PCV8: COMPARATIVE EFFECTIVENESS OF RIVAROXABAN AND STANDARD ANTICOAGULANT THERAPIES FOR PREVENTION OF PRIMARY VENOUS THROMBOEMBOLISM IN PATIENTS UNDERGOING MAJOR ORTHOPEDIC SURGERY
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OBJECTIVES: Venous thromboembolism (VTE) is one of the major complications after major orthopedic surgery (MOS). In 2011, FDA approved rivaroxaban for VTE prevention among patients undergoing MOS. The aim of our study is to empirically evaluate the comparative effectiveness of rivaroxaban, warfarin, and low molecular weight heparins (LMWHs) for VTE prevention among MOS patients using “real world” data. METHODS: A cohort study using IMS LifeLink First (2006-2013) data compared the risk of VTE and major bleed events among MOS patients exposed to rivaroxaban, warfarin, LMWHs, or fondaparinux with those who are not anti-coagulated. Sensitivity analysis with clinical trials comparing rivaroxaban and LMWHs and Cox proportional hazard models were used to assess the risk of VTE and major bleed events and to adjust for potential confounders. RESULTS: A cohort of 35,279 MOS was included which provided 68,340 person years of follow up including 1,044 rivaroxaban, 7,359 warfarin, 5,692 LMWH, 941 fondaparinux exposed patients and 20,403 patients who did not receive an initial anticoagulant. Risk of VTE was lower for rivaroxaban (HR=0.282; 95%CI:0.156-0.510) followed LMWHs (HR=0.671 [95%CI:0.582-0.773]), fondaparinux (HR=0.680 [95%CI :0.485-0.913]) and warfarin (HR=0.872 [95%CI:0.778-0.978]) when compared to no anticoagulant use in unadjusted Cox models. After adjusting for potential confounders, only rivaroxaban (HR=0.395 [95%CI:0.215-0.742]) and LMWHs (HR=0.75 [95%CI:0.643-0.873]) significantly reduced the incidence of VTE. However, these results were not significant in a sensitivity analysis using a more strict definition to detect VTE in claims data. There were no bleeds for rivaroxaban users and the risk of bleed events were not statistically significant only among anticoagulants and not LMWHs in both the adjusted and the unadjusted models. Conclusions: LMWHs and Rivaroxaban were associated with reduced VTE events and no detectable increase in major bleeds among MOS patients. These findings, particularly those on major bleed events, should be confirmed in larger study populations.

PCV9: ESTIMATING THE LIFETIME CLINICAL RISK/BENEFITS OF APPLIXAN versus EDOXABAN IN NON-VALVULAR ATRIAL FIBRILLATION
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OBJECTIVES: This analysis aimed to assess the potential clinical risk/benefits associated with long-term using Applixan versus Edoxaban in patients with non-valvular atrial fibrillation (NVAF) in the United States (US). METHODS: A Markov model was developed to extrapolate the observed clinical impact of Apixaban versus a regimen of edoxaban starting at 60 mg at the lifetime horizon. Outcomes assessed included the number of clinical events avoided for every 1000 patients treated, number of patients needed to treat to prevent one stroke, and number of patients needed to harm with an additional major bleed. Key sources of inputs used to populate the model included results from large randomized trials comparing data versus edoxaban from published blinded randomized trials vs warfarin; US life tables for life expectancy; published literature for increased mortality related to outcome events modeled. RESULTS: In a cohort of 1,000 patients, treatment with Apixaban at 5 mg twice daily versus Edoxaban at 150 mg once daily resulted in edoxaban 60 mg resulted in 6 fewer strokes and caused 10 fewer major bleeds over the average projected lifetime. This translated in 172 patients needed to treat with Apixaban versus 217 patients needed to treat with Edoxaban in clinical trials) in comparison with edoxaban 60 mg resulted in 6 fewer strokes and caused 10 fewer major bleeds over the average projected lifetime. This translated in 172 patients needed to treat with Apixaban versus 217 patients needed to treat with Edoxaban (mean age 56±16 years; 61% African-American; 55% female) and 299 historical controls (mean age 56±16 years; 74% African-American, 64% female) were included in our primary outcome, the treatment effect in time to first therapeutic INR was statistically significant (HR 0.58, 95% CI: 0.45, 0.74). In addition to the primary outcome, we also assessed the impact of the PGx service and several clinical outcomes. Conclusions: These models were adjusted for confounders, and inverse probability treatment weight propensity scoring was used. Our findings suggest that first therapeutic INR was significantly higher in African-Americans compared to Caucasians (HR 1.86, 95%CI: 1.3, 2.8 vs. HR 1.24, 95%CI: 0.4, 3.8, respectively). The treatment effect in time to therapeutic international normalized ratio (INR) was significant higher in African-Americans than in Caucasians over the initial 7 days of therapy (p< .052 days, HR 1.4, 9, 6 vs. p=0.78, 95%CI: 0.93, 10.8, respectively). The treatment effect in proportion of INRs at extremes (< 1.5 and > 4) was lower in African-Americans compared to Caucasians (p= .25, 56, 95% CI: 31.6, 19.6 vs. p=.22, 46.5, 95% CI: 36.8, 18.2, respectively). Additionally, relative to Caucasians, African-Americans in the PGx group were 2.17 times more likely to have an INR therapeutic range at discharge (OR: 2.17, 95% CI: 1.0, 4.7). Conclusions: A novel genotype-guided personalized warfarin dosing service was positively associated with anticipated related clinical outcomes, and this association was stronger in African-American patients.

