Gastrointestinal Disorders – Health Care Use & Policy Studies

PG125
STRUCTURED MANAGEMENT STRATEGY VERSUS USUAL PRIMARY CARE FOR GASTROESOPHAGEAL REFUX DISEASE: META-ANALYSIS OF FIVE EUROPEAN CLUSTER RANDOMIZED TRIALS ASSESSING HEALTH CARE UTILIZATION COSTS
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OBJECTIVES: Gastro esophageal reflux disease (GERD) is commonly associated with a significant adverse impact on the patient’s quality of life, his/her employ- ment, leisure time, and all social interactions. The objective of this meta-analysis was to pool the data of the five European studies (GERD Management Project) to assess the potential benefit for healthcare providers of a structured treatment pathway (STP) for the treatment of GERD. METHODS: We conducted a meta-anal- ysis of five cluster randomised clinical trials comparing a new management strat- egy with usual care in patients with GERD conducted in Austria, Italy, Norway, Spain and Sweden (NCT00842387). The educational intervention on investigators was based on the GERD questionnaire to stratify patients with classical symptoms of GERD according to the frequency and impact of symptoms. The most effective acid-suppressive therapy (esomeprazole 40 mg once daily) was proposed to be used only in patients with the highest GERD symptom impact score (≥ 3 of a possible 6). Calculations were performed using data on mean values for resource utilization (including emergency room visits, hospitalization, primary-care physi- cian visits, pharmacies, procedures, and endoscopies) multiplied by the unit costs by each variable. UK unit costs were applied to the entire European cohort. RESULTS: 1947 patients were included in the analysis, 944 (49%) on the STP group and 1003 (51%) on the usual clinical practice (UCP) group. In the STP group, GERD scores improved significantly more during therapy than in the UCP group. Patients in the STP group had lower overall healthcare costs, 107.56% per patient/year, than those in the UCP group, 137.56% per patient/year (i.e. 22% reduction in healthcare utilization costs). CONCLUSIONS: The implementation of a structured treatment pathway for the treatment of GERD based on the GERD questionnaire may considerably reduce the disease healthcare utilization costs compared with the usual clinical prac- tice.

PG126
PATIENT CHARACTERISTICS ASSOCIATED WITH USE OF ENTERAL VERSUS PARENTERAL ANTACID SUPPRESSIVE AGENTS IN INTENSIVE CARE UNIT PATIENTS
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OBJECTIVES: Administering acid suppressive therapy, AST (proton pump inhibi- tors, PPIs or H2 receptor antagonists, H2RAs) via enteral versus parenteral route in Intensive Care Unit (ICU) patients for stress ulcer prophylaxis (SUP) may save costs. As little is known on who can receive enteral vs. parenteral AST, our objective was to evaluate whether ICU patients on any oral medication or with an oro-gastric tube receive enteral versus parenteral AST. METHODS: In a retrospective study of elec- tronic medical records, patients ≥ 18 years or ≥ 15 years old (if length of stay > 15 days) admitted to a Midwest Academic Medical Center’s ICU and receiving an AST in 2008 were included. Patient data (age, gender, nonoperative/postoperative status, any oral medication use, oro- gastric tube, nothing by oral route [NPO], resource utilization variables [hospital days, days and AST use (enteral/parenteral)] were collected. Statistical differ- ences between enteral and parental AST (PPI and H2RA) patient groups were determined using Chi-square or fisher’s exact test and Wilcoxon rank-sum tests. RESULTS: P<0.03 was considered statistically significant. RESULTS: 54% and 43% of PPI (n=392) and H2RA (n=203) patients, respectively received drug through enteral route. The enteral and parental PPI groups did not differ by any characteristics. The enteral and parental PPI groups differed significantly by med- ian hospital days (8.0 versus 13.0), median ICU days (2.0 versus 4.0), and nonop- erative/postoperative patient-status (55%/45% versus 41%/59%). In multivariate lo- gistic regression analyses, any oral medication use increased the likelihood of enteral versus parenteral H2RA-use (p<0.05) and PPI-use (p<0.0001), however use of an oro-gastric tube was not significantly associated. CONCLUSIONS: To realize cost-effective quality of care, patients with an oro-gastric tube could receive enteral instead of parenteral AST and further study of cost savings from such use is un- derway.

