ABSTRACT BOOK

2013 Annual Meeting
American College of Allergy, Asthma & Immunology
November 7-11, 2013
Baltimore, Maryland

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SENSITIZATION TO AEROALLERGENS IN ADULT PATIENTS ATTENDED AT THE ALLERGY SERVICE OF THE UNIVERSITY HOSPITAL IN MONTERREY, MEXICO.

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Background. The aeroallergens are the most common cause of allergic sensitization in adults and have a preponderant role in the pathogenesis of allergic respiratory diseases. The biodiversity of airborne allergens varies by geographic area and climate of each region. The skin prick tests are the standard method for identifying sensitization IgE mediated. Objective. Identify the aeroallergens that most often cause allergic sensitization in patients treated in the allergy department at the University Hospital of Monterrey. Methods. We performed an observational and descriptive study, consisting of the review of medical records of patients who had undergone skin prick tests with extracts of aeroallergens, from 2009 to 2012. We obtained demographic and clinical data of patients, the results of skin tests. All skin testing included 36 different extracts of common aeroallergens in the northeastern region of Mexico. We evaluated the frequency of sensitization to allergens, as well as the pattern of that (out-door, in-door or mixed allergen sensitization). Data were analyzed using descriptive statistics using the SPSS 20. Results. The records of 2,170 patients were reviewed. 1,777 patients were sensitized to at least one of the tested aeroallergens. The mean age of these patients was 35.1 years and 57.3% were female. In relation to age, 12.4% had <20 years; 56.2% 21 to 40 years; 26.4% 41 - 60 years; and 5% 61 to 80 years. Aeroallergen sensitization was more frequent in the group of 21 to 40 years. The diagnoses of patients included allergic rhinitis (82.7%), asthma (8%), atopic dermatitis (2.4%) and urticaria (6.9%). 92% of patients were poly-sensitized and only 8% mono-sensitized. Sensitization to out-door aeroallergens only occurred in 15%, and the most frequent were Prosopis spp (32%), Cynodon dactylon (31%) and Amaranthus palmeri (28.9%). Sensitization to in-door aeroallergens only occurred in 33.6% and the most frequent were Dermatophagoides pteronyssinus (57.9%), Dermatophagoides farinae (52.4%) and Blattella germanica (25.7%). A mixed pattern was observed in 51.4% of patients. Conclusion. Most of the allergic adults attended in our service are poly-sensitized to aeroallergens. In-door allergens are the most frequently involved, the most common are house dust mites (Dermatophagoides pteronyssinus and Dermatophagoides farinae).

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EXTRACTABILITY OF TREE NUTS: A COMPARISON OF METHODS.

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Introduction: The aim of this study was to determine differences in extractability of tree nuts using varied extraction conditions. Methods: Prior to extraction, walnut (W), pecan (PN), Brazil nut (BN), almond (A) and pistachios (P) were macerated, defatted with 100% acetone or a 50% acetone, petroleum ether mix, and extracted overnight in 50% glycerin or aqueous extraction buffer using multiple extraction techniques (i.e., blending, persistent stirring or rocking). Extractions were performed at 4°C for all tree nuts, with additional room temperature extractions for walnut. Following extraction, all samples were adjusted to contain 50% glycerin, centrifuged and sterile filtered. The extracts were then evaluated for differences in protein profiles and concentrations using SDS-PAGE and Coomassie Blue. Results: The solvent used to defat the various tree nuts did not significantly alter final protein concentrations or protein banding patterns. The average protein concentrations for A, BN, PN and P extracts were 12.2 mg/ml, 10.2 mg/ml, 1.1 mg/ml and 10.2 mg/ml, respectively. There were no significant differences in protein profiles or concentrations, within the same nut species, with glycerin or aqueous extraction, nor were there differences when various extraction conditions were utilized. Walnut extraction, however, produced contrasting results. The final protein concentrations of the walnut extracts varied significantly, according to the extraction method. Glycerin extraction resulted in an average final concentration of 1.9 mg/ml, versus 0.3 mg/ml for aqueous extraction. Furthermore, room temperature extraction resulted in higher protein yields (2.8 mg/ml), when compared to extraction at 4°C (1.7 mg/ml), and persistent stirring was the superior method of agitation. Overall, the protein band intensity correlated directly with the final protein concentrations, regardless of species. Conclusions: Optimal extraction conditions for tree nuts vary according to species. No significant protein differences were observed in almond, pistachio, Brazil nut and pecan extracts, however, significant alterations in protein concentrations were observed among walnut extracts. Ideal conditions for walnut extraction include room temperature, glycerin extraction with persistent stirring. Further work is needed to evaluate correlations between extraction conditions and overall extract potency and stability.

