the warfarin and $10,195 (12,780) in the warfarin and NSAIDs groups (p < 0.01). CONCLUSIONS: This analysis did not identify a difference in the odds of having a GI bleed when on warfarin or warfarin plus NSAIDs. Unexpectedly, there were significantly lower costs for the warfarin plus NSAIDs group. These results should be interpreted with caution due to the small sample size and limitations of retrospective analysis.

ADVERSE EVENTS OF PROMETHAZINE AND ONDANSETRON IN YOUNG CHILDREN AND WOMEN OF CHILD-BEARING AGE: A PHARMACOVIGILANCE STUDY BASED ON THE FDA ADVERSE EVENT REPORTING SYSTEM

OBJECTIVES: Pregnant women may use promethazine or ondansetron for nausea and vomiting during pregnancy (NVP). The long-term safety and its potential risks on the fetus and newborns are widely unknown. Promethazine has a black boxing warning for contraindicating its use in infants and young children. The purpose of this study was to quantify and describe adverse events (AEs) related to these two medications in child-bearing age women and young children. METHODS: The data source was the FDA’s Adverse Events Reporting System database from 1997 to 2006. Using a retrospective data analysis, AEs for all patients with study drugs were compared to that for children ages 0-6 years old and women of child-bearing age (CBA) 15-50 years old. The annual frequencies of AEs for both study drugs were analyzed and stratified by age group and gender. The related AEs were categorized by clinical outcomes, pregnancy outcomes, route of administration, and duration of therapy. RESULTS: A total of 392,229 AEs for promethazine and 282,036 AEs for ondansetron were reported. Of those, 13.7% of ondansetron and 22.8% promethazine AEs were for CBA women with the peak for age 35-50, while 13.1% ondansetron and 13.8% promethazine AEs were for children age 0-6 with the peak for age 0-2. There were 23.6% and 13.5% AEs related to promethazine and ondansetron long-term use (greater than 90 days) among CBA women, respectively. The most common routes of administration were oral and intravenous. For CBA women, the frequent AE pregnancy outcomes were maternal complications (26%), premature labor (9%), maternal drug effects affecting fetus (8%) and spontaneous abortion (4%), while the most frequent AEs for children were neonatal respiratory arrest (0.25%) and neonatal apneic attack (0.1%). AEs of promethazine and ondansetron among children and CBA women are common. The risk of their off-label use for the long-term treatment of functional dyspepsia.

PREVALENCE, COSTS AND SERVICES OF COMORBID CONDITIONS ASSOCIATED WITH FUNCTIONAL DYSPEPSIA

OBJECTIVES: The etiology of functional dyspepsia (FD) is debated. However, no published data exist on the associated co-morbid conditions with FD. This study aimed to assess the prevalence, services, and costs related to co-morbid conditions associated with FD. METHODS: Retrospective database analysis on a 4-year study period, from January 1, 2001, through December 31, 2004 using payroll data and adjudicated health insurance claims and prescription claims from more than 300,000 employees. Study comparisons were performed among employees with FD and propensity-score-matched employees without FD (controls). Outcome measures included the prevalence, costs and utilization of health services for various comorbid conditions as defined by the Agency for Healthcare Research and Quality (AHRQ). RESULTS: Employees in cohort FD (N = 1669) and a 5:1 matched control-cohort (N = 83,450) were compared. Employee with FD were more likely to have all major diagnostic categories (MDC) including digestive system, blood and blood forming organs, mental disorders, infections and parasitic disease, etc. except pregnancy and prenatal related disease, compared to matched controls. The top MDC prevalence ratios between the two groups were for digestive systems (6.3:1), blood and blood form organs (2.6:1), mental disorders (2.1:1), and infectious & parasitic disease (2.0:1). More interestingly, 18 of the top 30 most prevalent AHRQ “specific” categories were non-specific with the terms like “other” or “undefined” in the title. Moreover, annual medical costs for the FD cohort were greater than for controls in 155 (59%) of the 261 AHRQ’s Specific Categories and significantly greater (p < 0.05) in 76 categories (29%). Similarly, the services were greater for 179 (69%) of the 261 Specific Categories and significantly greater (p < 0.05) in 110 categories (42%). CONCLUSIONS: Thsstudy showed excess comorbidity in employees with FD compared to employees without FD, might be a major determinant factors for excess health-care services and health-care costs of functional dyspepsia.