Mental Health – Clinical Outcomes Studies

PMH1
IS STIMULANT OR ATOMOXETINE UTILIZATION ASSOCIATED WITH NEUROLOGICAL ADVERSE EVENTS IN CHILDREN WITH ATTENTION-DEFICIT/ HYPERACTIVITY DISORDER (ADHD)? A RETROSPECTIVE ANALYSIS OF PROPENSITY SCORE MATCHED DATA
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OBJECTIVES: This study examined comparative safety of stimulant versus atomox- etine with the risk of neurological adverse events in children with Attention-Deficit/Hyperactivity Disorder (ADHD). METHODS: The IMS LifeLink Health Plan Claims Database was used for this retrospective, propensity score matched analy- sis of children and adolescents with ADHD on stimulant and atomoxetine. The study sample included children less than 18 years of age initiating stimulant or atomoxetine therapy between July 1, 2004 to December 31, 2005. Patients with stimulant and atomoxetine were matched on propensity score calculated based on baseline characteristics. The neurological adverse events included urinary incontinence (ICD-9-CM code-307.2x) and seizures (ICD-9-CM codes- 345.xx, 780.3, 780.39, 780.31). Conditional logistic regression was used to account for the matched pair design. The final logistic model was adjusted for duration of therapy/persistence along with other covariates which were significant after matching. Sensitivity analysis was also performed using pharmacoepidemiology as the main outcome measure for management of neurological adverse events. RESULTS: The propensity score matched cohort consisted of a total of 7,424 children with ADHD (3,712-Atomox- etine, 3,712-Stimulant). Conditional logistic regression revealed that stimulant or atomoxetine use did not differ in terms of the risk of neurological adverse events development (Odds Ratio [OR]- 0.86; 95% Confidence Interval [CI]- 0.57-1.28). However, central nervous system pathology was significantly associated with the development of neurological adverse events (OR-2.87; 95% CI-1.95-6.90). Sensitivity analysis showed that stimulant use (OR-1.36; 95% CI- 1.18-1.56) was positively associated. CONCLUSIONS: Stainulant use was not significantly associated with diagnosis of neurological adverse events compared to atomoxetine in children. However, sen- sitivity analysis revealed that the stimulant users had an increased chance of receiving treatments for neurological adverse events. The findings suggest that stimulant use can lead to neurological adverse events which are not documented in ADHD patients but are usually treated.

PMH2
RISK OF HOSPITALIZATION FOR PNEUMONIA ASSOCIATED WITH THE USE OF ATYPICAL VERSUS TYPICAL ANTIPSYCHOTICS IN A NATIONAL SAMPLE OF MEDICARE BENEFICIARIES
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OBJECTIVES: To evaluate the risk of hospitalization for pneumonia associated with typical and atypical antipsychotic use in an elderly Medicare population. METHODS: This retrospective cohort study used two years (2006-2007) of 5% na- tional sample of Medicare claims data. Medicare beneficiaries with continuous Part A, B, and D enrollment in 2006-2007 and who initiated atypical or typical antipsy- chotic drug therapy during July 2006-June 2007 were identified from Part D claims data. Propensity score matching was used to control for potential confounding. A conditional logistic regression model stratified on propensity score-patch matched pairs was used to compare the risk of hospitalization for pneumonia for new users of atypical vs. typical antipsychotic drugs within a 180 day follow-up period starting from the date of first prescription. RESULTS: A total of 15,637 new users of atypical and 2,337 new users of typical antipsychotic drugs were identified July 2006-June 2007. A total of 1,363(6.7%) subjects had a hospitalization for pneumonia during follow-up. The proportion of hospitalizations was similar in the atypical (7.5%) and the typical antipsychotic (8.0%) groups. A total of 2,335 propensity score matched pairs were obtained using the Greedy 5-1 matching algorithm. In the matched cohort, there were 186 (7.97%) pneumonia hospitalizations in typical users com- pared to 179 (7.67%) among atypical users. Typical antipsychotics users did not differ significantly from atypical users on the risk of pneumonia (odds ratio: 1.042, 95% CI: 0.843-1.288). Sensitivity analysis using propensity score as a continuous variable in a multivariable logistic regression model yielded similar results (odds ratio: 1.107, 95% CI: 0.828-1.450). Hospitalization for pneumonia was similar for new users of typical and atypical antipsychotic drugs. While this indicates that there is no added safety concern for users of atypical antipsychotics, it also suggests there is no added advantage of atypical use, espe- cially in patients at high risk for pneumonia.

