Prevalence, Awareness and Management of Hypertension, Dyslipidemia, and Diabetes Among United States Adults Aged 65 and Older

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Objective: Hypertension, dyslipidemia, and diabetes, which are established risk factors for cardiovascular disease (CVD), have been previously described among adults aged 65 and older, but have not been updated to reflect current national data. We assess prevalence, awareness, treatment and control rates among U.S. adults aged 65 and older with respect to hypertension, dyslipidemia, and diabetes, and describe predictors associated with awareness and management of these factors. Methods: Analysis of nationally representative data collected from adults aged 65 and older (n = 3810) participating in the National Health and Nutrition Examination Survey (NHANES) 1999-2004. Results: Women have a significantly higher prevalence of hypertension than men (76.6% vs 63.0%) and a significantly lower rate of control when treated pharmacologically (42.9% vs 57.9%). Dyslipidemia prevalence is 60.3% overall, and women are significantly more likely to be aware of their condition than men (71.1% vs 59.1%). Diabetes affects 21.2% of older adults, and 50.9% of prevalent cases are treated pharmacologically. Goal attainment among those treated is problematic for all three conditions–hypertension (48.8%), dyslipidemia (64.9%), and diabetes (50.4%). Having two or more doctor visits annually is associated with goal attainment for dyslipidemia. Conclusion: Knowledge of cardiovascular health in older adults and understanding gender gaps in awareness can help physicians and policymakers improve disease management and patient education programs.

Sigmoid Maximum Effect Modeling of Coronary Heart Disease Death and Myocardial Infarction Rate versus Low-Density Lipoprotein Cholesterol in Statin Secondary Prevention Trials

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Objective: Guidelines and expert opinion regard the relationship between low-density lipoprotein cholesterol (LDL-C) and coronary heart disease (CHD) event rates from prevention trials as linear or log-linear. However, these relationships require key assumptions that are typically invalid in biological systems, and may be more fully described by a sigmoidal maximum effect function. Methods: Data were extracted from statin secondary prevention trials of at least 4-years duration (CARE, LIPID, 4S, HPS, TNT, IDEAL; N = 57,042; average duration 5.2 yrs, range 4.8–6.1 yrs). Linear and modified nonlinear sigmoid maximum effect (sEmax) models were constructed using WinNONLIN (v.1.5, Pharsight Corporation, Mountain View, CA) to evaluate the relationship of annualized absolute rates of CHD death plus nonfatal myocardial infarction (NFMI) versus average on-treatment LDL-C. Model output included E0 (CHD death + NFMI %/yr at LDL-C = 0 mg/dL) and fit parameters [r2 and Akaike’s Information Criteria (AIC)]. The model-dependent number needed to treat (NNT) for one year to prevent one CHD death + NFMI event with LDL-C reduction from 100 mg/dL to 70 mg/dL was also calculated. Results: Fit parameters indicated that the sEmax was the more correct model (r2 = 0.906, AIC = 8.40; linear r2 = 0.876, AIC = 15.99). The sEmax model yielded an E0 of 1.37%/yr, whereas the linear model E0 was biologically implausible at −0.76%/yr. The CHD death + NFMI rate at LDL-C = 100 mg/dL (sEmax 1.91%/yr; linear 2.13%/yr) and LDL-C = 70 mg/dL (sEmax 1.58%/yr; linear 1.14%/yr) resulted in NNT of 303 and 101 based on sEmax and linear models, respectively. Conclusion: The relationship between LDL-C and annualized rate of CHD death + NFMI is sigmoidal and best described by a nonlinear maximum effect model (sEmax). This model demonstrates a marked diminishing rate of return with aggressive LDL-C lowering, strongly suggesting alternative risk modification measures be explored at LDL-C <100 mg/dL. These findings have clinical trial design, treatment guideline, managed care, economic, and public health implications.

