PHP92

EVALUATION OF A WIRELESS HANDHELD MEDICATION MANAGEMENT PROGRAM IN THE PREVENTION OF DRUG-DRUG INTERACTIONS

Saverno K, Malone DC

University of Arizona College of Pharmacy, Tucson, AZ, USA

OBJECTIVES: Drug-related adverse events impose a substantial burden on patients and health care systems. Electronic prescribing (e-prescribing) systems have been identified as effective tools to improve quality, safety, and efficiency in health care delivery. The purpose of this study is to evaluate the effectiveness of a wireless medication management program in a commercially available e-prescribing system in the prevention of serious drug-drug interactions (DDIs). **METHODS:** This study employed a retrospective pre-post with a control group design to evaluate the effectiveness of wireless handled medication management program in preventing serious DDIs. A total of 1975 prescribers who received personal digital assistants (PDA) between August 1, 2004 and June 30, 2005 constituted the technology user group. The comparison group included 1063 prescribers who sent a request to obtain, but did not receive, the technology during the same period. Multivariate regression analysis was used to determine if there were differences between the two groups of prescribers in the rate of prescribing clinically important DDIs. **RESULTS:** Prescribers in the two groups were significantly different in their specialty practice areas and number of pharmacy claims and at baseline. However both groups were similar in their average age, profession, and practice type. Prescribers varied in their use of the e-prescribing system to access patient medication history, the average number of patient medication history updates requested per prescriber in the user group was 42.09 (ranging from 0 to 1073). The most widely prescribed DDIs included those involving warfarin with non steroidal anti-inflammatory drugs (NSAIDs) and anticoagulants with thyroid hormones. Compared to the control group, PDA users did not have significantly greater decrease in the number of serious potential DDIs as compared to non users ($p = 0.65$). **CONCLUSIONS:** The availability of near real-time patient medication history did not have a significant impact on reducing the rate of prescribing clinically important DDIs.

PHP93

PRESCRIPTION PATTERNS OF CHINESE HERBAL PRODUCTS SUSPECTED OF CONTAINING ARISTOLOCHIC ACID: ANALYSIS OF REIMBURSEMENT DATA OF A COHORT FROM TAIWAN DURING 1997–2003

Hsieh SC[1], Wang JD[2]

[1]Center for Drug Evaluation, Taipei City, Taiwan, [2]National Taiwan University, College of Public Health, Taipei, Taiwan

OBJECTIVES: Although the nephrotoxic and carcinogenic effects of Aristolochic acid (AA) have already been well documented, there is a distinct lack of evidence on the long-term consumption of Chinese herbal products (CHPs) which either contain Aristolochia herb species, or which have been adulterated by herbs suspected of containing AA (SAA herbs). We set out to identify the risks and to determine the prescription patterns in Taiwan of CHPs containing SAA herbs (SAA CHPs) prior to the promulgation of the regulations banning their use. **METHODS:** A longitudinal analysis was carried out on a randomly sampled cohort of 200,000 patients using 1997–2003 data obtained from the Taiwan National Health Insurance (NHI) reimbursement database. **RESULTS:** During the seven-year study period, a total of 78,644 patients had been prescribed with SAA CHPs on at least one occasion, the majority of whom were females and/or middle-aged. A total of 526,867 prescriptions were issued containing 1,218 licensed SAA CHP items. Over 85% of SAA-exposed patients took less than 60 gms of SAA herbs; however, about 7% were exposed to a cumulative dose in excess of 100 gms of Xi xin, Mu tong or Ma dou ling. Diseases of the respiratory and musculoskeletal system were the most common indications for the SAA CHP prescriptions. The most frequently prescribed SAA CHPs were Shu jing huo xie tang, Chuan qiong cha diao san, and Long dan xie gan tang, respectively containing Fang ji, Xi xin, and Mu tong. **CONCLUSIONS:** About one-third of people in Taiwan have at some time been prescribed with SAA CHPs, and although the cumulated dosages may not be large, future studies are indicated to safeguard CHP usage.