PMH3
RISK OF HIP FRACTURES IN ELDERLY MEDICARE BENEFICIARIES USING ATYPICAL OR TYPICAL ANTIPSYCHOTICS: A PROPENSITY SCORE ANALYSIS
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OBJECTIVES: To study the association between the type of antipsychotic drug use and the occurrence of hip fracture in an elderly Medicare population. METHODS: Two years (2006-2007) of 5% national sample of Medicare claims data were used to identify new users of antipsychotic drugs within a 180 day follow-up period starting from continuous Part A, B, and D enrollment in 2006-2007 and who initiated atyp- ical or typical antipsychotic therapy July 2006 -June 2007 were identified from Part D claims data. All study subjects were followed for 180 days from index date, the date of first antipsychotic prescription. Propensity scores were calculated for each individual using a propensity index derived from the neurological adverse events included in the database. Users of atypical antipsychotics and typical antipsychotics were matched on propensity score using the Greedy 5-1 matching algorithm. Conditional logistic regression model stratified on propensity score matched-pair was used to compare the risk of hospitalization for hip fracture in new users of atypical versus typical antipsychotic drugs; sensitivity analysis was conducted using propensity score as a con- tinuous, linear term in the unmatched study cohort using logistic regression. RESULTS: 15,637 new users of atypical and 2,337 new users of typical antipsychotic drugs were identified July 2006-June 2007. Among new users of atypical antipsychotics, it also suggests there is no added advantage of atypical use, espe- cially in patients at high risk for pneumonia.
to be statistically significant (odds ratio: 1.056, 95% CI: 0.669-1.665) between atypical and typical antidepressant users. Similar results were obtained in sensitivity analysis (odds ratio: 1.089, 95% CI: 0.775-1.530). CONCLUSIONS: Typical and atypical antidepressant drug use in an elderly Medicare population has similar risks of hip fracture.

PMH4 RISK OF FALLS AND FRACTURES IN OLDER ADULTS USING ATYPICAL ANTIPSYCHOTICS: A MULTIPLE PROPENSITY SCORE ADJUSTED RETROSPECTIVE COHORT STUDY

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OBJECTIVES: The study evaluated the risk of falls and fractures associated with use of risperidone, olanzapine and quetiapine among community-dwelling older adults in the US. METHODS: The study involved a multiple propensity score-adjusted retrospective design and included adult older adults aged 65 years and above, who initiated prescriptions of risperidone, olanzapine or quetiapine between July 1, 2000 and June 30, 2008 using IMS LifeLink Health Plans claims data. Patients were followed until hospitalization/emergency room (ER) visit for accidental fall/hip fracture, or the end of the study period, whichever occurred earlier. Propensity score-adjusted Cox proportional hazard regression model was used to evaluate the relative risk of falls or fractures. The covariates in the final model included maximum dose of antipsychotic therapy, and exposure to other psychotropic medications that increase the risk of falls or fractures. RESULTS: There were 12,145 (5,083 risperidone, 4,377 olanzapine and 2,685 quetiapine) new users of atypical agents. A total of 380 cases of falls or fractures with at least one hospitalization/ER visit following the use of antipsychotic agents were identified. The rates of falls of patients for risperidone, olanzapine and quetiapine were 165 (3.65%), 109 (2.81%) and 106 (4.47%) respectively. After adjusting for propensity score and other covariates, the Cox proportional hazard model showed that there was no statistically significant difference with use of risperidone (hazard ratio, HR-1.10, 95% CI: 0.846-1.45) or olanzapine (HR-1.1.6, CI: 0.87-1.53) compared to quetiapine in the risk of falls or fractures. CONCLUSIONS: The study found no significant difference across the individual atypical agents in the risk of falls or fractures in a large cohort of older adults. Future studies are required to evaluate the overall safety profiles of atypical antipsychotics in the above population.