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IDENTIFICATION AND CHARACTERIZATION OF CYANOBACTERIAL ALLERGENIC PEPTIDES.

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Background: Health effects caused by cyanobacteria (blue green algae) remain poorly elucidated. The cyanobacteria specie, Microcystis aeruginosa (Ma), produces an array of diverse metabolites believed responsible for their toxicity and/or immunogenicity. Previously, chronic rhinitis patients were demonstrated to elicit a specific IgE response to non-toxic strains of Ma by skin-prick testing indicating that cyanobacteria allergenicity likely resides in the non-toxin producing component of the organism. This study's objective was to identify and characterize Ma peptide(s) responsible for allergic sensitization in susceptible individuals. Methods: Sera collected from Ma sensitized rhinitis patients were used to identify sensitizing proteins by IgE-specific direct and indirect ELISAs in response to Ma. Gel filtration chromatography followed by specific IgE immunoblots and mass spectroscopy was performed to identify relevant protein bands. Results:Specific IgE was increased in sera of Ma sensitized patients which was inhibited by pre-incubation of serum with the Ma lysate in a dose-dependent manner. Gel filtration chromatography revealed the relevant sensitizing peptides were isolated to the high molecular weight fraction of the lysate. Specific IgE immunoblotting revealed three distinct bands with molecular weights 105 kD, 75 kD and 50 kD. Mass spectroscopy identified one of these proteins to be C-phycocyanin which exhibits 85% sequence homology with the C-phycocyanin found in the food supplement, Spirulina, previously reported to cause anaphylaxis. Conclusions:Specific peptides in non-toxic strains of Ma that elicit specific IgE responses in Ma sensitized individuals have been identified. Further investigation is ongoing to determine the functional significance of this finding.

tional therapy with ecallantide against conventional therapy with placebo for ACEIA. Methods: In this phase 2 double-blind study, subjects were randomized 1:1:1:1 to receive conventional therapy with a single subcutaneous dose of ecallantide (10, 30, or 60 mg) or placebo. Adults presenting to the emergency department within 12 hours of onset of ACEIA of the head/neck were eligible. The primary endpoint was defined as meeting a predetermined set of 6 discharge eligibility criteria within 6 hours of treatment. Results: 176 subjects were planned for enrollment. An interim analysis of blinded study data indicated that a majority of subjects overall were meeting the primary endpoint, and the study was halted. In total, 76 eligible subjects were treated. Most patients had mild (45%) or moderate (42%) ACEIA at the time of presentation; 45% of patients were Ishoo Class I (facial rash, facial edema, lip edema), 5% were Class II (soft palate edema), 41% were Class III (tongue edema), and 8% were Class IV (laryngeal edema). The primary endpoint was met by 72% (13/18) of the placebo group, and by 85% (17/20), 89% (17/19), and 89% (17/19) of the 10, 30 and 60 mg ecallantide groups, respectively. Comparing all dosages of ecallantide to placebo, there was a non-significant absolute difference of 15.7% (95%CI -10.9 to 41.2) in favor of ecallantide. No new safety signals were identified. ICU admission rate was low and not significantly different between ecallantide and placebo groups (8.6% [5/58] vs 16.7% [3/18] respectively; p=0.385). Conclusion: Compared with conventional therapy alone, the addition of ecallantide did not demonstrate a significant benefit in this small study of ACEIA patients. The majority of patients met the discharge eligibility criteria within 6 hours of ED presentation regardless of intervention.