PHP94

WHEN COMPARATIVE EVIDENCE IS UNCERTAIN: USE OF QUANTITATIVE CONSENSUS METHODS TO FILL IN GAPS

Miller RM, Dubois R

Cerner LifeSciences, Beverly Hills, CA, USA

OBJECTIVES: In creating economic models or reimbursement dossiers, gaps in evidence inevitably arise. Typically, these gaps are addressed in a non-systematic and non-quantitative manner, leading to inter-expert variability and disagreement amongst clinicians and decision-makers. The RAND Appropriateness Method is a validated, structured multi-round Delphi consensus process that we have adapted to US and ex-US expert panels with broad stakeholders including varying groups of both clinicians and payers. We have successfully applied this adapted technique across multiple topics including diabetes, cancer, depression, and Alzheimer's disease. **METHODS:** Participants reviewed published evidence, guidelines and community practice data and completed multi-round ratings (9-point scale) with individual and group feedback. Panels rated (and sometimes ranked) in pre- and post-fashion the likelihood and importance of selected clinical and/or patient-reported outcomes, as well as the level of scientific evidence and appropriateness of therapeutic options to address them. Median scores and measures of dispersion/disagreement were calculated for each round of ratings. **RESULTS:** Utilizing this method consistently resulted in a lower median opinion post-rating of importance and/or decision categories that are "based on their own experiences or that of their peers" – i.e. a change to more evidence-based decisions rather than anecdotal. Additionally, while round 1 ratings often had high disagreement rates between payers and clinicians or between different treating clinicians, those rates of disagreement fell after evidence review and discussion. Moreover, using this method, payer experts were able to create narrower parameter estimates for the prevalence of disease complications and its resulting mortality for use in economic modeling. Although pre-ratings of value messages were highly variable, payers' post-evaluation ratings after evidence review had less variability and higher (more compelling) scores. **CONCLUSIONS:** Use of quantitative consensus processes can minimize idiosyncratic variation among experts and create a more reliable connection between evidence and decision making.

HEALTH CARE USE & POLICY STUDIES – Quality of Care

PHP95

MEDICATION ADMINISTRATION PROCESS CONDUCTED BY NURSES IN INTENSIVE AND ACUTE CARE UNITS OF A HOSPITAL: A TIME AND MOTION STUDY

Dasgupta A[1], Sansgiry S[2], Frost C[3], Tipton J[3], Sherer J[2]

[1]University of Texas at Austin, Austin, TX, USA, [2]University of Houston, Houston, TX, USA, [3]St. Luke's Episcopal Hospital, Houston, TX, USA

OBJECTIVES: To determine workflow variables associated with medication administration process conducted by nurses in intensive and acute care units of a hospital. **METHODS:** A time-and-motion study was conducted in intensive and acute care units of a hospital. Each medication administration was operationalised as a combination of five activities namely direct patient care (five tasks), indirect patient care (four tasks), administration (four tasks), miscellaneous (three tasks) and other. Time devoted to each medication administration and each task were evaluated by means of two pre-calibrated stop-watches. Perception of nurses regarding workflow burden during each medication administration was determined on a five point Likert scale as strongly disagree (1)—Strongly agree (5). Furthermore patient features (age, gender, number of co-morbidities, length of stay) and complexity of medication administration (frequency of each task, number of assistants involved, number of drugs administered through different routes) were used to predict medication administration time. Descriptive statistics were reported. Stepwise regression analysis was performed to examine predictors of medication administration time. **RESULTS:** Mean medication administration time in intensive ($N = 101$) and acute ($N = 100$) care units were 5.2 ± 3.7 minutes and 5.3 ± 3.5 minutes respectively. Overall nurses had positive perception regarding the supportive workflow structure of intensive (4.4 ± 0.08) and acute care (4.6 ± 0.5) units. Stepwise regression analysis indicated that significant ($p < 0.05$) predictors of medication administration time in intensive care unit were time devoted to administration ($\beta = 0.57$), direct patient care ($\beta = 0.30$), and miscellaneous ($\beta = 0.14$) activities. Likewise significant ($p < 0.05$) predictors of medication administration time in acute care unit were time devoted to administration activity ($\beta = 0.67$), gender of patient ($\beta = 0.21$) and number of inhaled drugs administered ($\beta = 0.16$). **CONCLUSIONS:** Administration activity played a predominant role during medication administration in both units. Measures taken by hospital pharmacy to optimize such an activity may result in reduction of workflow burden encountered by nurses in the units.

