TREATMENT SATISFACTION INSTRUMENTS FOR DIFFERENT PURPOSES DURING A PRODUCT’S LIFECYCLE—KEEPING THE END IN MIND

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OBJECTIVES: There are three main parts during a product’s lifecycle when satisfaction instruments are particularly useful. These are to aid: 1) getting the product to the market; 2) getting the market to the product; and 3) demonstrating value for health care practitioners during daily clinical practice. This study investigates whether the development and implementation of treatment satisfaction instruments during a product’s lifecycle are informed by their purpose. METHODS: A literature review was performed between 2000 and 2010 using electronic databases (PUBMED, PsycINFO, and EMBASE) and keywords such as “satisfaction” and “medication” or “drug” and “questionnaire.” Relevant articles were reviewed in detail to extract information regarding the satisfaction instrument used, its development and validation, and when the instrument was used during a product’s lifecycle. Additional information was collated including the type of studies the instruments were used in, clinical condition/ indication, type of data generated (e.g. descriptive), and whether satisfaction was associated with other endpoints. RESULTS: Of 875 abstracts, 103 articles were further considered. The review indicated similarities regarding the development and validation of satisfaction instruments, such as using patient input to derive the items and exploring classical measurement properties specific to the target population. However, the specificities of the implementation of treatment satisfaction instruments during the three main stages of a product’s lifecycle were rarely considered. CONCLUSIONS: The development and implementation of treatment satisfaction instruments during a product’s lifecycle rarely consider the purpose. By “keeping the end in mind,” data from treatment satisfaction instruments can help three key parts: 1) getting the product to the market but also generating evidence as part of an overall value proposition; 2) getting the market to the product; and 3) demonstrating the value to clinical practice. Furthermore, the development, validation and interpretation of scores from treatment satisfaction instruments should be sensitive to the intended purpose.

CONCEPTUAL PAPERS & RESEARCH ON METHODS – Statistical Methods

SYSTEMATIC REVIEW OF METHODS FOR META-ANALYSIS AND INDIRECT COMPARISON POTENTIALLY AVAILABLE TO USE IN SYSTEMATIC REVIEWS AND HTA REPORTS—RESULTS FROM THE FIRST PART OF EBAYESMET PROJECT

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OBJECTIVES: To collect information serve as a background for further activities of the eBayesMet project. To perform assessment of the frequency of use the particular statistical methods for meta-analyses and indirect comparisons in existing systematic reviews and HTA reports. METHODS: Databases: Reviews of Effectiveness (DARE) was searched for relevant reviews published between January 2009 and March 2010. RESULTS: The majority of meta-analyses were prepared by using direct statistical methods (97%). The most popular expression about fixed model was that fixed effect model with the Mantel–Haenszel was used (36%). In case of random model, information that method DerSimonian Laird was selected (38%) was used most often. Meta-analyses were prepared mostly based on randomized controlled trials (87%) and in 3% only on observational studies. In meta-analyses based on RCTs in 42% of cases authors mentioned that to make strong conclusion more studies were needed. Employing Bayesian methods was generally very rare. For indirect comparisons six methods were recognized and the most common type was MTC Bayesian Model (53%). Observational studies were not included in any identified analysis. In 40% of the review information indicating the need for additional studies was contained. CONCLUSIONS: Our systematic reviews demonstrates a wide range of approaches and methods for conducting meta-analyses and indirect comparison used in current practice. The most popular approach for indirect comparison is Bayesian included network and MTC (over 65%). However performed analysis indicated that Bayesian approach is still marginal methods for performing direct comparison based on head-to-head studies. Bayesian models have essential advantage: some additional data can be included (as a prior distribution). This extra information can be for instance data from observational studies. However it should be emphasized, that in the analyzed random sample of systematic reviews studies other than RCT were included in only 13%.

IMPROVED SURVIVAL CURVE FITS TO SUMMARY DATA FOR ECONOMIC EVALUATIONS

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OBJECTIVES: Estimates of mean cost and quality-adjusted-life-years are central to cost-effectiveness analysis of health technologies. They are often calculated from curve fits to overall survival and time on treatment, ideally by the method of maximum likelihood applied to individual patient data. However, such data is often not available. Instead, curves are commonly fit to summary Kaplan-Meier estimators, either by regression of the transformed estimator or by minimizing the sums of squares of differences between actual and fitted values. However, the tail of the estimator is often uncertain due to small numbers of patients at risk, and the curve fits do not yield estimates of the true uncertainty in survival times, which is a very important component of overall uncertainty in cost-effectiveness. Here, I describe a new, more accurate method of fitting survival curves to summary survival data. METHODS: I estimate the underlying individual patient data from the Kaplan-Meier estimator, numbers of patients at risk and from other published trial-related information. The fitted curve is then estimated by maximum likelihood given the estimated underlying individual patient data. RESULTS: Simulation applied to individual patient data shows that the method tends to give a more accurate curve fit than the traditional methods of fitting to the Kaplan-Meier estimator, numbers of patients at risk and from other published trial-related information. The curve fit is often very similar to that derived by fitting to the underlying individual patient data by method usually yields accurate estimates of the true uncertainty in survival times. When applied to economic evaluations submitted to NICE, the method often yields substantially improved estimates of cost-effectiveness compared to estimates based on fitting survival curves in the traditional manner. This highlights the sensitivity of many cost-effectiveness analyses to curve fits. CONCLUSIONS: When only summary survival data is available, I recommend the method for cost-effectiveness analysis.
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, in 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 included adverse events 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 2003–2007 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 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. 160/100 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.

PMC61 MONITORING OF HEALTH ECONOMIC DATA IN CLINICAL TRIALS

Wang L1, Baser O2

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% (n = 1,720) had a VTE event during hospitalization. After multivariable adjustment for pre-specified covariates, mortality was almost 30% 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 type 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.

PCV1 ESTIMATION OF STROKE-RELATED ADVERSE EVENTS, HEALTH CARE UTILITY AND COST OF PATIENTS WITH NON-VALVULAR ATRIAL FIBRILLATION

Wang L1, Baser O2

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 2003–2007 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 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. 160/100 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 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.

PCV2 ESTIMATION OF AVERSE 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% (n = 1,720) had a VTE event during hospitalization. After multivariable adjustment for pre-specified covariates, mortality was almost 30% 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 type 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 NON-VALVULAR ATRIAL FIBRILLATION VERSUS PATIENTS WITH OTHER TREATMENT

Wang L1, Baser O2

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 2003–2007 U.S. Medicare advantage insurance claim files, patients aged 65 years and older who 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 health care cost were compared. Risk adjustment was done 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.