

Contributed Poster Presentations

Poster Session I

ALLERGY

PAL1

DETERMINING THE MINIMAL CLINICALLY IMPORTANT DIFFERENCE FOR THE ESPRINT-15 QUESTIONNAIRE FOR PATIENTS WITH ALLERGIC RHINITIS

Baro E¹, On Behalf of Esprint Study Investigators²

¹3D Health Research, Barcelona, Spain; ²Esprint Study Investigators Group, Barcelona, Spain

OBJECTIVE: To determine the minimal clinically important difference (MCID) for improving interpretation of the recently validated Esprint-15 questionnaire, to measure health-related quality of life for patients with allergic rhinitis. **METHODS:** An observational multicenter study was carried out with allergic rhinitis patients to validate the Esprint questionnaire (15 items of symptoms, daily life activity, sleep and psychological impact). It uses 7-point response options. Global score range from zero (worse) to 5.8 (better). MCID was determined by applying the method previously used by Juniper et al. (1996) in the case of the Rhinoconjunctivitis Quality of Life questionnaire. Patients completed twice the Esprint-15 and assessed their change on health status in a 13-point scale from -6 (a very great deal worse) to 0 (no change) to +6 (a very great deal better). Patients were classified as “no change” (-1, 0 or +1), “MCID” (+3 or +2), “moderate change” (+4 or +5) and “large change” (+6). **RESULTS:** Valid responses for the 2 visits were obtained from 245 patients (mean age 32, 62.2% women, average of moderate symptoms at inclusion, mean 7 years from diagnosis, 58% were following AR treatment) of which: 30 (12.2%) reported “large change”, 86 (35.1%) reported “moderate change”, 55 (22.4%) reported “MCID”, 48 (19.6%) reported “no change” and 25 (10.2%) reported deterioration in health status. Mean (SD) increases in the Esprint-15 global score were: 0.2 (0.9) for patients with “no change”, 1.1 (0.9) for patients at the “MID”, 2 (1.1) for patients reporting “moderate change”, and 2.9 (1.2) for patients reporting “large change”. Because of the small sample size, results for patients reporting negative changes are not presented, although they suggest an attenuate but similar tendency. **CONCLUSION:** There is evidence that mean positive changes in global score from Esprint-15 questionnaire of about 1 or more may be considered of clinical importance.

PAL2

ATTRIBUTES FOR PREFERENCE OF NEW FAST DISSOLVING TABLET (FDT) FORMULATION OF EBASTINE IN PATIENTS WITH ALLERGY

Roger A¹, Fortea J², Artes M³, Montilla L³

¹Centre Roger Barri d'Asmologia i Al·lèrgia, Barcelona, Spain;

²Laboratoris Almirall, Barcelona, Spain; ³Adelphi Targis, S.L., Barcelona, Spain

OBJECTIVE: The main objective of the research is to understand the perceived key attributes and strengths of the FDT formulation of Ebastine. **METHODS:** The new formulation Ebastine

FDT was tested using placebo both in patients (60) and physicians (82) throughout qualitative face-to-face interviews in Belgium, France, Finland, Germany and Italy. Patients suffering from chronic or acute/seasonal allergies regularly taking prescription antihistamines and physicians who are high prescribers of antihistamines were included. **RESULTS:** The key attributes for preference of the new FDT formulation are convenience and ease of use (can be taken everywhere, not water is needed) and the perception of faster onset of action. After tasting there's a positive evaluation for the majority (57 patients out of 60 and 75 physicians out of 82) on most FDT formulation attributes (correct texture, appearance, colour and size and very rapid dissolving). Taste evaluation was controversial (mint flavour) and patients difficulties handling the blister disappeared when instructed. The FDT formulation is perceived as suitable for any type of patients, particularly those with acute episodes, active lifestyle, difficulties to swallow and gastrointestinal problems according to patients; and those with an active lifestyle according to physicians. Most patients consider that the new formulation can improve compliance (45 out of 60). The likelihood of taking/prescribing Ebastine FDT is quite high, rating 7.9 (4.2) and 7.6 (5.7) respectively for patients and physicians on a 1–10 scale (1–7 scale in Finland). Most patients (47 out of 60) and physicians (54 out of 82) preferred the new FDT formulation. **CONCLUSIONS:** The new FDT formulation is preferred by both physicians and patients, because it's easier to comply, more convenient and it's associated with a perception of faster onset of action.

