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PDB61

BURDEN OF ACROMEGALY– A RETROSPECTIVE CHART AUDIT

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OBJECTIVES: Acromegaly, a relatively rare chronic endocrine disorder, results from excessive growth hormone (GH) secretion from a pituitary adenoma. Information on treatment practices and burden of acromegaly is limited. This study focused on assessing the burden of disease based on data retrieved from a large series of these patients. **METHODS:** A retrospective chart audit was conducted in September 2012 in US, France Italy and Brazil. Ninety-seven endocrinologists completed structured case report forms for the 4 most recently-seen acromegaly patients (N=380); those on the last choice of medical therapy ≥6 months 'qualified' for this this analysis (N=335). Patient demographics, comorbidities, treatment history, insulin-like growth factor [IGF-1], random growth hormone [GH]), symptoms and health care resource utilization were recorded. Control of IGF-1 was defined as IGF-1≤1ULN, control of GH as GH≤2.5 µg/L. **RESULTS:** Fifty-two percent of patients were males, mean age 51 years; 63% with controlled IGF-1; 34% with controlled IGF-1+GH. The prevalence of comorbidities (hypertension, diabetes, arthritis) was similar in patients with controlled versus uncontrolled IGF-1 and in patients with controlled versus uncontrolled IGF-1+GH. The rate of paresthesia was significantly lower in patients with controlled versus uncontrolled IGF-1 (10% vs. 23%, p=0.003) and in patients with controlled versus uncontrolled IGF-1+GH (9% vs. 25%, p=0.015). Utilization of health care resources was similar in patients with controlled versus uncontrolled IGF-1 except for days hospitalized, which were significantly higher for patients with uncontrolled IGF-1 (p<0.05). Patients with controlled IGF-1+GH had significantly lower number of HCP visits, hospitalizations and length of hospitalization than those uncontrolled (p<0.01). In multivariable models predicting resource utilization based on biochemical control and comorbidities, IGF-1+GH control remained a statistically significant predictor of HCP visits, hospitalizations, and days hospitalized (p<0.05). **CONCLUSIONS:** This retrospective chart audit demonstrated that acromegaly patients with controlled IGF-1+GH have reduced symptom burden and resource utilization than uncontrolled patients.

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PATIENT-REPORTED FREQUENCY AND IMPACT OF HYPOGLYCEMIA IN TYPE-2 DIABETES PATIENTS RECEIVING PREMIXED INSULIN IN SEVEN EUROPEAN COUNTRIES

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OBJECTIVES: Hypoglycaemia is a common complication of insulin therapy and can impede optimal diabetes management, with implications for patients and health care resourcing. Many patients with Type-2 diabetes mellitus (T2DM) use premixed insulin regimens, but data on frequency and impact of hypoglycaemia in these patients are limited outside clinical trials. **METHODS:** A total of 3827 insulin-treated patients in Austria, Denmark, Finland, Norway, Netherlands, Sweden and Switzerland were recruited, mainly via online panels, to complete four questionnaires at week-intervals. Data were collected on demographics and non-severe hypoglycaemic events (NSHE) in the preceding seven days. NSHE was an event with symptoms of hypoglycaemia, with or without blood glucose measurement (BGM), or low BGM (≤55 mg/dl) without symptoms, which the patient managed without assistance. Severe hypoglycaemic events (SHE) — defined as events requiring third-party assistance — were also reported. **RESULTS:** The 258 T2DM patients on premixed insulin reported 826 patient-weeks. Mean insulin-treatment duration was 7 years, mean HbA_{1c} 7.9% (SD 1.6). Mean self-reported NSHEs were 0.52 per patient-week (SD 1.15), 33% of which were nocturnal (versus 23% in overall study). Mean annual frequency of SHEs was 0.2. Impaired awareness or unawareness of hypoglycaemia (answering 'usually/sometimes/never' to question 'can you feel when your blood sugar is low?') was reported in 57% (versus 63% in overall study). Of the 36% employed, 5% reported lost work time due to the last NSHE. Mean increase in BG test-strips was 3.2 over the 7 days following each NSHE. Nine percent of patients contacted a health care professional following a daytime, 10% following nocturnal NSHE. **CONCLUSIONS:** NSHE are common amongst premixed-insulin-treated T2DM patients; a third occurring at nighttime. NSHE were associated with work time loss and increased health care resource use, however hypoglycaemia awareness was low, and events not often reported to patients' GP/specialist. The real-world rates — and burden — of hypoglycaemia may therefore be underestimated.

