Treatment Comparison using the Bayesian approach. Nevertheless, for each of these methods there are specific assumptions which have to be satisfied in order to obtain correct estimation.

CONCEPTUAL PAPERS & RESEARCH ON METHODS – Study Design

PMC60

INCLUSION OF CONFERENCE ABSTRACT DATA IN SYSTEMATIC REVIEWS OF PHARMACOLOGIC INTERVENTIONS IN DIFFERENT DISEASE AREAS

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OBJECTIVES: Conference searching is a common part of systematic review methodology, this study investigates what proportion of study/trial data included in systematic reviews of pharmacologic interventions is derived solely from data published in conference abstracts, for 3 different disease areas. **METHODS:** The Cochrane Library of systematic reviews (SRs) was searched for SRs on pharmacologic interventions which state that they include conference abstracts in their Specialized Registers and include conference searching as part of the stated SR methods. Included studies lists of completed systematic reviews were reviewed and the total number of included studies and the number of studies for which data was obtained only from conference abstracts were extracted. In disease areas where a large number of SRs met the inclusion criteria, the 10 most recently published SRs were selected. The following disease groups were considered: psychological disease (depression and bipolar disorder), female cancers (breast cancer and ovarian cancer), and arthritis (osteoarthritis and rheumatoid arthritis). **RESULTS:** 3/10, 9/10 and 4/10 SRs contained studies solely from conference abstracts, for psychological disease, female cancers and arthritis respectively. For psychological disease 5% (5/226) of all studies included in 10 SRs came only from conference abstracts, for female cancers this was 14% (31/220) and for arthritis this was 14% (33/232). **CONCLUSIONS:** The proportion of studies from conference abstracts only included in SRs varies in the 3 examined disease areas. From these results, there is some evidence to suggest that the disease area of the review should inform the decision of whether to include conference searching as part of the protocol. To answer this question more conclusively, a more expansive review of SRs should be conducted covering a greater number of SRs and disease areas.

PMC61

MONITORING OF HEALTH ECONOMIC DATA IN CLINICAL TRIALS

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OBJECTIVES: Health care decision makers are increasingly requesting health economic (HE) data, both to support product approval and for marketing purposes. Currently, there is limited information available to aid decisions surrounding the clinical monitoring of HE endpoints when they are collected as part of a clinical trial. It is necessary to understand the current level of monitoring activities surrounding HE data and evolve best practices for monitoring such data. **METHODS:** To better understand monitoring activities, a literature review was performed and qualitative in-depth interviews were conducted with six clinical research associates (CRA) who had experience collecting HE data as part of clinical trials in a range of therapy areas. The literature review and interviews focused on understanding current clinical trial monitoring practices, monitoring activities specific to HE data, the challenges faced during monitoring and recommendations for the future. **RESULTS:** All CRAs interviewed reported working either with patient-reported outcome (PRO) measures—quality of life questionnaires, patient diaries—and/or health care resource utilization data, in different therapy areas. Data monitoring activities in clinical trials can include a number of specific tasks ranging from full source data verification (SDV) to partial SDV to just checking for accuracy, legibility and completeness. The most common challenges in monitoring of HE data included incomplete questionnaires, misinterpretation of questionnaire data by the sites, and difficulty in SDV of health care resource utilization data by the CRA. Recommendations for the future included optimizing methods for documentation of health care resource utilization data, improving patient/site training in PRO use, and selecting the type of PRO and mode of PRO administration based on the patient population being examined. **CONCLUSIONS:** Health economic endpoints are increasingly being used in clinical trials, and CRAs are becoming familiar with PRO and health care resource utilization data. Monitoring activities for HE data vary by the study design and type of data collected.

CARDIOVASCULAR DISORDERS – Clinical Outcomes Studies

PCV1

ESTIMATION OF STROKE-RELATED ADVERSE EVENTS, HEALTH CARE UTILITY AND COST OF PATIENTS WITH NON-VALVULAR ATRIAL FIBRILLATION