PAL3

DEVELOPMENT, PILOT TESTING, SCORING AND VALIDATION OF A MANAGEMENT TOOL FOR PATIENTS UNDERGOING SPECIFIC IMMUNO-THERAPY

Arnould B¹, Benmedjahed K², Fadel R³, Bos C³, Fontaine JF⁴, Haddad T⁵, Mathelier Fusade P⁵, Rufin P⁵, Saint Martin F⁶, Zekri J⁷, Viala M²

¹Mapi Values, Lyon, Rhone, France; ²Mapi Values, Lyon, France;

³Stallergènes, Antony, France; ⁴Private practice, Reims, France; ⁵Private practice, Paris, France; ⁶Private practice, Villebon sur Yvette, France;

⁷Private practice, Toulouse, France

OBJECTIVE: Clinicians in charge of allergic rhinitis patients miss specific questionnaires assessing patients' expectations, satisfaction, adherence, persistence, attitudes toward Specific Immuno-therapy (SIT). Our aim was to provide them with a specific instrument allowing better adapting care to the patient's characteristics, perceptions and behaviour. **METHODS:** A conceptual model was identified from a literature review, 5 clinician and 21 patient interviews. A test version of the questionnaire was developed and independently validated by an Advisory Committee (AC). Five patients suffering from allergic rhinitis and treated by SIT completed the questionnaire and were asked to comment the questionnaire in-depth. It was redrafted and included in a pilot study (10 clinicians, 30 patients) in real conditions of use. A revised questionnaire was administrated by 211 clinicians to 571 patients (380 having a SIT and 191 about to)

between February and May 2005 in a cross-sectional, observational study. **RESULTS:** Fourteen global and 57 detailed concepts were included in the conceptual model. The test questionnaire contained 64 items. After cognitive debriefing, 7 items were excluded. The questionnaire was well-accepted by the patients in the pilot study. Clinicians were delighted to have a helpful patient-management tool. The pilot questionnaire contained 52 items in 10 sections (symptoms, allergy in daily life, motivations for SIT, advantages, constraints, intake, outcomes, satisfaction, intention, information). The majority of the 211 clinicians reported high patient acceptability and major interest in using the questionnaire routinely. The items presenting missing data, not clearly related to a specific domain, or redundant were not selected for final format and score calculation. The scores were assessed for internal consistency reliability, construct validity and predictive validity. **CONCLUSION:** This instrument covers the major domains impacting the patient's persistence in SIT. It is a promising patient-management tool for use in clinical practice.

ARTHRITIS

PAR1

COSTS AND EFFECTS OF CELECOXIB IN THE TREATMENT OF PATIENTS WITH RHEUMATOID ARTHRITIS AND OSTEOARTHRITIS IN THE NETHERLANDS

Al M¹, Janssen M², Monteban HC³

¹Institute for Medical Technology Assessment, Rotterdam, The Netherlands; ²Rijnstate Hospital, Arnhem, The Netherlands; ³Pfizer bv, Capelle a/d IJssel, The Netherlands

OBJECTIVE: To assess the balance between costs and upper GI side effects of treatment with celecoxib (a COX-2 specific inhibitor) compared with non-specific NSAIDs alone, non-specific NSAIDs plus misoprostol, non-specific NSAIDs plus histamine-2 receptor antagonists (H2RA), non-specific NSAIDs plus proton pump inhibitors (PPI), and Arthrotec, in The Netherlands. **METHODS:** A model was used to convene data from various sources. The probabilities of GI side effects for celecoxib and non-specific NSAIDs alone were derived from trial data, while all other probabilities were derived from published sources. Resource use was derived from databases and an expert panel. Calculations were based on 6 months of treatment, and were from a societal perspective but were limited to direct medical costs (2004 Euros; €). Distinction was made between risk groups based on risk factors such as older age, use of corticosteroids and history of GI events. **RESULTS:** Treatment with celecoxib was associated with the lowest number of GI side effects and related deaths. Assuming an average patient, the total costs per 6 months of therapy were: celecoxib €212, non-specific NSAIDs alone €151, NSAIDs plus misoprostol €227, NSAIDs plus H2RAs €268, NSAIDs plus PPIs €269, and Arthrotec €171. Incremental costs per life-year saved for celecoxib compared with non-specific NSAIDs alone were €12,417 for all patients, and -€760 for high-risk patients. Comparing celecoxib and Arthrotec, the incremental costs per life-year saved were €32,757 for all patients and €7759 for those at high-risk of GI events. **CONCLUSION:** Celecoxib is a more effective and less costly treatment than non-specific NSAIDs plus misoprostol, NSAIDs plus H2RAs, and NSAIDs plus PPIs. It is cost-effective compared with non-specific NSAIDs alone for patients at medium- to high-risk of GI events, and also for high-risk patients. Compared with Arthrotec, celecoxib showed an improving cost-effectiveness profile with increasing GI risk.