SYSTEMATIC REVIEW AND META-ANALYSIS OF PUBLISHED RANDOMIZED CONTROLLED TRIALS COMPARING THE EFFICACY OF PEGERIFEN-ALPHNA-2A VERSUS PEGERIFEN ALPHALPHA-2B PLUS PLURIBARVING IN CHOLANGITIS

OBJECTIVES: Hepatitis C affects approximately 180 million people worldwide. It is one of the main causes of liver disease and is the predominant etiology for liver transplantation. This study performs a systematic review and meta-analysis of published randomized controlled trials comparing efficacy of peginterferon-alfa-2a versus peginterferon-alfa-2b both in association with ribavirin in order to assess which is more effective in the treatment of HCV infection. METHODS: A thorough search in MEDLINE, Lilacs, Cochrane library and Embase databases was conducted in the last quarter of 2009. Manual searches in specialized websites were also carried out. Included studies were those which evaluate treatment efficacy of peginterferon-alfa-2a versus peginterferon-alfa-2b both plus ribavirin for hepatitis C treatment in naive patients or nonresponders to other therapies not co-infected with HIV. According to heterogeneity test, a fixed or a random-effect models was adopted for meta-analysis. RESULTS: A total of 570 citations (databases citation without duplicates plus manual searches) were found but only seven met the inclusion criteria: 1) Ascione, 2009; 2) Rumi, 2009; 3) McHutchison, 2006; 4) Venic, 2006; 5) Scorto, 2006; 6) Košakowa, 2008; 7) Berak, 2007. All studies are randomized controlled trials. Overall, peginterferon-alpha-2a has shown higher sustained virological response (SVR) as compared to peginterferon-alfa-2b: 51.7% versus 42.4% (RR = 1.23, IC 95%: 1.10 – 1.38, assuming a fixed-effect model). For genotypes 1/4: 42.1% versus 33.3% (RR = 1.11, IC 95%: 1.02 – 1.20, assuming a fixed-effect model) and for genotypes 2/3: 79.2% versus 73.8% (RR = 1.11, IC 95%: 1.01 – 1.22, assuming a fixed-effect model). CONCLUSIONS: These findings suggest that peginterferon-alfa-2a is associated with a higher clinical response than peginterferon-alfa-2b indicating that it should be used as the standard-of-care therapy. Our results are in line with another recent published systematic review (Awad, 2009) which concluded that peginterferon-alfa-2a has a higher SVR as compared to peginterferon-alfa-2b, with similar safety profile.
surgical procedures among younger patients for the management of DD. METHODS: Using a nationwide commercial claims database, a retrospective cohort was identified who had undergone LC (n = 2095) or OC (n = 5971) between 4th quarter, 2003 through 1st quarter, 2009. 2000 U.S. Census data was used to calculate age-adjusted temporal trends in the overall surgical procedure and logistic regression was used to determine the time trends in each surgical procedure, adjusting for age, gender, and the type of benefit plan. RESULTS: A total of 8,066 surgical procedures were performed during the study period (mean age = 53 ± 11, 55.7% Male). Quarterly mean number of surgical procedures (LC+OC) performed was 576 (SD = 39) and the mean number of LC+OC from 2006 to 2008 was 2297 (SD = 107). Quarterly age-standardized surgical procedures(LC+OC) for DD declined by 9.26% for patients younger than 45, whereas overall surgical rate increased by 3.2% for older patients. That was a slight decline over time in surgical procedures for younger patients. The reasons for the decline in surgical procedures for younger patients may be due to recent studies suggesting that DD is not as more aggressive in younger patients as initially reported, and that the conservative medical treatment may be more appropriate with this population.