Assessment of Safety for Bromocriptine: Comparisons of Reporting Systems and a Retrospective Cohort Study

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Objective: Because of recent attention to public adverse event reporting systems, we assessed findings from published case reports and adverse drug reactions reported to the World Health Organization (WHO) Programme for International Drug Monitoring and findings from an analysis of patients in the General Practice Research Database (GPRD) regarding bromocriptine and risk of myocardial infarction and stroke (CVD). Methods: We tallied reports of adverse CVD events related to bromocriptine in the medical literature using PubMed (years 2000–2014). Results: Clopidogrel is commonly co-prescribed with aspirin in patients with heart disease, and therefore the associated risk of gastrointestinal adverse events may be high. We sought to determine the incidence of medical claims for potential gastrointestinal adverse events among clopidogrel users in an administrative database. Methods: Clopidogrel users were identified in a large US database (representing a network of over 70 managed care plans) based on the following criteria: an initial clopidogrel prescription between between October 2003 and January 2004, a clopidogrel-free window in the prior 6 months, and at least 24 months of continuous eligibility over the study time-frame. ICD9 codes were used to identify new peptic ulcer and gastrointestinal bleeding events in the 12 months after the first clopidogrel prescription. Results: There were 368,061 subjects identified who met the selection criteria. Of these subjects, 58% were male and 72% were greater than or equal to 60 years of age. The average duration of clopidogrel use was 200 days. The proportion having a medical claim for peptic ulcer or gastrointestinal bleeding was 6.2%. Higher incidences were seen in women compared to men (7.4% vs. 5.4%; p < 0.000001) and those who were greater than or equal to 60 years of age compared to those under 60 (6.9% vs. 4.3%; p < 0.000001). Conclusion: There is a high incidence of medical claims for peptic ulcer or upper gastrointestinal bleeding among patients who receive clopidogrel, especially in women and those who are greater than or equal to 60 years of age.
Abstracts

1950–2007) and from the WHO (years 1997–2006). Global person-year exposure to bromocriptine was estimated using data from IMS. Next, we conducted a retrospective matched cohort study using data from the GPRD (years 1990–2006). Age- and multivariate-adjusted Cox proportional hazard models were constructed to calculate a hazard ratio (HR) and 95% confidence interval (CI) of CVD events among bromocriptine users compared to controls. RESULTS: We identified 24 CVD events published in the worldwide medical literature and 56 CVD events reported to the WHO over an estimated 19.3 million person-years of bromocriptine exposure. At least 92% of reported CVD events were among women in either data set. In our GPRD cohort, 88% of patients exposed to bromocriptine for any specified indication were women. After multivariate adjustment, patients exposed to bromocriptine appeared to have lower risk of a CVD event, although not statistically significant, HR 0.82 (95% CI 0.29 to 2.31). Gender was not a significant confounder in the multivariate model. CONCLUSION: Using public reporting systems, CVD events appear to occur infrequently among patients taking bromocriptine but predominately among women. Results from our GPRD analysis are not consistent with an increased risk of CVD events among patients taking bromocriptine; rather, they suggest a decreased risk. These findings highlight the need for careful epidemiologic study to consider the potential risks associated with bromocriptine specifically and medications in general.

PCV25

IMPROVEMENTS IN CARDIOVASCULAR DISEASE OUTCOMES IN MANAGED CARE PATIENTS MANAGED ACCORDING TO NATIONAL LIPID TREATMENT GUIDELINES

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OBJECTIVE: Evaluate cardiovascular disease (CVD) outcomes in managed care patients upon adherence to lipid treatment guidelines [National Cholesterol Education Program’s Third Report on Detection, Evaluation, and Treatment of High Blood Cholesterol and Adult Treatment Panel’s (NCEP-ATP III)].

METHODS: Patients with laboratory values for low-density lipoprotein-cholesterol (LDL-C), high-density lipoprotein-cholesterol (HDL-C), & triglycerides (TG) between January 1, 2003-December 31, 2005 [index date], no lipid therapy 6-months pre-index date, and minimum 12 months health plan eligibility pre- and post-index date were analyzed using the HealthCore integrated managed care database. Patients were classified as appropriately (AM) or inappropriately managed (IAM) using baseline lipid levels and the first post-index follow-up lipid panel (goal attainment), and risk stratification per NCEP-ATP III guidelines. Impacts on lipid parameters between groups were descriptively analyzed, while multivariate logistic regression was performed to estimate risk of CVD events (ischemic heart disease, peripheral vascular disease, stroke and related occurrences and interventions).