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ADVERSE DRUG REACTIONS: FACTORS THAT PLAY A ROLE IN READMISSION.

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Introduction: An estimated 5.3% of hospitalizations are related to adverse drug reactions (ADRs); however, there is little data on the readmission rate of patients experiencing these reactions. Our objective was to determine the rate and factors affecting readmission (within 30 days) after being discharged from an ADR-related hospitalization. Methods: A retrospective chart review of 238 patients with ADRs identified through pharmacy records over a 12-month period was conducted with IRB approval. The severity of the ADR was based on treatment, length of stay and/or disability. Patients were separated into an inpatient and outpatient group based on whether the initial ADR occurred in the hospital or community setting. Only patients who were admitted solely for the ADR were included for analysis. Results: A total of 111 outpatients and 78 inpatients were analyzed. The readmission rate for ADRs in the community was 16.2% versus 17.9% in the inpatient setting (p=0.8). Readmission related to the initial ADR was seen in 4 inpatients (ie. bradycardia, neutropenia) and 5 outpatients (ie. renal failure, hypoglycemia). Both inpatients and outpatients who were readmitted had a mean number of 8.0 concurrent medications. The mean age for readmission was 74.7 years (outpatient group) versus 70.0 years (inpatient group). COPD was the most common comorbidity in ADR-related readmissions (55.5%) while diabetes was most common in non-ADR-related readmissions (52.2%). More serious initial ADRs occurred in the community usually from anticoagulants and angiotensin converting enzyme inhibitors (ACEIs)/angiotensin II receptor blockers (ARBs). Contrast dye and opioids were predominant causes of ADRs in the hospital. The ADR severity in the initial admission did not increase the likelihood of an ADR-related readmission. Conclusion: The readmission rates for ADRs in the community versus hospital were nearly identical. The severity of the initial ADR did not affect the readmission rate. Patients with COPD and diabetes are more likely to experience readmission thus we suggest careful review of discharge criteria in these populations.

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PREVALENCE OF PERIODONTAL DISEASE IN PATIENTS WITH RESPIRATORY ALLERGY.

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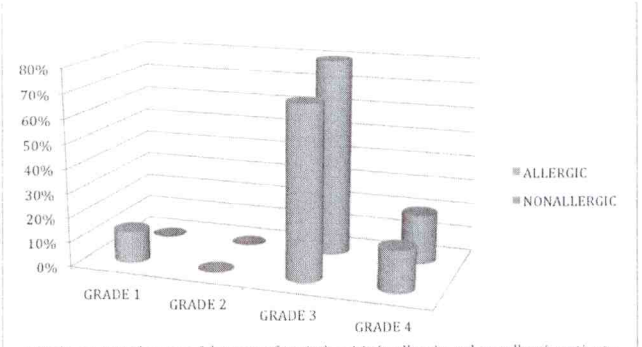
Background. Periodontal disease results from childhood exposure and accumulation of bacteria at the gingiva and teeth. In contrast to the "hygiene hypothesis", several studies have found an association between respiratory allergy and periodontitis. The aim of this study is to determine the prevalence of periodontal disease in patients older than 15 years with respiratory allergy. Method. We performed an observational, transversal and comparative study that assessed two groups. Group 1 included patients with a diagnosis of respiratory allergy, with sensitization to aeroallergens identified by skin tests. Group 2 (control) included non-allergic subjects with negative skin tests to aeroallergens. All subjects were evaluated by the Periodontal Clinic to identify the presence of periodontal disease. Subjects with periodontal disease were divided into 4 subgroups (I: gingivitis, II: mild periodontitis, III: moderate periodontitis, and IV: advanced periodontitis). Results. We included a total of 60 subjects (30 in each group). The mean age was 30 years in both groups (p = 0.4). There was no difference in relation to gender (p = .78). Allergic diseases in Group 1 included: allergic rhinitis (100%), asthma (66%), and atopic dermatitis (33%). All subjects in both groups had some degree of periodontal disease. Within the group of allergic patients, the distribution according to the degree of periodontal disease was: grade I, 13% (n = 4); grade II, 0%; grade III, 70% (n = 21); and grade IV, 17% (n = 5). In the control group, the distribution by degree of periodontal involvement was: grade I, 0%; grade II, 0%; grade III, 80% (n = 24); and grade IV, 20% (n = 6) (Graphic 1). No association was found between the degree of periodontal disease with gender, duration of respiratory allergic disease, or a history of previous dental cleaning. Conclusions. The high prevalence of periodontal disease found in our study population did not identify differences between the groups evaluated. We suggest further studies with larger sample population and study design modifications.