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OBJECTIVES: To estimate mortality, health care utility and health care cost burden of patients who suffered a stroke during the 180 days after diagnosis of non-valvular atrial fibrillation (NVAF) and compare it with patients who did not suffer a stroke. **METHODS:** Based on 2005–2007 U.S. Medicare advantage insurance claim files, patients aged 65 years and older who had 2 or more primary diagnoses for NVAF within 30 days of one another were selected. The 180-day follow-up event rates, health care facility use and health care cost for patients with a stroke and those without were compared. Risk adjustment was done by using the propensity score matching method with the ProbChoice™ algorithm. **RESULTS:** Out of patients identified with NVAF (n = 18,575), 575 suffered a stroke during the 180 days after NVAF diagnosis. 94% (n = 541) did not have stroke during the baseline period (180 days before NVAF diagnosis). Patients were not significantly different in terms of gender, region, and baseline comorbid conditions. After risk-adjustment for pre-specified covariates, mortality (7.14% vs. 2.09% $P < 0.0001$), outpatient emergency room (ER) visits (79.97% vs. 46.34% $P < 0.0001$), acute coronary syndrome (43 vs. 16/100 person years), transient ischemic attack (73 vs. 4 /100 person years), major bleeding (85 vs. 4 /100 person years) and myocardial infarction (32 vs. 9/100 person years) were all higher for patients who suffered a stroke compared to those who did not. Besides inpatient cost ($24,116 vs. $20,828), risk-adjusted outpatient ER costs ($921 vs. $873) were also higher for stroke patients. Overall risk-adjusted difference in health care costs is significant ($33,430 vs. $16,375 $P < 0.0001$). **CONCLUSIONS:** Most of the adverse events analyzed were higher for patients who suffered a stroke after NVAF relative to patients who did not. Total health care utility and health care cost were also significantly increased.

PCV2

ESTIMATION OF ADVERSE EVENTS IN 3 MONTHS AFTER VENOUS THROMBOEMBOLISM EVENT FOR MEDICARE PATIENTS WHO UNDERWENT HIP FRACTURE SURGERY

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OBJECTIVES: To estimate mortality, re-hospitalization and bleeding 180 days after a venous thromboembolism (VTE) event in patients following hip fracture surgery and to compare the outcomes with patients without VTE. **METHODS:** Based on 2004–2006 national Medicare claims, all patients who underwent hip fracture surgery were identified. a total of 180 days follow-up event rates for patients who had a VTE event during their initial hospitalization were calculated. Events were compared between patients who suffered a VTE event and those that did not. Risk adjustment was done using propensity score matching (using the ProbChoice™ algorithm) controlling for baseline demographic and clinical characteristics between patients with and without VTE. **RESULTS:** In patients who underwent hip fracture surgery (n = 77,743), 2.23% had post-operative VTE events during their initial hospitalization. Almost 72.96% (n = 1263) of these patients suffered deep vein thrombosis (DVT), 20.97% (n = 363) had a pulmonary embolism (PE), and 6.07% (n = 105) had both DVT and PE. After multivariate adjustment for pre-specified covariates, mortality was almost 50% higher for patients with VTE compared to those without VTE. Differences in mortality rate were more pronounced for PE patients, whom the event was associated with almost two-fold. The VTE group was more likely to be re-hospitalized in one year (odds ratio: 1.18, p = 0.2720). Bleeding was 1.8 times higher (p = 0.0080). **CONCLUSIONS:** VTE events during initial hospitalization for hip fracture surgery increased patients' mortality, re-hospitalization and bleeding compared to patients with no VTE events.

PCV3

COMPARISON OF MORTALITY, HEALTH CARE UTILITY AND COST OF PATIENTS WITH WARFARIN TREATMENT FOR NON-VALVULAR ATRIAL FIBRILLATION VERSUS PATIENTS WITH OTHER TREATMENT

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OBJECTIVES: To estimate the economic and clinical burden of patients who used warfarin during the 180 days after diagnosis of non-valvular atrial fibrillation (NVAF) and compare it with patients who did not use warfarin. **METHODS:** Based on 2005–2007 U.S. Medicare advantage insurance claim files, patients aged 65 years and older who have had 2 or more primary diagnoses for NVAF occurring within 30 days of one another were selected. The 180 days follow-up event rates, health care facility use and cost were compared. Risk adjustment was done by using the propensity score matching method with the ProbChoice™ algorithm. **RESULTS:** In patients who identified with NVAF (n = 18,575) 12,186 used warfarin during the 180 days after NVAF diagnosis and 6,389 used other drugs or did not use any drugs. Patients were significantly different in terms of age, gender, comorbid conditions and baseline CHADS score. After risk-adjustment for pre-specified covariates, mortality (0.75% vs. 2.26%), outpatient emergency room (ER) visits (48.79% vs. 53.30%), acute coronary syndrome (105 vs. 154 /100 person years), and myocardial infarction (61 vs. 112 /100 person years) were all lower for patients who had warfarin with non-valvular atrial fibrillation. Even though drug cost is higher for the warfarin group ($1,687 vs. $1,595), risk-adjusted outpatient ER costs ($756 vs. $861) were lower. Overall risk-adjusted health care costs did not differ ($12,739 vs. $15,359). **CONCLUSIONS:** Most of the adverse events analyzed were lower for patients who had warfarin after non-valvular atrial fibrillation relative to patients who did not. However, the economic burden of both groups of patients on the health care system was similar.