DIABETES/ENDOCRINE DISORDERS – Clinical Outcomes Studies

PDB1

LITERATURE REVIEW OF THE IMPACT OF OBESITY ON CARDIOVASCULAR OUTCOMES IN THE GENERAL POPULATION AND IN PATIENTS WITH TYPE-2 DIABETES

Smith-Palmer J[1], Kalsekar A[2], Boye KS[2], Goodall G[1]

[1]IMS Health, Basel, Switzerland, [2]Eli Lilly and Company, Indianapolis, IN, USA

OBJECTIVES: There is an established causal link between obesity and cardiovascular outcomes. The aim of this review was to determine whether an independent relationship exists between anthropometric measurements of weight (typically body mass index [BMI]) and cardiovascular outcomes (e.g., angina, myocardial infarction, congestive heart failure, stroke, mortality) in the general population and in patients with type-2 diabetes. **METHODS:** A review of the medical literature was conducted between 1988 and May 2008 using the PubMed, EMBASE, Cochrane and Center for Review and Dissemination databases. We included studies that were longer than 12 months, had greater than 500 adult subjects and were written in the English language. **RESULTS:** In studies conducted in general populations there was an overall trend towards increased risk for cardiovascular outcomes with increasing BMI. However, a few studies reported a J-shaped or U-shaped between BMI measurements and cardiovascular events. The nature and strength of this relationship varied according to the measurement used (e.g., BMI, waist circumference, waist-to-hip ratio) and the population studied, with notable differences observed in Asian/Asia-Pacific based studies compared with those conducted in European or North American populations. There was limited data from prospective, long-term, longitudinal studies examining the relationship between degrees of weight and cardiovascular disease in patients with type-2 diabetes. **CONCLUSIONS:** In general, the degree of being overweight or obese

was associated with an elevated risk of adverse cardiovascular events and mortality. Although inextricable links exist between obesity, type-2 diabetes and cardiovascular disease in the general population, the extent to which findings can be extrapolated to a diabetes-specific population is limited.

PDB2

A1C AND WEIGHT OUTCOMES FOLLOWING 6 MONTHS OF ANALOG BASAL INSULIN IN INSULIN NAÏVE PATIENTS WITH TYPE-2 DIABETES IN AN AMBULATORY CARE SETTING

McAdam-Marx C[1], Brixner D[1], Ye X[1], Misurski D[2], Fabunmi R[3]
[1]University of Utah College of Pharmacy, Salt Lake City, UT, USA, [2]Eli Lilly and Company, Indianapolis, IN, USA, [3]Amylin Pharmaceuticals, Inc., San Diego, CA, USA

OBJECTIVES: This study evaluated real world outcomes for type 2 diabetes (T2D) patients treated with analog basal insulin (glargine or detemir) on glycemic control and weight after 6 months in a national electronic medical record (EMR) database. **METHODS:** Patient data were extracted from the General Electric (GE) EMR database from January 1, 2000 through December 31, 2007. Patients were ≥18 years old with T2D defined by ICD-9 codes, ≥2 fasting blood glucose levels ≥126 mg/dL, or A1C > 7.0%. Patients had prescription orders in the previous 395 days for metformin, a sulfonylurea or a thiazolidinedione, alone or in combination, or had no prior antidiabetic treatment. Patients were initiated on a basal insulin with no prior insulin use, had no other insulin prescribed within six months of basal insulin initiation, and had at least one additional order for the prescribed basal insulin within six months. Baseline A1C and weight were documented ≤45 days prior to ≥15 days post basal insulin initiation and at six months post initiation ± 45 days. **RESULTS:** Of patients with 6 month A1C or weight follow-up data (n = 841 and n = 1817, respectively), mean (±SD) baseline A1C was 9.0 ± 1.9% and weight was 99 ± 25.0 kg. Mean BMI was 34.7 ± 8.1 kg/m^2. The majority were treated with insulin glargine (n = 1754; 91.2%). At six months mean (SEM) A1C reduction was –1.2(0.1)% with 20.0% (n = 393) achieving A1C goal of <7.0%;. Mean weight gain was 1.0(0.1) kg ($p < .001$) and 60% (n = 1103) of patients gained weight. **CONCLUSIONS:** In a real world setting, most patients (80%) did not reach ADA targets for glycemic control with analog basal insulin treatment. Additionally, the majority of patients (60%) experienced weight gain.