RESULTS: Among 8176 study patients (3493 AM; 4683 IAM), AM patients were significantly older [51.4 ± 9.1 and 50.0 ± 9.6 years, p < 0.01] and comprised of fewer males (43.2% vs. 56.2%; p < 0.01). Mean LDL-C, HDL-C, and TG baseline levels were significantly different among AM patients (127 ± 35, 55 ± 15, and 131 ± 66 vs. 132 ± 37, 45 ± 13, and 181 ± 81 respectively; p < 0.01). During follow-up, AM patients had greater decreases in LDL-C and TG levels versus IAM patients (~12% vs. ~3% and ~8% vs. ~5%; p < 0.01), while HDL-C levels showed greater increases (5% vs. 2%; p < 0.01). AM patients were 38% less likely to experience a CVD event versus IAM patients (Odds Ratio = 0.62; 95% CI, 0.48–0.80; p < 0.01). CONCLUSION: Greater improvement in all three lipid parameters and reduction in CVD event risk occurred among dyslipidemia patients managed in accordance with clinical guideline treatment recommendations in this managed care population.

PCV26

BELGIAN BUDGET IMPACT ANALYSES OF ALISKIREN (TEKTURNA/RASILEZ) IN HYPERTENSION

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OBJECTIVE: To assess the budget impact of reimbursing aliskiren (Tekturana/Rasilez), the first drug from a new class of antihypertensive drugs (direct renin inhibitors), for the management of essential hypertension, from the health care payer (RIZIV/INAMI), patient, and societal perspectives in Belgium.

METHODS: Following ISPOR’s budget impact guidelines, the pharmacy costs of the current therapy distribution of patients treated for essential hypertension in Belgium was compared to an alternative scenario, where aliskiren gains market share from conventional ARB therapy over a 3-year time horizon. IMS databases and literature data were used to estimate the total number of treated hypertensive patients and to derive market shares of the different antihypertensive medication classes (Beta-blocker, CCB, Diuretic, ACEi, ARB) and all possible dual and triple combinations thereof. The antihypertensive market share uptake of aliskiren was assumed to be identical to that observed previously for telmisartan in Belgium (0.16% year 1; 0.24% year 2; and 0.28% year 3). Only drug acquisition costs (obtained from official Tariffs) were considered in this analysis. Univariate sensitivity analyses were performed as well as sub-populations analyses.

RESULTS: The predicted Belgian populations treated for hypertension in 2008, 2009, and 2010 were estimated at 1,398,446 patients; 1,426,137 patients; and 1,525,827 patients, respectively. Over 3 years, it was estimated that RIZIV/INAMI hypertension drug budget following aliskiren reimbursement would increase by 0.02% (i.e. €148,395), from €755,522,606 to €755,671,001. Patients’ co-payments would decrease by €20,613, resulting in societal incremental costs of €127,782. Sensitivity analyses confirmed that the net budget impact would remain of the same magnitude.

CONCLUSION: Our analyses suggest that, under current assumptions, reimbursing aliskiren in Belgium would only slightly increase costs from the RIZIV/INAMI and societal perspectives, while generating savings for patients. Moreover, this budget impact does not consider aliskiren potential savings due to end organ protection.

PCV27

COST EFFECTIVENESS STUDIES IN HEART FAILURE: AN UPDATE OF THE LITERATURE

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OBJECTIVE: Heart failure (HF) is a major public health burden in terms of mortality, morbidity and costs. Economic analyses of clinical trials and real-world studies have assessed the cost-effectiveness of drugs used to treat HF. Although a few papers have summarized the results of the earlier economic studies, new evidence has emerged necessitating an update of the cost-