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SELF-MONITORING BLOOD GLUCOSE: STRIPS CONSUMPTION RATE AND COSTS IN ARGENTINA

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BACKGROUND: Self-monitoring blood glucose (SMBG) is a useful tool to optimize diabetes control but increases its care cost. However, there is no data about its usage and cost in Argentina. **OBJECTIVES**: To estimate, in Argentina, the number of strips used for SMBG at the Social Security system (SSS) and its relationship with the type of treatment and degree of metabolic control. **METHODS**: An observational-retrospective study employing registries from the Pharmaceutical College of the Province of Buenos Aires (COLFARMA, 8115 anonymized recipes of drugs and strips prescribed in the period February to April 2012) and from one organization of the SSS (OSPERYH, 681 affiliates, strips consumption plus laboratory data during 2010). Statistical analysis includes ANOVA, t-test, U de Mann-Whitney and Kruskall-Wallis. **RESULTS**: *OSPERYH*: strips were provided under an audit system that assesses diabetes education, type of treatment and degree of metabolic control. Monthly overall average consumption was 24.6±14.5 (mean±SD) and it was strongly related to the treatment: insulin 34.5±16.6 and oral antidiabetic drugs (OAD) 22.5±12.6. In each group, people with HbA1c values < 7% consumed more strips than those above such value. *COLFARMA*: the overall average strips consumption was 97.5±70.1. The types of treatment significantly affect strips consumption: insulin alone 111.0±76.3, insulin+OAD 89.0±62.5, combined OAD 74.7±47.3 and OAD monotherapy 66.2±45.0 strips. Despite this consumption was almost four times larger than in OSPERYH, the treatment-dependent consumption pattern was similar in both groups. The strips represent, on average, 44 and 66% of the total cost of the prescription in COLFARMA and OSPERHY, respectively; and vary according to the treatment (OSPERHY and COLFARMA): OAD monotherapy 66 and 85%; combined OAD 39% and 62%; insulin 28 and 53%, respectively. **CONCLUSIONS**: The number of strips increased as a function of the type of treatment and attainment of therapeutic goals. Prescription audit significantly decreased such consumption.

DIABETES/ENDOCRINE DISORDERS – Patient-Reported Outcomes & Patient Preference Studies

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A SYSTEMATIC LITERATURE REVIEW OF METHODOLOGIES USED TO ASSESS MEDICATION ADHERENCE IN PATIENTS WITH DIABETES

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OBJECTIVES: Adhering to prescribed medication can be problematic for patients with diabetes yet there is no gold standard for measuring adherence in this patient population. This systematic literature review aimed to critically review and summarize the methods used to measure medication adherence in patients with diabetes in original research published between 2007-2012, and to highlight novel methods that are particularly relevant in assessing adherence to variable-dosed insulin regimens. **METHODS:** A systematic search for articles describing methods to assess medication adherence in patients with type I or type II diabetes (on oral hypoglycemic agents, and/or insulin) was conducted using PubMed, EMBASE, PsychInfo, and Cochrane Databases. Two researchers independently screened abstracts for initial eligibility, then applied the inclusion/exclusion criteria to the relevant full-text articles. **RESULTS:** Fifty-five articles met the criteria for inclusion. In prospective studies, the identified medication adherence evaluation methods included subjective assessment (observer-reported and patient-reported), pill counts, Medication Event Monitoring System (MEMS), cell-phone real-time assessment and logbooks. Biochemical measurement as a proxy for adherence was also employed in some prospective studies. In all pharmacy claims database studies, medication possession ratios (MPRs), or some derivation thereof was utilized. Few approaches specifically addressed issues unique to assessing insulin adherence. However, two novel approaches (using cell-phone real-time assessment, and computerized logbooks) provided insight as to timing and dosing issues that could be useful for highlighting interventions to improve insulin adherence. **CONCLUSIONS:** No gold standard exists for measuring medication adherence in patients with diabetes. The plethora of adherence evaluation methods and different approaches to defining adherence/non-adherence precludes the comparison of adherence rates across studies. Greater consistency is therefore needed in adherence measurement, including question content, recall period, and response options for self-report measures, and definitions of "good adherence" for MPR. Novel methods for understanding adherence to variable-dosed insulin require further research.