PAR2

METAL ON METAL (MOM) HIP RESURFACING (BIRMINGHAM HIP RESURFACING (BHR)) IN YOUNG PATIENTS WITH SEVERE HIP DAMAGE—A COST UTILITY ANALYSIS

Richardson JB¹, Band T², Barnes DC¹, Buckland AG³, Posnett J⁴

¹RJAH Orthopaedic & District Hospital NHS Trust, Oswestry, Shropshire, UK; ²Smith & Nephew Orthopaedics Ltd, Birmingham, UK; ³Abacus International, Bicester, Oxfordshire, UK; ⁴Smith & Nephew Wound Management, Hull, UK

OBJECTIVES: Total Hip Replacement (THR) is regarded as gold standard treatment for degenerative hip disease in elderly patients. Young, active patients, however, are a more challenging group for THR due to the high risk of revision and associated complications. In 2002, the National Institute for Health and Clinical Excellence (NICE) recommended MoM hip resurfacing as a treatment option for this patient group. An alternative treatment for these patients is watchful waiting (WW) whereby patients are maintained on drug-based regimens until they are old enough to warrant a THR. The aim of this study was to evaluate the cost-effectiveness of BHR vs. WW in 45–55 year old patients with severe hip damage. For completeness the cost-effectiveness of BHR vs. THR was assessed in the same patient group. **METHODS:** A health economic model was constructed to assess the efficacy, cost and health-related quality of life associated with BHR, WW and THR treatments. Efficacy data for BHR were obtained from a large, prospective database (n = 4424), which provided up to 5 years follow-up for individual BHR patients. Resource use and utility data were obtained from published sources. The primary outcome from the model was the cost per quality-adjusted life-year (QALY). **RESULTS:** Preliminary results demonstrate that at year 5 BHR has an incremental cost/QALY (ICER) of £1,101 compared to WW and an ICER of £13,125 compared to THR. Over time the ICER decreases and BHR becomes dominant (i.e. it is more effective and costs less) compared to WW and THR by year 20 and 15, respectively. **CONCLUSIONS:** This study demonstrates that in patients aged 45–55 years with severe hip damage, BHR offers an extremely cost-effective alternative to WW with an equivalent improvement in quality of life to THR. Patients treated with BHR will benefit from significant health gains at an acceptable cost.

PAR3

PRODUCTIVITY BENEFITS FROM CONTROLLED-RELEASE VS SHORT ACTING OPIOIDS FOR TREATMENT OF PERSISTENT MODERATE TO SEVERE OSTEOARTHRITIS (OA) PAIN OF THE HIP/KNEE

Marshall DA¹, Strauss ME², Pericak D¹, Buitendyk M¹, Codding C³, Torrance G¹

¹Innovus Research Inc, Burlington, ON, Canada; ²Purdue Pharma LP, Stamford, CT, USA; ³Oklahoma Sports, Oklahoma City, OK, USA

OBJECTIVES: OA is associated with significant disability, reduced productivity, decreased HRQoL, and increased health care costs. The objective was to evaluate the cost-effectiveness of controlled-release oxycodone (CRO) from a societal perspective incorporating time loss (paid and unpaid work for patients and friends/relatives). **METHODS:** Open-label, active-controlled, randomized, naturalistic 4-month study of effectiveness and cost-effectiveness of CRO vs. short-acting opioids. Outcomes, resource utilization and time loss were collected by telephone. Quality-adjusted-life-years (QALYs) were calculated from HUI3 scores. Cost-effectiveness was measured as cost/QALYs gained and cost/patient improved. **RESULTS:** Patients treated with CRO compared to short-acting opioids were more productive