PMH5 PSYCHIATRIC ADVERSE EFFECTS RELATED TO PRESCRIPTION OF METHYLPHENIDATE IN TAIWAN

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OBJECTIVES: Attention deficit hyperactivity disorder (ADHD) is a common psychiatric disorder of childhood, and the methylphenidate hydrochloride (MPH) is the most frequently and well-established prescribed pharmacotherapy for ADHD. Warnings by the United States Food and Drug Administration on psychiatric adverse effects have concerns for drug safety. Existing studies to date demonstrate that MPH’s safety of children with ADHD which get inconsistent results. The purpose was to evaluate the potential association between MPH treatment and the subsequently development of psychiatric disorders such as disruptive, anxiety, mood, learning, tic and substance-related disorders. METHODS: A retrospective cohort study was conducted. Study subjects selected were aged 6 to 18 years on the date of the first diagnosed for ADHD between 2001 and 2006. Patients were divided into 2 groups: ex-MPH and not-using MPH. The authors conducted case-control matching on the propensity score to reduce selection bias. The Cox Proportional Hazards Model was used to assess the association of use of MPH with the subsequent risks of psychiatric events occurring. RESULTS: The results shows that the MPH group had a significantly higher hazard ratio (HR) of patients diagnosed with oppositional defiant disorder (ODD) (HR = 1.807, P < 0.001), conduct disorder (CD) (HR = 1.225, P = 0.0460), and anxiety disorders (AD) (HR = 1.921, P < 0.001). The MPH group had a significantly higher HR of ODD and CD and a significantly higher HR of LD in boys only. CONCLUSIONS: Our study found that MPH treatment is associated with a higher risk of development of oppositional defiant disorder, conduct disorder and anxiety disorders and a lower risk of learning disorders.

PMH6 DIFFERENTIAL RATES OF SIDE EFFECTS IN DEPRESSED ADULTS AND ADOLESCENTS BEING TREATED WITH ANTIDEPRESSANTS

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OBJECTIVES: Antidepressants are first line treatment of depression. Effectiveness may be compromised because of discontinuation, which is commonly associated with side effects. Using a national database of medical and pharmacy claims, we sought to identify and compare the prevalence of side effects in newly depressed adults and adolescents when taking different classes of antidepressants. METHODS: A new-user design was implemented using 11 years of data to identify a retrospective cohort of newly depressed subjects on antidepressant monotherapy, defined as SSRI, SNRI, TCA, MAOI, bupropion, phenylpiperazine, or tetracyclic antidepressants (per 1,000 person-months of exposure) were calcu- lated within each antidepressant group; relative risks were calculated (SSRI as referent group). Propensity-adjusted Cox Proportional Hazards regression was used to model the likelihood of side effects adjusted for demographic, clinical and treatment characteristics. RESULTS: A total of 40,017 patients had a new episode of depression and were on antidepressant monotherapy within 30 days of diagnosis [SSRI (66%), Bupropion (14%), SNRI (12%), other (8%)]. The most common side effects were headache (up to 16.8 per 1,000 person-months of therapy in adults, 17.6 per 1,000 in adolescents) and nausea (up to 7.2 per 1,000 in adults, 9.3 per 1,000 in adolescents). Relative to adults receiving SSRIs, those receiving SNRIs had higher risk of nausea (HR=1.28, 95%CI=1.08-1.50), and of having one or more side effect of any type (HR=1.23, 95%CI=1.10-1.37). Adults taking bupropion were less likely to have sedation (HR=0.36, 95%CI=0.16-0.79). Adolescent receiving an SNRI were more likely to experience sedation compared to adolescents receiving an SSRI (HR = 3.14, 95%CI=1.90-8.92). CONCLUSIONS: Side effects detected in claims must be significant enough to be reported to the provider and medically coded, so these rates are underestimates. Nevertheless, the reported rates are nontrivial. Future work will account for side effects in the likelihood of discontinuation and associated reduced comparative effectiveness.