PCV10: CARDIOVASCULAR SAFETY WITH THE CONCURRENT USE OF MOOD STABILIZERS OR ATYPICAL ANTIPSYCHOTICS AND STIMULANTS IN CHILDREN AND ADOLESCENTS WITH ATTENTION DEFICIT/HYPERACTIVITY DISORDER AND BIPOLAR DISORDER
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OBJECTIVES: This study compared the cardiovascular safety of the addition of mood stabilizers or atypical antipsychotics to stimulants monotherapy. Only patients who had continuous eligibility 6 months before and 12 months after the index stimulant date were selected. Exposure to a mood stabilizer or atypical antipsychotic was defined as receiving prescriptions of mood stabilizers or antipsychotics at least once every 30 days. RESULTS: A total of 339 patients managed by the PGx service and anticoagulation related clinical outcomes. Conclusions: Multivariate linear, logistic, and survival models were used to examine differences across indices of warfarin service and several clinical outcomes. These models were adjusted for confounders, and inverse probability treatment weight propensity scoring was used. Our findings suggest that first therapeutic INR was significantly higher in African-Americans compared to Caucasians (HR 1.86, 95%CI: 1.3, 2.8 vs. HR 1.24, 95%CI: 0.4, 3.8, respectively). The treatment effect in time to therapeutic international normalized ratio (INR) was significantly higher in African-Americans than in Caucasians over the initial 7 days of therapy (p< .52 days, HR 1.4, 9, 6 vs. p=0.78, 95%CI: 0.93, 10.8, respectively). The treatment effect in proportion of INRs at extremes (< 1.5 and > 4) was lower in African-Americans compared to Caucasians (p= .25, 56, 95% CI: 31.6, 19.6 vs. p=.22, 46.5, 95% CI: 36.8, 18.2, respectively). Additionally, relative to Caucasians, African-Americans in the PGx group were 2.17 times more likely to have an INR therapeutic range at discharge (OR: 2.17, 95% CI: 1.0, 4.7). Conclusions: A novel genotype-guided personalized warfarin dosing service was positively associated with anticipated related clinical outcomes, and this association was stronger in African-American patients.
the only eHealth component were excluded. Two authors independently screened by two authors independently screened the literature was undertaken to identify the primary studies used to populate

