Systemic Disorders/Conditions - Clinical Outcomes

PSY2
THE ESTIMATED RISK REDUCTION OF ANAPHYLACTIC REACTIONS ASSOCIATED WITH AR101 ORAL IMMUNOTHERAPY FOLLOWING ACCIDENTAL PEANUT EXPOSURE: AN ANALYSIS BASED ON CLINICAL TRIAL DATA

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Objectives: AR101 is an investigational oral immunotherapy (OIT) for the treatment of peanut allergy. Results from the phase III PALISADE trial demonstrated that a significantly higher percentage of AR101-treated subjects tolerated higher doses of peanut protein after one year of therapy compared to placebo. However, the benefit of AR101 in reducing anaphylactic reaction (AR) risk after accidental exposure has not been studied. This study aimed to estimate the reduction in accidental exposure related AR risk associated with AR101 using PALISADE data. ***Methods:*** Parametric interval-censoring survival analysis with maximum likelihood estimation was used to construct a real-world distribution of peanut protein exposure using baseline AR history and maximum tolerated dose (MTD) from a double-blind, placebo-controlled food challenge. The AR risk reduction was estimated using exposure distribution, and MTD assessed at both baseline and trial exit for AR101- and placebo-treated subjects, respectively. ***Results:*** Among those who completed the PALISADE trial, the estimated reduction of accidental exposure related AR risk was 94.9% for AR101 and 6.4% for placebo. For AR101-treated subjects who achieved the primary endpoint of 600 mg MTD or higher, the associated AR risk reduction was 97.2%. The results were consistent across different parametric distribution assumptions. ***Conclusions:*** OIT with AR101 resulted in a significantly higher reduction in AR risk related to accidental exposure compared to placebo. In contrast to previous analyses that used unintended allergen residue from packaged food as the peanut intake assumption, this approach more closely reflects the real-world dietary experience of patients practicing peanut avoidance and thus provides a more appropriate estimate of treatment benefit.

PSY3
THERAPEUTIC SUCCESS OF POPULATION WITH MODERATE-SEVERE PSORIASIS EVALUATED IN A PSORIASIS INTEGRATED CLINIC (CLIPSO), MEDELLIN COLOMBIA

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Objectives: Describe the results of therapeutic success CLIPSO's patients based on the Psoriasis Area Severity Index (PASI). ***Methods:*** A retrospective observational cross-sectional study in patients treated from May-2018 to November-2019. To measure therapeutic success we used the delta PASI and absolute PASI and stratified the population in two groups according to begin therapy time. The first group was one who the patient began their pharmacological therapy before their enrollment in CLIPSO (prevalent) and the second group the one who started therapy in CLIPSO (incident). For the first group, we used the absolute PASI <5 (because we did not have previous information of PASI) and for second group, we used the delta PASI ≥75% and/or an absolute PASI <5. A univariate analysis and normality test (Shapiro Wilk) were performed. Association test (Spearman's correlation) to define differences between initial and final PASI and the proportion of patients who achieve therapeutic success were calculated. R Core Team statistical package (2019) was used. ***Results:*** 1007 patients were evaluated (28% incidents patients with a median time of 43 days [ICR 27-56] and 72% prevalent patients with a median time of 157 days [RIC 89-290]), with a mean age of 50±15 years, the youngest was 6 and the oldest 89. The male:female ratio was 1:1. 48% were treated with non-biologic systemic therapy, 37% with biological and 14% with topical. The therapies used were Methotrexate (37.2%), Daivobet (10.7%), Adalimumab (9.4%), Ustekinumab (9%), Secukinumab (7.7%), Chemophototherapy (7.6%), Etanercept (7.3%), Acitretin (3.2 %), Ixekizumab (2.3%), Clobetasol (2.2%). 93% of the population achieved therapeutic success, with a rho between the initial and final PASI of 0.313 (p-value: 6.826e-08). ***Conclusions:*** The scope of the therapeutic success of CLIPSO's patients had a clinically relevant and statistically significant improvement.