PDB3

EFFECTS OF SUSTAINED-RELEASE VERSUS IMMEDIATE-RELEASE GLIPIZIDES FOR TYPE-2 DIABETES MELLITUS: A SYSTEMATIC REVIEW OF 16 RANDOMIZED TRIALS

Wang L[1], Li Y[2]
[1]Sichuan University, Chengdu, Sichuan, China, [2]West China Hospital, Sichuan University, Chengdu, China

OBJECTIVES: Sustained-release glipizide has a more appealing pharmacological profile over immediate-release glipizides. However, individual trials have not reliably ascertained its effects. This study systematically reviewed the trials that compared the effects of sustained-release glipizide with the conventional immediate-release glipizide for type 2 diabetes mellitus. **METHODS:** We searched Medline, EMBASE, the Cochrane Library and three other Chinese databases from their inception to July 2008, as well as screened the reference lists of eligible trials and reviews, and contacted the company (Pfizer) for unpublished data. Two reviewers judged the trial eligibility, assessed the validity, and extracted data independently. We pooled the trial data using the random-effect model and explored the heterogeneity by the pre-specified variables. **RESULTS:** A total of 16 trials (n = 1033) were included. Sustained-release glipizide significantly decreased FPG by 0.33mmol/L (weighted mean difference, 95%CI 0.05 to 0.61), postprandial insulin levels by 3. iIU/ml (0.89 to 5.47), and C-peptide by 0.12 ng/ml (0.04 to 0.20). Sustained-release glipizide did not reduced the HbA1c (–0.02, –0.20 to 0.15), postprandial plasma glucose (0.38, –0.47 to 1.22), fasting insulin levels (1.20, –0.14 to 2.54). No statistical differences were found in the change of total cholesterol (0.09, –0.06 to 0.23), triglyceride (0.13, –0.04 to 0.29), LDL (–0.03, –0.12 to 0.05), HDL(0.04, –0.02 to 0.10), and hypoglycemia (RR 0.79, 95%CI 0.22 to 2.86). No trials reported diabetes-related morbidity and mortality. **CONCLUSIONS:** Sustained-release glipizide could reduce FPG, postprandial insulin levels, and C-peptide, but has not shown benefits in reducing HbA1c, PPG, and fasting insulin levels when compared to immediate-release glipizide. Uncertainty remained in the benefits of sustained-release glipizide over immediate-release glipizide. This was mainly driven by the small sample size of the trial and lack of long-term morbidity and mortality data.

PDB4

METFORMIN TREATMENT FOR IMPROVING OUTCOMES RELATED TO INFERTILITY IN POLYCYSTIC OVARY SYNDROME – A BAYESIAN ANALYSIS

Perera PN, Malone DC
University of Arizona College of Pharmacy, Tucson, AZ, USA

OBJECTIVES: This study was conducted to determine the usefulness of metformin therapy in improving outcomes related to infertility in patients with polycystic ovary syndrome (PCOS). A Bayesian meta-analytic and mixed treatment comparison (MTC) approach was used. **METHODS:** An electronic literature search was performed using PubMed and the Cochrane Central Register of Controlled Trials to identify randomized controlled trials that reported at least one of the outcomes of interest – ovulation, pregnancy and live birth in PCOS patients randomized to treatment with either metformin, clomiphene citrate (CC) or combination of these drugs, which included a comparison with either placebo or each other. Reference lists of meta-analyses and reviews were hand searched to identify any additional articles. Bayesian meta-analyses were conducted for each outcome separately and for different therapeutic comparisons with metformin. Additionally, Bayesian MTCs were also conducted for each outcome. Analyses were performed using random effects models. **RESULTS:** A total of 27 RCTs were identified and 24 studies reported outcomes in a usable form for inclusion in the analysis. The total number of patients was 2217. The meta-analyses revealed that metformin was superior to placebo for ovulation induction (median OR = 2.9 with 95%[CrI] 1.6–6.0). Comparison of metformin and CC to CC alone revealed that combination therapy was superior in both ovulation induction (median OR = 4.2 with 95%[CrI] 1.5–12.3) and pregnancy (median OR = 5.0 with 95%[CrI] 1.7–22.4). When live birth was considered there was no significant difference between combination therapy and CC alone (median OR = 2.2 with 95%[CrI] 0.4–55.5). In the MTC, the efficacy of the therapeutic comparisons for ovulation and pregnancy in descending ranking order was combination therapy, CC alone, metformin alone and placebo. **CONCLUSIONS:** Combination therapy with metformin and CC is more effective than CC alone in ovulation and pregnancy outcomes in women with PCOS.

PDB5

SYSTEMATIC REVIEW IN TYPE-2 DIABETES – WHAT IS THE INFLUENCE OF LIFESTYLE CHANGE?