Graphic 1-Distribution of degrees of periodontitis in allergic and nonallergic patients.

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IMPLEMENTING A COMPREHENSIVE STANDARDIZATION PROCESS (DEFINE, INTERVENE, ANALYZE, CLOSE THE LOOP) LEADS TO BOTH SHORT-TERM AND LONG-TERM CHANGES IN CLINICAL PRACTICE.

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Introduction: We present a comprehensive process (Define, Intervene, Analyze, Close the loop) to standardize clinical practice and improve patient care. Methods: We implemented a comprehensive process (Define, Intervene, Analyze, Close the loop) in order to standardize our penicillin and cephalosporin allergy evaluation. Define: Inconsistent evaluation of patients with a history of anaphylaxis to penicillin; amoxicillin allergy; cephalosporin allergy. Intervene: A literature search was conducted regarding the defined problem and the studies presented to all providers. A consensus was achieved and practice parameter was written and reviewed addressing the problem. Analyze: Those who participated in the defined process (intervention group) and control group (providers who did not participate) were tested on the material with 4 questions with different clinical scenarios addressing the defined problem. Close the loop: Both groups were then tested six months later to evaluate for long-term retention of the material and change in practice. Results: Correct answers to the 4 questions from the intervention group (n=7) compared to control group (n=6) were as follows: Question 1(86% vs. 0%), 2 (86% vs. 67%), 3 (86% vs. 33%), 4 (57% vs. 0%) shortly after intervention. The same questionnaire was administered to both groups 6 months later: Question 1 (100% vs. 40%), 2 (100% vs. 100%), 3 (100% vs. 60%), 4 (66% vs. 40%). Conclusion: Implementing a comprehensive standardization process (Define, Intervene, Analyze, Close the loop) can lead to both short-term and long-term changes in clinical practice compared with controls.

ology, natural course and epidemiology is not clear yet. The underlying pathologies and other contributing factors should be carefully examined. GER and atopy should be scanned. Recurrent croup patients with atopy should be followed closely for developing bronchial asthma.

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THE ALLERGIES, IMMUNOTHERAPY AND RHINOCONJUNCTIVITIS (AIRS) PROVIDER SURVEY: HOW PROVIDERS DIFFER.

