Abstracts

CLUSIONS: Five methods of measuring BLISS attainment using four pre-specified threshold levels of pain were able to statistically discriminate between treatment groups. This method may potentially provide an approach, to defining which patients not only improve but also achieve a good state of health, at low and very low levels of pain intensity. BLISS – 10 is a therapeutically attainable very low symptom state at which clinically important, statistically significant between group differences are detectable, and therefore may provide a benchmark against which therapeutic interventions can be assessed. However, the value to patients, of this and other low and very low intensity pain states, requires further elaboration.

PAR16
CAN OSTEOARTHRITIS PATIENTS EVALUATE TRADEOFFS BETWEEN NSAID RISKS AND BENEFITS?
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OBJECTIVE: To evaluate osteoarthritis (OA) patients’ ability to state valid preferences for tradeoffs between treatment-related serious adverse events (SAEs) and specified treatment benefits.
METHODS: A web-enabled, choice-format, conjoint or stated-preference survey was developed to elicit OA patients’ willingness to accept tradeoffs between SAE probabilities and treatment efficacy. The treatment attributes included in the tradeoff tasks employed graphical elements indicating pain and stiffness severity on a continuous visual analog scale, mild-to-moderate gastrointestinal (GI) symptoms measured by type of intervention required, and bleeding ulcer, heart infarct, and stroke probabilities shown numerically and visually on a 100-square grid. The instrument was pretested with a convenience sample of 8 OA patients and administered to a sample of OA patients in a large-scale pilot survey. Random-parameter logit estimates were used to calculate maximum acceptable 10-year MAR various levels of clinical benefit. RESULTS: A total of 156 patients completed the pilot survey. Only 4% of subjects failed the irrational-choice and 14% failed the cross-question monotonicity internal validity tests. Patients discriminated successfully among pain and SAE risk levels. Mild-to-moderate gastrointestinal side effects had no significant effect on treatment choices. Pain control was about twice as important as control of stiffness, and stroke likelihood was the most important SAE risk. Maximum acceptable risk (MAR) increased as expected with greater therapeutic benefits and decreased inversely with the importance of SAE risks. Mean MAR for a maximal improvement from moderate daily symptoms to full symptom control was significantly greater than 0.05 for ulcer, infarct, and stroke (p < 0.001 for all). CONCLUSIONS: All medical interventions carry risks of adverse outcomes that must be evaluated against their clinical benefits. OA patients in this pilot study indicated they were willing to accept SAE risks in excess of clinical levels for sufficiently large improvements in symptom control.

PAR17
A COMPARISON OF HEALTH RELATED QUALITY OF LIFE (HRQOL) OF PERSONS WITH AND WITHOUT ARTHRITIS OR CHRONIC JOINT SYMPTOMS (CJS)
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OBJECTIVES: To characterize health related quality of life (HRQoL) among persons with and without arthritis or chronic joint symptoms (CJS). METHODS: Data obtained from the 2004 Behavioral Risk Factor Surveillance Survey (BRFSS), an ongoing, state-based, random-digit dialed telephone survey of non-institutionalized persons aged >/= 18 years conducted in all states. Data from nine states (54,116 participants) were included in the analysis as these states had included both components of arthritis and HRQoL measures (mental, physical, and poor health) in the 2004 survey. Multiple linear regression analyses were used to examine the associations between selected sociodemographic and behavioral determinants and HRQoL among participants with arthritis or CJS. RESULTS: Of the respondents 32% had been diagnosed with some form of arthritis by a health care professional and 46% had joint pain in the past 30 days. The respondents with arthritis had a mean of 6.75 physically and 4.58 mentally poor health days and 6.41 poor health days during the past 30 days compared with 2.29, 3.14, and 2.76 among those without arthritis. Only 36.9% of participants with arthritis reported very good general health versus 60.9% of respondents without arthritis (p = 0.000). For each unit of age increase of participants with arthritis there was an increase in physical, mental, and poor unhealthy days. Based on WHO’s classification of obesity, the respondents with arthritis included approximately 30.9% normal weight, 37.3% overweight, 27% obese, and 4.7% severely obese respondents. Regression analysis indicated that severely obese, obese, and over weight experienced more unhealthy physical and poor days than respondents with normal weight. Active men and women were less likely to report poor unhealthy days compared with those who did not exercise in the past 30 days. CONCLUSIONS: Findings indicate that persons with arthritis or CJS experience a decrease in HRQOL as compared to those without arthritis.