PSY4
WEATHER CONDITIONS BEFORE ROSACEA-RELATED FLARES IN THE UNITED STATES: A RETROSPECTIVE CLAIMS-BASED ANALYSIS

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Objectives: Rosacea is a progressive, chronic inflammatory condition characterized by flushing and blushing of the facial skin. Weather is one of its primary triggers. This study examined the weather conditions before the occurrence of rosacea-related flares. ***Methods:*** IBM Watson Health linked Claims and Marketscan Weather data was used to identify adult patients with ≥1 diagnosis of rosacea (ICD-9-CM 695.3 or ICD-10-CM L718 and L719) from 7/1/2015 to 9/30/2018 (index date = first rosacea diagnosis date). All patients had ≥6 months pre-index period, ≥12 months post-index period, and ≥1 dermatologist visit. Due to the lack of information on rosacea-related flares in claims data, rosacea-related dermatologist visits were used as a proxy. Weather data were examined 30 days prior to each dermatologist visit. ***Results:*** A total of 262,777 dermatologist visits were observed for 26,139 patients with rosacea (mean age 57.5 years, female 67.5%); 12.2% patients had one, 40.5% had two, and 47.4% had three or more dermatologist visits during a mean 28.5 months of follow-up. The distribution of patients with 1, 2, and 3+ visits were similar across age group, gender, and region. A mean ± SD temperature of 61.1 ± 15.7°F, an ultraviolet index (UVI) of 1.4 ± 0.7, and relative humidity of 68.2 ± 9.8% were observed before all dermatologist visits. 9.5% of all dermatologist visits were preceded by a high temperature of ≥80°F and 12.7% by a cold temperature of <40°F; 93.4% visits preceded by relative humidity >55, and 78.8% preceded by UVI ≤2. Dermatologist visits were relatively evenly distributed among four seasons (21.9% – 26.8%). ***Conclusions:*** Existing literature has demonstrated that high/low temperature and high/low relative humidity are primary contributors to rosacea-related flares. An understanding of the weather conditions prior to rosacea-related flares is important for better managing the risk of flares and the progression of rosacea.

Systemic Disorders/Conditions - Economic Evaluation

PSY5
ECONOMIC VALUE DRIVERS IN SEVERE RED BLOOD CELL DISORDERS: A REVIEW AND DEVELOPMENT OF AN ECONOMIC CONCEPTUAL FRAMEWORK

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Objectives: Anemia treatments have greatly improved patient life expectancy in the past decade. However, few economic studies have evaluated the budgetary impact and cost effectiveness of these new therapies. The purpose of this study is to review published economic studies in severe red blood cell disorders, including autoimmune hemolytic anemia, beta-thalassemia, chemotherapy-induced anemia, chronic kidney disease anemia, and severe aplastic anemia to inform the conceptual framework for future economic research in severe anemia. ***Methods:*** Economic literature for the various types of anemia was reviewed by a targeted search. The review considered cost-effectiveness analyses (CEA), cost-utility analyses (CUA), and budget impact models (BIM) and evaluated the main assumptions impacting their validity. Primarily, the assumptions assessed included the model structure (decision tree, Markov model), the time horizon, the perspective, and the included costs. Based on these assessments, an optimal conceptual framework was proposed for future economic research, accounting for the criteria used previously. ***Results:*** A total of eleven studies were analyzed: five CEAs, four BIMs, and two CUA. The studies were predominantly from G8 countries. The time horizon varied significantly from 15 weeks to lifetime, which is important as smaller timeframes do not take into consideration the long-term impact of treatment outcomes. Additionally, the types of costs included varied among studies, and mortality costs were rarely included. Furthermore, the association between serum ferritin and mortality was neglected in most of the studies considering adverse events. Lastly, uncertainty was not always assessed properly, particularly for lifetime models. ***Conclusions:*** The economic analyses found in red blood cell disorders seem to overlook core elements, particularly the included costs. Importantly, adverse events, administration, and mortality costs were not calculated in most of the studies. The conceptual framework proposed will help identify and reduce gaps related to economic model conceptualization in red blood cell disorders.

PSY6
COSTS AND BENEFITS OF METHOTREXATE IN PSORIATIC ARTHRITIS

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Objectives: Although not indicated for psoriatic arthritis (PsA), methotrexate (MTX) is commonly prescribed as first-line treatment in this population. While inexpensive, the efficacy, treatment burden, and effectiveness of MTX over time in PsA patients is still unclear. Therefore, the objective of this study was to evaluate the costs and benefits of first-line MTX in MTX- and bio-naïve PsA patients over time. ***Methods:*** We performed a decision tree analysis, using clinical and utility inputs for 4, 8, 12, 16, 24, 36, and 48 weeks of MTX use from the MTX arm of Amgen's randomized controlled trial assessing etanercept and MTX as monotherapy or in combination for PsA (SEAM-PsA). We estimated cost inputs from Medicare Fee Schedule, AnalySource, and published studies. For year 1, we calculated cumulative costs and quality-adjusted life years (QALYs) from observed data in SEAM-PsA. We modeled costs and QALYs for years 2-5 post-MTX use using data from SEAM-PsA and observational studies. We performed a probabilistic sensitivity analysis (PSA) to test the robustness of the results. ***Results:*** Mean utility increased in the first year of MTX use, then generally decreased over time, decreasing below baseline by year 3. Costs and cost/QALY increased after the first year of MTX use, and generally continued to increase over time with MTX use. We present our results in an interactive ShinyApp tool. ***Conclusions:*** MTX may have