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Introduction: Allergic Rhinoconjunctivitis (ARC) is one of the most common chronic diseases in the US. Management of ARC encompasses avoidance, pharmacologic agents, and use of specific immunotherapy (SIT). The Allergies, Immunotherapy & RhinoconjunctivitiS (AIRS) provider survey was designed to assess provider's perceptions of allergy symptoms, allergy testing and SIT. Methods: A telephone survey was administered to 500 healthcare providers offering outpatient care to >1 ARC patient per week. Providers were randomly selected from professional society lists by specialty to yield completed surveys from 100 Allergy/Immunology (AI), 100 Otolaryngology (ENT), 75 Family Medicine (FM), 75 Pediatric (PED) and 50 Ophthalmology/Optometry (OPH/OPT) physicians along with 50 Nurse Practitioners (NP) and 50 Physician Assistants (PA). Results: Overall, providers reported itchy eyes (62%) as the primary reason allergy patients sought treatment followed by nasal congestion (58%). Specialty-level results showed nasal congestion as the most frequent symptom among patients seen by AI (79%), FM (64%), and ENT (85%) with itchy eyes as the second most common (64%, 51%, 45%, respectively). Eye symptoms were the most common for OPH/OPT. Nearly all providers (>90%) reported at least a moderate amount of impact of allergies on a patients' quality of life. Allergy testing was performed primarily by AI (95%) and ENT (63%) versus other specialists (OPH/OPT: 4% - FM: 37%). Greater than 90% of all specialists agreed that patients with severe symptoms should be treated with SIT. AI recommended SIT to the largest proportion of ARC patients (adult: 41%; pediatric: 39%) while FM recommended to the smallest proportion (adult: 11%, pediatric: 10%). Likewise, AI reported SIT as being currently used by the greatest number of their patients (adult: 33%, pediatric: 28%) and least by FM (adult: 8%, pediatric: 8%). Fewer OPH/OPT(86%) either provided or referred for SIT compared to other specialists with >95% provide or refer for SIT. One of the major barriers for not recommending SIT was that providers (N=64) did not feel it was in their scope of practice. Conclusions: Provider differences exist for diagnosis and management of ARC. Targeted educational efforts and development of collaborations across provider specialties could maximize care and enhance appropriate use of SIT for allergy patients.

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MP29-02 EFFECTIVELY RELIEVES BOTH NASAL AND OCULAR SYMPTOMS IN ADOLESCENTS AGED 12-17 YEARS: RESULTS FROM 4 RANDOMIZED CONTROLLED SEASONAL ALLERGIC RHINITIS (SAR) TRIALS.

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Introduction: Two large pediatric studies are currently underway in the United States to investigate the efficacy and safety of MP29-02 (Dymista) in children, with a view to extending its indication to those aged ≥ 6 years. In line with FDA recommendations, these studies compare MP29-02 to placebo. In preparation for these clinical trial results, and in order to mimic the clinical trial design of these on-going pediatric studies, this meta-analysis assessed all the data available for moderate-to-severe SAR patients aged 12-17 years, who received either MP29-02 or placebo in the same vehicle and device. Methods: Data from 4 multi-centre, parallel-group, randomized, double-blind, placebo-controlled, 14-day studies were pooled. A total of 97 patients aged 12-17 yrs received MP29-02 (a novel intranasal formulation of azelastine hydrochloride [AZE] and fluticasone propionate [FP]) 1 spray/nostril bid (total daily dose: AZE 548 mcg; FP 200 mcg) and 112 patients received placebo spray 1 spray/nostril bid. The primary efficacy variable was change from baseline in reflective total nasal symptom score (rTNSS; AM +PM; MAX=24), over 14-days. Reflective total ocular symptom score (rTOSS; AM + PM; Max = 18) was an important secondary endpoint. Results: Patients aged 12-17 yrs treated with MP29-02 experienced a 4.29 point mean improvement from baseline in their rTNSS, significantly more the 2.06 point improvement observed in those treated with placebo (diff: 2.23; 95% CI: 3.23; 1.22; p<0.0001). Similarly, in this adolescent patient population treatment with MP29-02 produced a significant mean improvement in the rTOSS of 2.23 points from baseline compared to 1.04 points with placebo (diff: 1.19; 95% CI: 2.06, 0.32; p=0.0080). Conclusion. These results show that adolescent SAR patients treated with MP29-02 experience significant relief from both their nasal and ocular symptoms. Similar beneficial effects may be expected in pediatric patients.

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MP29-02 RELIEVES ALL INDIVIDUAL NASAL AND OCULAR SYMPTOMS IN SEASONAL ALLERGIC RHINITIS (SAR) PATIENTS, PARTICULARLY NASAL CONGESTION AND OCULAR ITCH.

