured during 30 days following a flare. If a flare of higher severity occurred within 30 days, the length was limited to the period up to the start of the new flare.

**CONCLUSIONS:** Flares occurred in almost all SLE patients and were associated with a significant economic burden.

**PSY27**

**COST EFFECTIVENESS OF TREATMENT WITH ETANERCEPT OR USTEKINUMAB FOR MODERATE TO SEVERE PSORIASIS**

Villacorta R, Hay J, Messali A
1University of Southern California, Los Angeles, CA, USA
2Villacorta R, Hay J, Messali A

**OBJECTIVES:** Immune tolerance induction (ITI) is generally accepted as first choice treatment to eradicate inhibitors in hemophilia A patients. Little is known about the outcomes and cost consequences of this treatment option. **METHODS:** The Immune Tolerance and Economics Retrospective (ITER) study is an observational, retrospective, multicenter, multinational study aiming to estimate cost of treatment in hemophilia A patients, undergoing ITI. Data on hemostatic treatment given in the following time periods were collected: up to 12 months before the diagnosis of Inhibitors, between Inhibitors diagnosis and ITI start, during ITI, and 12 months after ITI. Costs of treatment were calculated in the perspective of the third party payer and expressed as mean €/patient-month.

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**CONCLUSIONS:** Flares occurred in almost all SLE patients and were associated with a significant economic burden.

**PSY28**

**COST-EFFECTIVENESS ANALYSIS OF CELECOXIB IN THE TREATMENT OF CHRONIC PAIN IN PATIENTS WITH OSTEOARTHRITIS OR RHEUMATOID ARTHRITIS**

Kan H1, Song X2, Bechtel B3, Johnson BH4, O’Sullivan D4, Molta CT5
1University of California, Los Angeles, CA, USA
2University of Buenos Aires, Buenos Aires, Argentina
3University of Southern California, Los Angeles, CA, USA
4University of Southern California, Los Angeles, CA, USA
5IMS Health Consulting Group, Alexandria, VA, USA

**OBJECTIVES:** Patients with chronic pain due to osteoarthritis (OA) or rheumatoid arthritis (RA) do not often obtain adequate relief or experience unacceptable side effects due to their pain-control treatments. The objective of this study was to perform a cost-effectiveness analysis comparing celecoxib, etanercept and lumira- numab in the treatment of chronic pain in patients with OA and RA, from the Mexican Social Security Institute (IMSS) perspective. **METHODS:** A decision-tree model (12-weeks time horizon) was used to compare pain reduction and direct medical costs associated to competing alternatives. A systematic literature review was performed to identify the pain reduction (reported through visual analogue scales) and adverse events (AE) incidence rate associated. Comparators were: celecoxib 200mg/day, etanercept 90mg/day and lumira- numab 100mg/day for patients with OA and RA. A meta-analysis with selected publications (n=10) was performed. Resource utili- zation was extracted from clinical guidelines, ICERs were derived from IMSS official sources. Probabilistic sensitivity analysis was performed. Acceptability curves were developed. **RESULTS:** Pain reductions vs. placebo were: celecoxib 14.18% (C95% 10.48-17.87, p=0.00001); etanercept 12.70% (7.67-17.73, p=0.00001); and lumira- numab 17.11-17.77, p<0.00001). Differences between celecoxib and lumira- numab was meaningful (p<0.05). The odds ratios of AE incidence rate versus placebo were: 1.06 (0.71-1.46, p=0.37); 1.09 (0.87-1.36, p=0.73) and 1.44 (0.88-2.34, p=0.14), respectively. The expected medical costs (2011 US$) were: $159,935 ($89.52), $221,541 ($7.86) and $306,653 ($12.86), respectively. The cost of management of AE contributed with $101,28, $95.00 and $146.17 of the overall expected costs, respectively. In regards to etanercept (basecase), etanercept showed to be a cost-saving strategy with a cost-effective proportion of 76.7% (74.1%-79.3%); while lumira- numab was the less effective and more costly strategy. **CONCLUSIONS:** At baseline patients who suffer OA or RA would reach a higher incremental reduction in pain intensity at 12 weeks reducing overall costs in comparison to etanercept.