LOW PREVALENCE OF HEPATITIS C VIRUS (HCV) DIAGNOSIS IN US HEALTH CARE DATA

hsvski K, Velez FP, Fitch K, Pyronen B

*Milliman Inc, New York, NY, USA, **Vertex Pharmaceuticals Incorporated, Cambridge, MA, USA

OBJECTIVES: The National Health and Nutrition Examination Survey (NHANES) estimates chronic HCV infection prevalence at 1.3% of the US population or ~3 million individuals, with a peak HCV antibody prevalence of 4.5% for those born in the 1950s. From NHANES we can assume that 79.7% of HCV antibody positive patients will not clear the virus; therefore we expect to observe 3% chronic HCV infection in this peak population. METHODS: Patients diagnosed with HCV (ICD-9 codes 070.41, 070.44, 070.51, 070.54, 070.70, 070.71, V02.61) between 2002 and 2006 were identified in MedStat commercial health insurance claims. We calculated age-sex prevalence of diagnosis by birth year. A log-regression model was constructed to examine the relationship between prevalence of HCV diagnosis and number of observation years. RESULTS: The prevalence of patients with a HCV diagnosis in 2002 was 0.12%. The prevalence of patients with HCV diagnosis was consistent in each year’s claims, peaking in those born between 1950–1955. Longitudinal data across five years demonstrated increasing diagnosis rates with additional years of observation, according to a log function. Modeled for 10 years of observation, total diagnosed prevalence was estimated at 0.29% (R² = 0.92; peak prevalence was 1.13% for males and 0.64% for females for those born in the early 1950s. CONCLUSIONS: In each year examined, the claims-based prevalence of an HCV diagnosis was about 10% of the NHANES estimated prevalence (0.12% vs. 1.3%). Although diagnosed HCV prevalence increased with years of observation, the 10-year modelled diagnosis prevalence was only 22% of NHANES estimated prevalence. Like in NHANES, peak prevalence of HCV in claims was observed in patients born in the 1950s. This suggests that many patients have long-standing HCV infection and are at possible risk of decomposition. Further research is warranted to examine whether HCV-related advanced liver disease is more commonly coded in claims data.

GASTROINTESTINAL DISORDERS – Cost Studies

PG91 BUDGET IMPACT MODEL TO EVALUATE MEDICATION PERSISTENCE AND ASSOCIATED HEALTH CARE COSTS


The University of Cincinnati Medical Center, Cincinnati, OH, USA

OBJECTIVES: Low persistency for oral 5-ASA drugs is associated with increased risk of relapse of ulcerative colitis(UC) and subsequent costs. We constructed a one-year budget impact model to compare annual all-cause and direct incremental costs of treatment for the health plan(HP) per mild-to-moderate UC patient using oral 5-ASA drugs and associated persistency rates(Prs). METHODS: Assuming a budget holder’s perspective for a one-year horizon, the model analyzed the impact of Pr on total UC related all-cause direct IC. Prs for 5-ASA drugs/mesalamine CR[CRM] 250mg 7% & 500mg 10%, balsalazide disodium[BD] 10%, olsalazine[OLS] 10%, mesalamine DR[DRM] 9%, multi matrix system mesalamine[MMX] 20% were derived from published literature. UC patients within the HP were distributed to drugs based on September 2009 market share and classified as persistent if they refilled at a timeframe of up to twice the duration of their prescription. Annual UC-related pharmacost were calculated using net wholesale acquisition cost, and additional all-cause direct ICs for patients with/without relapse were cited from published literature. Sensitivity analyses varying net drug costs and ICs were performed to evaluate model impact on health care costs. RESULTS: Average annual all-cause UC costs per patient were: $13,135 CRM-250; $13,065 CRM-500; $12,914 BD; $12,804 OLS, $12,688 DRM; $12,253 MMX. Inpatient costs were lower for MMX,$5,667 as compared to market leader(DRM,$6,216) and lowest priced drug alternative(OLS,$6,343). Sensitivity analyses indicated higher savings/patient for MMX than DRM($462 vs. $30, respectively). The primary driver for inpatient cost differences was the frequency of relapse reduced by persistency. A health plan with 1 million covered lives,2,300 UC patients diagnosed in 2006 may save $401,000,$403 per parenthesis by switching 50% of UC patients to MMX. CONCLUSIONS: This analysis illustrates the impact of medication persistence on reduction of UC relapse and associated health care costs. Health plans may achieve savings by including drugs with high Prs in their formulary.