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Introduction: Nasal congestion is the most bothersome nasal symptom of SAR, but any symptom can predominate in a given patient. Ocular symptoms, particularly itch, have the greatest impact on quality of life. Here, we assess the efficacy of MP29-02 (a novel intranasal formulation of azelastine hydrochloride [AZE] and fluticasone propionate [FP]) in providing individual nasal and ocular symptom relief, plus relief for patients with a predominant symptom. Methods: 610 patients (≥ 12 years old) with moderate-to-severe SAR were randomized into a double-blind, 14-day, parallel-group trial comparing MP29-02, AZE, FP or placebo (PLA) nasal sprays (1 spray/nostril bid; total daily doses: AZE 548 µg; FP 200 µg). Change from baseline (CFB) in nasal and ocular symptom scores was assessed by ANCOVA. CFB in patients' predominant symptom was assessed post-hoc. Patients were defined as congestion-, itching-, rhinorrhoea- or sneezing-predominants based on max. symptom scores at baseline. Results: MP29-02 provided superior relief from all individual and predominant symptoms of congestion, nasal itch, rhinorrhoea, sneezing and ocular itch than either AZE or FP. The magnitude of this effect was particularly evident for congestion and ocular itching (Table). Conclusion: MP29-02 universally relieves all symptoms associated with SAR, especially nasal congestion and ocular itch, including those patients who present with nasal congestion or ocular itch predominantly. Compared to AZE or FP alone, MP29-02 is a superior SAR treatment.

Treatment	Baseline (sd)	LS Mean CFB	Relative Diff+	p-value
CFB nasal congestion (all patients)				
MP29-02 (n=153)	5.25(0.79)	-1.24*	-	-
FP (n=151)	4.97(0.93)	-0.86*	54%	0.0034
AZE (n=152)	5.04(0.88)	-0.75	70%	0.0001
PLA (n=150)	5.15(0.78)	-0.54	-	<0.0001
CFB nasal congestion (congestion-predominants)				
MP29-02 (n=98)	5.60(0.47)	-1.41*	-	-
FP (n=84)	5.34(0.78)	-0.90	71%	0.0018
AZE (n=93)	5.36(0.77)	-0.83	81%	0.0001
PLA (n=93)	5.47(0.65)	-0.69	-	<0.0001
CFB ocular itch (Baseline rTOSS >= 8)				
MP29-02 (n=128)	4.91(0.89)	-1.40*	-	-
FP (n=125)	4.75(1.00)	-0.83	70%	0.0003
AZE (n=118)	4.90(0.91)	-0.98*	51%	0.0098
PLA (n=121)	4.94(1.01)	-0.58	-	<0.0001
CFB ocular itch (ocular itch-predominants)				
MP29-02 (n=85)	5.10(0.88)	-1.41*	-	-
FP (n=90)	4.98(0.85)	-0.87	76%	0.0026
AZE (n=77)	5.05(0.87)	-1.04*	51%	0.0551
PLA (n=81)	5.20(0.81)	-0.69	-	<0.0001

+ [1-(FP or AZE - PLA)/(MP29-02 - PLA)] x 100
* significant vs PLA

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TYMPANOMETRIC ALTERATIONS IN PATIENTS FROM 12 TO 20 YEARS OF AGE WITH ALLERGIC RHINITIS.

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Background: Allergic rhinitis is an inflammatory process of the nasal mucosa,caused by exposure to allergens in previously sensitized individuals.