PCV15

OBJECTIVES: The complexity of therapy and pill burden has a direct impact on treatment compliance. Compliance is improved when agents are prescribed in combination rather than separately. This could be of particular value in elderly patients with multiple morbidities requiring polypharmacy. This systematic review aims to at evaluating efficacy and safety of the once-daily fixed-dose combination (bisoprolol-amlodipine) on SAH. METHODS: Electronic searches included MEDI LINE, LILACS, EMBASE, CRD, among others until June 2014. Search terms included “Amlodipine”, “Bisoprolol” and “Hypertension” via MEDSH controlled vocabulary. Where included studies with information on patients using the combination for hypertension treatment. Two reviewers performed the search. RESULTS: From 704 articles found, 3 evaluated feasibility. Mean reduction of 19.7% in DBP; from 103 33.6 mmHg at baseline to at baseline to 34.6 62 mmHg (p<0.0001). SBP decreased from 20.4% to 21.6% and DBP decreased 19.7% to 21.2%. SBP/DBP goal (<140/90 mmHg) was reached or exceeded from 82.5 to 89.0% of patients by the end of 8 weeks. HR presented reductions from 10.4% to 21.6% to the end of 8 weeks (from 73 ± 11.07 bpm to 68 ± 8.13 bpm). Pedal edema was observed in 5% to 8%. Excellent/good tolerability was reported by 90.6% to 94% of patients. Combination therapy is likely to cause fewer AEs with lower doses. Benefits of fixed-dose include reduced pill and improved BP control, compliance and cost savings. Persistence rate of 54.3% compared to 14.9% and a compliance rate of 76.9% versus 54.4% were observed. Patients with HR > 79 bpm had an 89% greater risk of mortality than those with HR ≤ 79 bpm. CONCLUSIONS: In summary, bisoprolol plus amlodipine in a fixed-dose combination showed significant benefits over a single agent, with a similar safety profile when compared with amlodipine and bisoprolol in monotherapy, potentially leading to an increase in SAH treatment compliance.

PCV16

OBJECTIVES: The objective of this investigation was to assess the evidence base for the use of a fixed drug combination of miblerimus (PCV18) for the treatment of hypercholesteremia for the treatment of hypercholesteremia. METHODS: Studies published in English language were collated from PubMed and Cochrane databases using validated search strategies. Pre-specified inclusion/exclusion were employed to identify randomized controlled trials. RESULTS: Nine studies were finally included for data extraction. Overall effect size (WMD(95%CI)) were -0.42 (-0.66, -0.18) to -0.24 (-0.37, -0.12), -0.48 (-0.57, -0.35, -0.53) to -0.51 (-0.60, -0.33), -0.51 (-0.60, -0.42). The relative risks of ‘VTE or VTE-related death’ was lower with apixaban compared with both dabigatran (0.74, 0.57 [0.46, 0.92]), edoxaban (0.79, 0.60 [0.46, 0.94], 0.82 [0.34, 2.05], 0.75, 0.75 [0.47, 1.21], respectively). CONCLUSIONS: While the NOACs have similar efficacy in the terms of reduction in VTE or VTE-related death, apixaban had a significantly better safety profile versus the NOACs. Terms of reduction in ‘major or CRNV events and decrease rising healthcare costs. However, measurement of long term disease specific outcomes, while few studies provided economic outcomes. Long term outcomes were not commonly assessed but implied through surrogate outcomes. CONCLUSIONS: Current evidence suggests that eHealth has the potential to cause fewer AEs with lower doses. Benefits of fixed-dose include reduced pill

PCV17

EFFECTIVENESS AND COST-EFFECTIVENESS OF CATHETER-DIRECTED THROMBOLYSIS IN MASSIVE PULMONARY EMBOLISM

Recently, 79% of patients were excluded from the study. As a result, a total of 344 papers were included in the analysis. The final analysis showed that CDT was more effective and less costly (dominant) in 23% of all simulations. The difference in the expected utility is about 0.0039 from baseline at the primary efficacy time point. The mean percentage change in LDL-C concentration was significantly greater with Mipomersen than with placebo. For the secondary and tertiary outcome measures, percentage changes from baseline were significantly greater with Mipomersen than with placebo for apo B, total cholesterol, non-HDL-C. Mipomersen treatment also resulted in a significant percentage reduction when compared with the placebo group in lipoprotein (a) concentration and LDL-C:HDL-C ratio. The most common adverse events were injection-site reactions, influenza-like symptoms, patients in Mipomersen group, increase in intrathoracic triglyceride content, increased ALT concentrations. CONCLUSIONS: The findings show that evidence in favor of being and safe effective intervention as an adjunctive drug for lowering LDL-C.

PCV19

THE USE OF LOW MOLECULAR WEIGHT HEPARIN AND PNEUMATIC COMPRESSION DEVICES FOR DEEP VEIN THROMBOSIS PROPHYLAXIS IN MAJOR TRAUMA PATIENTS: A COMPARATIVE EFFECTIVENESS ANALYSIS