PG10 PATIENT FINANCIAL BURDEN, SURGICAL COSTS AND REIMBURSEMENTS FOR OPEN AND LAPAROSCOPIC COLECTOMY PROCEDURES IN DIVERTICULAR DISEASE

Chung JK, Knight TK, Nichol MB

University of Southern California, Los Angeles, CA, USA

OBJECTIVES: Colectomy is a standard procedure in complicated colonic diverticular disease (DD) including diverticulitis and diverticulosis. Although laparoscopic colectomy (LC) has demonstrated some clinical advantages over open colectomy (OC), the true financial burden, cost and reimbursement structures between the two surgical procedures remain unclear. The purpose of this study was to compare patient financial burden, direct surgical costs and reimbursements for OC and LC procedures in BD. METHODS: Nationwide commercial claims database from 2003 through 2007 was used to identify 1,614 patients who had undergone OC (n = 1,327) or LC (n = 287) for DD. Patient financial burden (defined by out-of-pocket [OOP] costs including co-pay, deductible and coinsurance), direct surgical costs, reimbursements and cost-to-charge ratios for OC and LC were compared using the Student’s t-test and chi-square test where appropriate. RESULTS: OC and LC groups differed with respect to mean age (60 and 64 years, respectively; p < 0.001) but did not differ in male/ female ratio, OOP costs were significantly greater for OC ($410 vs. $350 for LC; p < 0.001). Both surgical costs and reimbursements per case were significantly less for OC ($4231 ± 98 and $4142 ± 35, respectively) than LC ($5246 ± 231 and $1809 ± 80 respectively; both p < 0.001). Cost-to-charge ratios were the same for both surgical procedures (0.38). CONCLUSIONS: This analysis demonstrated that patient financial burden and potential savings by including drugs with high Prs in their formulary, but the direct costs and reimbursements of OC were significantly lower than LC. However, low surgical costs may be offset by potential increases in length of hospital stay due to longer recovery time for OC. Understanding differences in cost structures may be helpful in further investigations of the cost-effectiveness of these two surgical procedures in diverticular disease.

PG11 PEDIATRIC HOSPITALIZATIONS FOR INFLAMMATORY BOWEL DISEASE: RESULTS FROM 2006 KIDS’ INPATIENT DATABASE

Tunda N, Heaton PC, Kelton CM

University of Cincinnati, Cincinnati, OH, USA

OBJECTIVES: Crohn’s Disease (CD) and Ulcerative Colitis (UC), collectively termed Inflammatory Bowel Disease (IBD), are associated with hospitalizations, surgical procedures, and long-term medical follow up. The objectives of the current study were to quantify the national pediatric IBD burden in 2006 and stratify by demographics by determining the (1) number of hospitalizations; (2) number of days spent in the hospital; and (3) hospitalization costs. METHODS: The 2006 Kids’ Inpatient Database was used to examine IBD in hospitalized children and adolescents 20 years and younger with a primary diagnosis of either CD or UC. Frequency of discharges, the total and mean length of stay (LOS) and costs were calculated, stratified by various patient and hospital characteristics such as age, gender, expected primary payer, patient income, surgery status, teaching status, hospital size, location and region. RESULTS: In 2006, there were 17,777 IBD-related pediatric visits, of which 6,599 were due to CD and 4,178 were due to UC. For CD and UC, respectively, there were 37,175 and 27,810 days spent in the hospital; mean LOS was 5.63 and 6.66 days. The total and mean costs for CD were $66.3 million and $10,176, respectively. The total and mean costs for UC were $48.6 million and $11,836, respectively. For UC, older (0-5 years) patients had the highest mean LOS (7.49 days) and mean cost ($13,407). Patients with Medicaid had a higher mean LOS and cost than those with private insurance. Surgery increased mean LOS over 3 days and almost doubled the cost for IBD hospitalizations. CONCLUSIONS: IBD is a burdensome illness. Future research will determine if newer treatment options can reduce hospitalizations.

PG12 FUNCTIONAL DYSPEPSIA DECREASE PRODUCTIVITY AND INCREASED MEDICAL COSTS

Brook RA, Kleiman NL, Chong RS, Melkonian AK, Smeding J*, Talley N

The JSTArg Group, Newfoundland, NJ, USA, *HCMs Group, Pasadena, CA, USA, Mayo Clinic Rochester, MN, USA, *HCMs Group, Chesterfield, MO, USA, *JSTArg Group, Dallas, TX, USA, Mayo Clinic Jacksonville, FL, Rochester, MN, USA

OBJECTIVES: Functional dyspepsia is a common, morbid condition but data are limited on the indirect and direct costs for employees with functional dyspepsia or on its impact on absenteeism and work output (productivity). METHODS: We performed a retrospective analysis of payroll data and adjudicated health insurance