Otitis media with effusion is among the main conditions associated with allergic rhinitis which can lead to tympanometric alterations Objective: To determine the tympanometric alterations that occurs in adolescent patients with allergic rhinitis and compared with a control group. Method: We included 55 patients aged 12 to 20 years which were divided in two groups: a group of patients with allergic rhinitis (29 patients) and a control group without allergic rhinitis (27 patients), both groups underwent skin tests with aeroallergens, ISAAC survey was applied. Additionally all patientts underwent tympanometry. Using SPSS 20 program we analyzed nominal and ordinal variables, frequencies and percentages, plus contingency tables and correlation of variables with Pearson test and Chi-square; being considered statistically significant a $P < 0.05$. Results: The mean age of patients included in the study was 18.1 years. Symptoms in patients with perennial allergic rhinitis were predominantly perennial and the average time of evolution was 9 years. In all control subjects, skin tests were negative. The allergen to which were sensitized with more frequency the patients with allergic rhinitis was Dermatophagoides pteronyssinus. Tympanometric alterations were identified in only 3.4% of patients with allergic rhinitis and in 7.7% of subjects in the control group ($p = 0.6$). No difference in the frequency of tympanometric alterations in relation to the duration of allergic rhinitis or the number of positive allergen skin tests was found. Conclusion: We found no statistically significant difference in the frequency of tympanometric alterations between the group of patients with allergic rhinitis and control groups.

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AN ELECTRONIC PATIENT DATA ACQUISITION TABLET (EPDAT) IDEAL FOR RAPID ONSET-OF-ACTION DATA COLLECTION.

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Introduction: The onset of action (OOA) of allergy medication relief is an important measure to both patients and researchers. To date, the use of paper diary cards has limited the ability to capture the earliest post-treatment time point and thereby the earliest OOA. An Electronic Patient Data Acquisition Tablet (ePDAT) has been created which allows for rapid, easy collection of patient-reported outcomes (PRO). Methods: Sixty-four subjects with a confirmed history of allergic rhinitis to ragweed allergen participated in a 6 hour Environmental Exposure Chamber (EEC) visit. During their exposure patients recorded Total Nasal Symptom Scores (TNSS) using the ePDAT at 0, 15, 30 minutes and every 30 minutes thereafter for the remainder of the visit. ePDAT is an electronic PRO (ePRO) system that has an intuitive graphical user interface to display fully customizable questionnaires or visual analog scales on a touch-screen tablet. Results: We have developed an ePDAT that is fully validated and CFR21 part 11 compliant for use in our EEC, mobile EEC (mEEC) and at home. During a 6 hour exposure period in an EEC our ePDAT captured over 5800 unique study data values at specific time points. 93% of all instantaneous TNSS (including nasal itching, rhinorrhea, sneezing and congestion) data values were captured within a minute of the symptom score assessment time, and 100% of all TNSS were captured within 4 minutes and therefore 100% patient compliance was obtained within 4 minutes. Conclusions: ePDAT is an innovative ePRO device that allows patients to report their symptoms rapidly and accurately. This will improve the quality of PRO and will lead to a better understanding of the drug response time course and ensure patient compliance.

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BECLOMETHASONE DIPROPIONATE NASAL AEROSOL FOR PERENNIAL ALLERGIC RHINITIS: SATISFACTION WITH INTRANASAL CORTICOSTEROIDS AFTER THREE MONTHS.