PMH7 LIKELIHOOD OF POTENTIAL DRUG-DRUG INTERACTIONS AMONG PERSONS INITIATING THERAPY WITH SELECTIVE SEROTONIN REUPTAKE INHIBITORS: EFFECT OF INITIAL SSRI AND OTHER FACTORS

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OBJECTIVES: Selective Serotonin Reuptake Inhibitors (SSRIs) are pharmacokinetic and pharmacodynamic differences among the SS-RIs can give rise to differences in drug–drug interaction (DDI) potential. This study estimated the effect of initial SSRI choice on the likelihood of receiving a potentially interacting drug (and thus a potential SSRIs-DDI) among subjects initiating therapy with SSRIs in the United States managed health care plans. METHODS: Using a large health insurance claims database (IMS LifeLink Database), we examined retrospective cohorts of new SSRI users between 2002-2008. For each new SSRI user, we used medical and pharmacy claims to identify instances and crude rates of potential DDIs according to compendia and expert panel-based lists of interactions. We calculated crude and adjusted incidence rates for potential SSRIs-DDI based on the initial SSRI prescribed, adjusting for demographic, clinical, and prescription related factors, length of SSRI exposure and propensity for receiving escitalopram as the initial SSRI using Poisson regression methods. RESULTS: A total of 121,616 subjects met inclusion criteria. Using the compendia list of SSRIs-DDI, 48.5-52.0% of subjects had at least one instance of co-prescribing of potentially interacting drug(s) with SSRI. Compared to escitalopram users, citalopram (HR [Hazard Ratio]= 1.05, P < 0.01), fluoxetine (HR = 1.03, P < 0.01), and paroxetine (HR = 1.17, P <.01) and sertraline (HR = 1.06, P < 0.01) users all had a significantly higher potential of potential SSRIs-DDI. Sertraline (HR = 0.99, P = 0.02) users demonstrated a similar likelihood of potential SSRIs-DDI as escitalopram. Results were similar for the expert panel list of SSRIs-DDI. CONCLUSIONS: SSRIs are widely used, and co-prescribing of drugs with the potential to elicit SSRIs-DDI may be more frequent than is often reported. Among SSRIs, escitalopram and sertraline are associated with a lower likelihood of being co-prescribed with a potentially interacting drug. Clinicians, pharmacists and patients should be aware of the potential for such interactions, and further study is needed to identify subsequent patient outcomes.

PMH8 EFFECT OF VARIOUS ANTIDEPRESSANT GROUPS ON BONE MINERAL DENSITY (BMD)

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OBJECTIVES: Research shows a significant association between low bone mineral density (BMD) and persons receiving antidepressant medication, with levels of BMD loss varying with the type of pharmacological agent used. This study compared the BMD of depressed patients on different groups of antidepressants. METHODS: One hundred forty female and male depressed subjects between the ages of 25-70 years were recruited from the psychiatrics in Penang General Hospital and Penang Adventist Hospital. The groups of antidepressant medication included selective serotonin reuptake inhibitors (SSRI), tricyclic antidepressants (TCA) and other types of antidepressants (OTA). BMD was ascertained by measuring the bone mineral density at the lumbar spine and the proximal part of the femur using an Ultrasound bone densitometer by Functus Electric. RESULTS: ANOVA found no significant differences in mean BMD across the different groups of antidepressants (p>0.055). CONCLUSIONS: This study finds no association between BMD loss and the type of antidepressant employed in a depressed Malaysian pop-