Arora A[1], Aneja G[1], Shukla H[1], Alnwick K[2]
[1]Heron Health Private Limited, Chandigarh, India, [2]Heron Evidence Development Ltd, Letchworth Garden City, UK

OBJECTIVES: The aim of this review was to assess whether lifestyle education programs significantly improve glucose levels or lower the incidence of type-2 diabetes in people at high risk, compared with conventional education programs. **METHODS:** English language trials assessing lifestyle interventions (physical exercise, diet control and counselling programs) compared to usual care controls were searched via electronic databases. Two investigators independently reviewed abstracts and included studies in which subjects had impaired glucose tolerance, impaired fasting glucose or borderline values. Data was extracted from each included full-text publication. The outcomes of interest included change in glucose levels two hours after a 75g oral glucose load, change in fasting plasma glucose levels, and cumulative diabetes incidence during the intervention period. **RESULTS:** Eleven citations met the eligibility criteria, out of 198 retrieved from the databases. Of these, only four presented sufficient data for meta-analysis. Meta-analysis of two studies indicated that the decrease from baseline in 2-hour plasma glucose was significantly greater in the lifestyle intervention group than in the control group (WMD = –11.292 mg/dL, 95% CI: –17.718, –4.866). Results were similar for fasting plasma glucose, with a fixed-effects meta-analyses of data from the same two studies showing a significantly greater decrease from baseline in the intervention group compared to control (fixed effects WMD = –2.158 mg/dL, 95% CI: –4.239, –0.077). Meta-analysis of two other studies indicated that the cumulative diabetes incidence in the lifestyle intervention group was significantly lower than in the control group (fixed effects RR = 0.619, 95% CI: 0.522, 0.733). **CONCLUSIONS:** Structured lifestyle interventions involving a healthy diet and physical activity are an effective way to treat, prevent, and possibly delay type-2 diabetes. If lifestyle interventions are cost-effective from a health system perspective, they should be more frequently considered as a valid treatment option.

PDB6

18 MONTH A1C AND WEIGHT OUTCOMES OF EXENATIDE THERAPY IN PATIENTS WITH TYPE-2 DIABETES IN A REAL-WORLD STUDY

Brixner D[1], McAdam-Marx C[1], Ye X[1], Misurski D[2], Wintle M[3], Fabunmi R[3]
[1]University of Utah College of Pharmacy, Salt Lake City, UT, USA, [2]Eli Lilly and Company, Indianapolis, IN, USA, [3]Amylin Pharmaceuticals, Inc., San Diego, CA, USA

OBJECTIVES: Six-month real-world outcomes were previously reported for exenatide, a GLP-1 receptor agonist for the treatment of type- 2 diabetes (T2D). A1C reductions were –0.7%, weight reductions were –2.8 kg, and BMI reductions were –0.94 kg/m^2. The current 18 month analysis evaluated A1C, weight, and BMI outcomes to establish real-world durability of glycemic control and weight loss in patients using exenatide. **METHODS:** Data were extracted from the General Electric electronic medical record database from January 1, 2000 to December 31, 2007. Adults with T2D per ICD-9 codes, ≥2 fasting blood glucose levels ≥126 mg/dL, or A1C > 7.0% starting exenatide in or after 2005 were included. Patients had 2+ additional prescription orders including at least one 12 to 18 months after the initial prescription to indicate ongoing therapy, and had prior prescription orders for metformin, a sulfonylurea, or a thiazolidinedione alone or in combination. A1C, weight and BMI were documented at exenatide initiation (–45 to + 15d) and at 18 months (±45 d). Outcomes were evaluated in those with baseline and follow-up A1C, weight and BMI measures. **RESULTS:** In 102 study patients, baseline A1C was 8.2+1.1%, weight was 111 ± 12.3 kg. Baseline BMI was 38.6≥ ± 7.4 kg/m^2 in those with baseline and follow up data (n = 89). After 18 months of exenatide therapy, mean (±SEM) A1C decrease was –0.7(±0.2)% ($p < .001$), weight decrease was –4.7(±0.7) kg ($p < .001$), and BMI decrease was –0.8 (±0.3) kg/m^2 ($p < .001$). A total of 72.0% had an A1C reduction, 76.7% lost weight, and 57.0% had reductions in A1C and weight. Mean A1C reduction was identical and weight loss was approximately 2 kg greater at 18 months relative to 6 month cohort exenatide outcomes. **CONCLUSIONS:** Exenatide therapy was associated with significant reductions in A1C, weight and BMI at 18 months. These reductions demonstrate treatment durability with exenatide and continuous benefit from long term therapy.