PAR18
HEALTH-RELATED QUALITY OF LIFE (HRQL) IN OSTEOARTHRITIS: A SYSTEMATIC REVIEW TO ASSESS THE MEASUREMENT PROPERTIES OF THE WOMAC (WESTERN ONTARIO McMASTERS) OSTEARTHRITIS INDEX) FOR DISCRIMINATIVE AND EVALUATIVE RESEARCH
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OBJECTIVES: Osteoarthritis is prevalent and debilitating disease that affects nearly 21 million Americans. For clinicians to assess the impact of treatment strategies require reliable, valid and interpretable measures. We conducted a systematic review of WOMAC which is a disease specific instrument measuring HRQL of patients with osteoarthritis. The review considered the evaluative, discriminative properties and interpretability of the instrument. The last systematic review was published in 2001. METHODS: A structured literature review was performed to identify evidence related to measurement properties (reliability, internal consistency, responsiveness, and interpretability) of WOMAC using two databases (MEDLINE and HealthSTAR) from 1982 to December 2005. We included randomized controlled trials and observational studies. RESULTS: Of 307 and 137 papers, 14 met the inclusion criterion. Discriminative: We found high reliability (correlation coefficients) for domains of pain and physical function (>0.7), compared to the stiffness domain (>0.6). All domains had generally high construct validity in differentiating among patients with better/worse HRQL. The internal consistency (Cronbach’s alpha) was high (>0.8). WOMAC generally had high construct validity. Responsiveness varied by domain and by intervention. WOMAC was more responsive in patients who underwent total hip or knee arthroplasty compared to other interventions. We found that the physical function domain was more responsive than other domains.
and this was more evident in patients with arthroplasty. The minimal score difference on 0–10 scale needed to detect clinical improvement (worsening) was 0.64(0.75), 1.03(0.67), and 0.29(0.72) for pain, physical function, and stiffness domain, respectively. CONCLUSIONS: WOMAC has good discriminative and evaluative properties. These properties provide an opportunity to measure new health technologies and other interventions in this cohort of patients with confidence. To benefit from the use of this measure as an interpretable one we need additional research in patients, particularly within clinical trials where other objective and interpretable measures are used.

CONCLUSIONS: Patient preferences can be used to make explicit, the latent trade-off decisions made by patients at the characteristics level in arriving at treatment choice decisions. This study methodology can also be used to understand physician preferences for treatment choices.

PAR20

BENEFIT-RISK-COST TRADE-OFF ANALYSES USING PATIENT PREFERENCES FOR THE TREATMENT OF RHEUMATOID ARTHRITIS
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OBJECTIVE: To estimate the benefit-risk-cost (BRC) trade-off at the patient level, utilizing patient preferences for treatment choices in rheumatoid arthritis (RA). METHODS: Published patient preferences on 120 RA patients with mean disease duration of 8 years was used to conduct these trade-off analyses. Utilities (preferences) for 5 benefit characteristics (route, physician experience, onset, chance of benefit, bone erosions), 6 common adverse effects (injection site reaction, rash, oral ulcers, alopecia, nausea, diarrhea), 4 rare adverse effects (cancer, nephrotoxicity, hepatotoxicity, pneumonitis), and 1 cost characteristic (monthly co-pay) were estimated using adaptive conjoint analysis. The 16 characteristics were based on four treatment choices: methotrexate, gold, leflunomide, and etanercept. Based on the estimated utilities for the 16 characteristics, the marginal rates of substitution between pairs of characteristics were computed. RESULTS: Multiple BRC trade-off utilities were calculated and will be presented. A subset of three of these BRC trade-off utilities is presented below. The utility lost by patients switching from oral to subcutaneous injection was equal to the utility gained from: incidence of rash decreasing from 40% to 9.5%; nausea decreasing from 30% to 6.5%; diarrhea decreasing from 30% to 10.4%; or monthly co-pay lowered from $30 to $7.14. For chance of benefit versus onset trade-off, the range was from −0.086 weeks%/ (0.086 weeks of delay in the onset of the drug, for a 1% increase in the chance of benefit) to −0.244 weeks%/week. For onset versus diarrhea trade-off, the range was from −2.08%/week (2.08% reduction in the incidence of diarrhea, for a one week delay in onset) to −7.23%/week. CONCLUSIONS: Patient preferences can be used to make explicit, the latent trade-off decisions made by patients at the characteristics level in arriving at treatment choice decisions. This study methodology can also be used to understand physician preferences for treatment choices.

PDB1

RETROSPECTIVE STUDY OF INSULIN GLARGINE USE IN PREVIOUSLY INSULIN-NAIVE U.S. MANAGED CARE PATIENTS WITH TYPE 2 DIABETES
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OBJECTIVES: Patient characteristics, treatment patterns, and clinical effectiveness were assessed for insulin naïve patients with type 2 diabetes (T2D) who initiated treatment with insulin glargine. METHODS: Administrative and pharmacy claims were linked with laboratory results from a large managed care database and were analyzed between May 1, 2001 and May 31, 2004. Patients with a diagnosis of T2D who were insulin-naïve prior to filling prescriptions for glargine were selected for analysis and followed for a minimum of 12 months. The initial claim for glargine served as the index date. Other antidiabetic therapy was assessed for the month prior to the index date. Glargine treatment patterns included persistence and concomitant medications. A subset of patients receiving HbA1c results both within 90 days pre- and no sooner than 60 days post-index periods were analyzed for HbA1c changes. RESULTS: A total of 936 insulin-naïve patients with T2D who initiated glargine therapy were identified. Prior to starting glargine, 50% of patients received no antidiabetic therapy, 21% received oral antidiabetic monotherapy, and 29% received combination oral therapy. The average length of glargine therapy was 185 days until a change in the index therapy occurred. In patients with both pre-and post-index values (N = 49), HbA1c decreased from 8.7% to 7.6% post-index (p = 0.0003). The average length of time between index and post-index HbA1c measurement was 216