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ADHERENCE TO THERAPY AMONG DIABETES PATIENTS IN A NIGER DELTA REFERRAL CENTER

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OBJECTIVES: Information on adherence among diabetes patient is rare in Bayelsa State, Niger Delta. The objective of the study was to determine the rate of adherence to therapy among diabetes mellitus patients. **METHODS:** It was a cross sectional survey with the use of an interviewer-administered questionnaire. A 4-item Morisky self-reported adherence scale in addition to other self-developed, validated and pretested questionnaires were used. This was administered to 263 patients receiving treatment at the Outpatient Department of the hospital after seeking and obtaining their consent between June and August 2012 on clinic days. Questions related to demographics, medication history, adherence rate, etc., were included. In addition, the respective case notes (263) of the same set of patients were examined, and relevant data extracted (such as blood glucose level). Data was appropriately analysed using SPSS. Descriptive statistics were used in presentation of results. **RESULTS:** Majority of the 210 patients (80.0%) were taking both metformin and glibenclamide tablets. About 60 percent, 156 (59.3%), of patients were adjudged adherent with prescribed medications on the 4-item Morisky scale of adherence with a score of 1.22±0.2, which differs significantly from the non-adherent group with a score of 3.34±0.87. (p<0.0001). However, overall adherences to all aspects of diabetes management were poorer as only 80 (30.5%) had normal fasting blood glucose level of less than 6.1mmol/l after at least five visits to the hospital. Only

42 (16.0%) patients self monitor their glucose level. The most frequently reported factor affecting adherence is high cost of drug therapy, 118 (44.8%), and forgetfulness, 99 (37.6%). Most of the patients, 201 (76.4%), have developed one complication or the other such as hypertension and glaucoma. **CONCLUSIONS:** There is poor adherence to anti-diabetic therapy among the patients. Financial constraint was found to be the most important factor affecting optimal adherence to therapy.

PDB66

NEED FOR CASE-MIX ADJUSTMENT IN EVALUATING GEOGRAPHIC DISPARITIES IN MEDICATION ADHERENCE TO ORAL HYPOGLYCEMICS

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OBJECTIVES: To examine adherence to oral hypoglycemics among Mississippi Medicaid beneficiaries and to evaluate the need for case-mix adjustment when examining disparities among counties. **METHODS**: The study was a retrospective analysis of Mississippi Medicaid claims data from 2008-2011. Beneficiaries were included in the analysis if they had at least two claims for oral hypoglycemics, had 90 or more days of therapy, were at least 18 years old, were not dual-eligible, and were not in long term care. Medication adherence was measured using Proportion of Days Covered (PDC) with a gap of 60 days being considered a discontinuation of therapy. PDC was calculated for each drug being taken and an average PDC was computed for each beneficiary for the time on any therapy. Beneficiaries with a PDC greater than 80% were considered to be compliant to therapy. Overall comorbidity was measured with an RxRisk score. Percentage of beneficiaries compliant in each county was calculated. Counties were classified as high, medium and low compliance. A multivariable logistic regression model was used to assess the relationship between compliance and beneficiaries' age, sex, race and comorbidities. The relationships among county compliance level and beneficiary characteristics associated with compliance were evaluated to determine case-mix confounders that need to be adjusted for in evaluating county level disparities. **RESULTS**: Percentage of compliant beneficiaries in the counties ranged from 33.3% to 66.7%. Beneficiary characteristics related to compliance were gender (odds ratio for male to female = 0.870), race (odds ratio for African-Americans to Caucasians = 0.647), and RxRisk score (odds ratio for score of 0 to 6+ = 0.717). Race and RxRisk scores were significantly related to county compliance levels. **CONCLUSIONS**: Beneficiary characteristics are strong predictors of compliance. Any evaluation of county level disparities in adherence rates must use adjustments for variations in the patient mix among the counties.