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Introduction: Beclomethasone Dipropionate (BDP) in a non-aqueous or "dry" aerosolized spray has been FDA-approved for treatment of nasal symptoms associated with perennial allergic rhinitis (PAR), and is being investigated in a prospective, observational, patient-centered registry, the BALANCE study. Outcome measures include treatment satisfaction with intranasal corticosteroids (INS). This analysis shows the interim results for patient-reported treatment satisfaction with INS after 3 months of use. Methods: BALANCE study participants were enrolled at allergy, otolaryngology and primary care clinics in the US between July and December 2012. IRB approval and informed consent for all subjects was obtained. Enrollees with a minimum one-year history of PAR were initiated on BDP nasal aerosol. Web-based surveys were used for patient follow-up. INS treatment satisfaction was assessed at baseline when used within the prior 2 years and at follow-up if INS was being used. The validated brief Treatment Satisfaction Questionnaire for Medication (TSQM-9) consisted of 9 items in 3 subscales: Effectiveness, Convenience and Global Satisfaction with medication. Each subscale was scored from 0-100 with higher scores representing greater satisfaction with INS. Results: The 43 study centers enrolled 824 patients; mean age was 38.0 years, 61.7% female; 85.9% Caucasian; and their mean duration of PAR was 15.7 years. Of those enrolled, 491 (59.6%) had used a prior INS and completed the TSQM-9 at baseline. The mean baseline Effectiveness score was 50.2 (Standard Deviation [SD]: 16.5); the mean baseline Convenience score was 67.6 (SD: 16.9); and the mean baseline Global Satisfaction score was 53.3 (SD: 19.4). At three months, 227 (46.2%) patients completed the TSQM-9 and 194 (85.5%) were continuing to use BDP nasal aerosol. Their mean change from baseline for the Effectiveness subscale was 14.5 (Standard Error [SE]: 1.8; 95% Confidence Interval [CI]: 10.8-18.1); mean change from baseline for the Convenience subscale was 10.4 (SE: 1.6; 95% CI: 7.2-13.6); and mean change from baseline for the Global Satisfaction subscale was 12.4 (SE: 1.9; 95% CI: 8.8-16.1). Conclusions: BDP nasal aerosol was associated with three-month improvement in patient-perceived treatment effectiveness, convenience and global satisfaction compared to previous INS use.

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REAL-WORLD USE OF BECLOMETHASONE DIPROPIONATE NASAL AEROSOL BY PATIENTS WITH PERENNIAL ALLERGIC RHINITIS: EFFECTIVENESS ON RHINITIS CONTROL AFTER THREE MONTHS.

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Introduction: A prospective, observational, patient-centered outcomes registry, Investigation of the Real World Effectiveness of Beclomethasone Dipropionate (BDP) Nasal Aerosol in Perennial Allergic Rhinitis (PAR) Subjects (BALANCE), was implemented in 2012. BALANCE assessed monthly changes in patient-reported rhinitis control over six months. The objective of this analysis was to show the interim results for rhinitis control at three months. Methods: BALANCE study participants were enrolled at allergy, otolaryngology and primary care clinics in the US between July and December 2012. IRB approval and informed consent for all research subjects was obtained. Enrollees with a minimum one-year history of PAR were initiated on BDP nasal aerosol. Web-based surveys were used for patient follow-up. The primary outcome, rhinitis control, was measured by change from baseline on the validated Rhinitis Control Assessment Test (RCAT), with a clinically important difference of three points. Higher scores indicated better rhinitis control. Interim analyses, planned at three months of follow-up, are shown here. Results: The 43 study centers enrolled 824 patients. Mean age was 38.0 years; 61.7% were female; 85.9% were Caucasian; 75.6% also had seasonal allergic rhinitis (SAR); 48.2% had used other intranasal corticosteroids in the past two years; and their mean duration of PAR was 15.7 years. Of the 824 patients, 755 (91.6%) completed three-month follow-up surveys, and, of these, 655 (86.8%) continued using BDP nasal aerosol. The mean RCAT score at baseline was 15.8 (Standard Deviation [SD]: 3.4), and the mean 3-month change for all respondents was 5.8 (Standard Error [SE]: 0.2; 95% Confidence Interval [CI}: 5.4-6.2). For those continuing to use BDP nasal aerosol the mean change in RCAT score was 6.1 points (SE 0.2; 95% CI: 5.7-6.5) while for those who had stopped BDP nasal aerosol the mean change in RCAT score was 3.8 points (SE: 0.5; 95% CI: 2.8-4.7). The percent of responders to BDP nasal aerosol with at least three-point improvement on the RCAT at three months was 76.6% (95% CI: 73.4-79.9). Conclusions: The real-world effectiveness of BDP nasal aerosol on rhinitis control in patients with PAR was confirmed after three months of use.