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ASSOCIATIONS BETWEEN CLAIMS BASED ADHERENCE, WEIGHT LOSS AND, GLYCEMIC CONTROL IN PATIENTS WITH TYPE 2 DIABETES

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OBJECTIVES: The association between anti-diabetic adherence, weight loss, and glycemic control in patients with type 2 diabetes (T2DM) remains largely uncharacterized**.** This study examined the relationships between these variables in T2DM patients in an integrated health system. **METHODS:** This was a historical cohort study of patients treated in the Geisinger Health System. Included patients were ≥18 years, with T2DM, prescribed a class of anti-diabetic not previously prescribed (index date) between 11/1/10-4/30/11, with HbA1c and weight values at index date and 6-months follow-up, and had Geisinger Health Plan insurance with ≥1 claim for the index date medication. Anti-diabetics were grouped as weight loss (metformin and GLP-1 agonists) versus weight gain/neutral (sulfonylureas, thiazolidinediones, DPP-4 inhibitors, insulin, and others) to help control for weight effects of drug therapy. Adherence was calculated using the modified Medication Possession Ratio (mMPR) with a score ≥0.8 considered adherent. The primary outcomes were weight loss ≥3% and HbA1c control (<7.0%) at 6 months follow-up. A structural equation model (SEM) was used to simultaneously assess the associations between claims adherence, weight loss, and HbA1c control. **RESULTS:** There were 166 patients included with a mean (SD) age of 61.1 (12.1) years, 56% were women, 98.8% were white, 58 were prescribed metformin or a GLP-1, and 108 were prescribed a sulfonylurea, thiazolidinedione, DPP-4 inhibitor, insulin, or other class. Adherence per mMPR was high with 77.1% of patients classified as adherent with no significant difference between anti-diabetic groups. Results of the SEM showed that both anti-diabetic adherence (OR 2.71 95%CI 1.22-5.98) and weight loss ≥3% (OR 2.99 95%CI 1.45-6.17) were associated with HbA1c control. **CONCLUSIONS:** This study adds to the body of literature highlighting the importance of weight loss and adherence in glycemic control. It also emphasizes the importance of anti-diabetic agent selection and strategies promoting adherence and weight management goals.

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ASSESSING ADHERENCE AMONG PATIENTS WITH TYPE 2 DIABETES USING INSULIN: PSYCHOMETRIC ANALYSIS OF THE MORISKY MEDICATION ADHERENCE SCALE

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OBJECTIVES: The Morisky Medication Adherence Scale (MMAS) provides a unique perspective on adherence because of its patient-reported nature. However, as it is not a condition-specific instrument, evidence of its reliability and validity within the population of interest must be obtained. This study examined the psychometric properties of the recently developed eight-item MMAS (MMAS-8) among those with type 2 diabetes (T2D) using insulin. **METHODS:** Data from the US 2012 National Health and Wellness Survey (NHWS) were used (N=71,141). Only respondents who reported a diagnosis of T2D, were currently using an insulin (any type), and reported their last value of HbA1c were included (n=1,198). Among this subsample, the reliability and validity of the MMAS-8 (when asked only about diabetes medications) were examined using both classic test theory and item response theory (IRT) analyses. **RESULTS:** A total of 61.44% of respondents were male and the mean age was 60.65 (standard deviation = 10.74). Engagement of non-adherent behaviors (the individual items of the MMAS-8) varied considerably from "stopping medication when feeling worse" (5.76%) to "having difficulty remembering to take all your medications" (32.22%). Internal consistency was adequate (Cronbach's α=0.68), though would have been improved upon removal of the "did you take your medicine yesterday" item (α=0.70 if removed). One factor was retained using exploratory factor analysis (eigenvalue=1.80). In IRT analyses, most items exhibited solid psychometric properties (e.g., discrimination > 1.40); however, "did you take your medicine yesterday", provided little information (discrimination=0.20; information=0.02). Overall, the MMAS-8 functioned best when distinguishing among those with above average non-adherence (θ>0). **CONCLUSIONS:** These results suggest the MMAS-8 is a reliable and valid instrument to use to assess non-adherence, though certain items are less useful than others for this population. Despite its generic nature, the MMAS-8 should be considered as an adherence measurement tool among those with T2D using insulin.

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SYSTEMATIC LITERATURE REVIEW OF UTILITIES RELATING TO PATIENTS WITH TYPE-2 DIABETES MELLITUS EXPERIENCING A STROKE OR MYOCARDIAL INFARCTION

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OBJECTIVES: Patients with type-2 diabetes mellitus (T2DM) are at increased risk of stroke or myocardial infarction (MI) resulting in decrements in their health-related quality of life. A systematic literature review identified estimates of utility decrements for these events in patients with T2DM to better understand the impact of avoiding or delaying them with treatment. **METHODS:** Electronic databases (2001-2011) and conference abstracts (2009-2011) in English were searched for utility-elicitation studies in T2DM and for cost-effectiveness analyses that included disutility estimates for stroke and MI. **RESULTS:** Nine utility-estimation studies using data from 11 countries were identified. Seven of these studies presented results adjusted for confounding variables including age and other comorbidities. Of those, two also adjusted for time since the event or event severity. Disutilities ranged from 0.035 to 0.129 for MI and from 0.044 to 0.269 for stroke. One study presented disutilities for an event experienced the previous year (MI, 0.081 - 0.129; stroke, 0.091 - 0.181) and >1 year ago (MI, 0.042 - 0.078; stroke, 0.069 - 0.269). The study presenting estimates by event severity adjusted for confounding variables had disutilities of 0.044 for stroke or transient ischemic attack without disability and 0.072 for stroke with residual disability. Of the 15 economic evaluations identified that included estimates of disutilities for MI and/or stroke, 12 used values from one of the utility-estimation studies described above. Two used disutilities from US studies in patients with any type of diabetes, and one used general population disutilities. **CONCLUSIONS:** The wide range of utility estimates for MI or stroke in T2DM patients could impact the results of cost-effectiveness analyses for new treatments that avoid or delay these events and calls for research to create consistent estimates, accounting for event severity and valuing event sequelae over time, such as poststroke disability.

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PATIENT-REPORTED OUTCOMES (PROS) IN DIABETES CLINICAL TRIALS

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OBJECTIVES: To assess prevalence and type of Patient-Reported Outcomes (PROs) in Type 2 Diabetes clinical trials. **METHODS:** A search of www.clinicaltrials.gov was conducted using the search criteria of Type-2 diabetes (T2DM) as the disease and drug as the intervention, in addition to limiting the studies to Phase 3. This resulted in 810 trials. Trials were excluded if any of the following exclusion criteria were met: sample size <50, start date before 2000, main condition other than T2DM, and trial did not include clinical outcomes. Phase 2/3 studies, pediatrics trials, and both double-blind and open-label studies were included. The remaining 632 trials were then assessed for prevalence and type of PROs. **RESULTS:** Only 47 (7.4%) of trials in the sample used PROs. There is no discernable trend for PRO use over time. For these 47 trials, 1.9 PROs were used on average, with a range of 1 to 7 PROs. A total of 90 PROs were included in these 47 trials. Forty-three (48%) of these PROs measured Health-Related Quality of Life (HRQL)/Utilities, 22 (24%) measured treatment satisfaction, five (6%) were unknown. Within the HRQL measures, 37% (16) were diabetes-specific, 37% (16) were generic (e.g., SF-36), and the remaining 26% of PROs were not specified. Among treatment satisfaction, 82% were diabetes-specific. Thirty-three (70%) of the studies using PROs were for drugs that are injectables (i.e., not oral). **CONCLUSIONS:** PRO use in T2DM clinical trials remains low. Despite their underuse, the need to assess effectiveness of an intervention from a patient perspective continues to grow in relevance. Although there are a host of diabetes-specific PROs available, the development of a clinical trial-specific, user-friendly instrument may be needed