warranted to identify steps for increasing treatment effectiveness in these patients.

INFLUENCE OF DIABETES AND BASELINE ST-SEGMENT CHANGE STATUS ON THE COST-EFFECTIVENESS OF AN EARLY INVASIVE VS. CONSERVATIVE STRATEGY FOR THE TREATMENT OF ACUTE CORONARY SYNDROMES: APPLICATION OF A NET-BENEFIT REGRESSION APPROACH TO DATA FROM THE TACTICS-TIMI 18 TRIAL

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OBJECTIVES: Prior results from the TACTICS-TIMI 18 trial demonstrated that an early invasive approach to the management of patients with unstable angina (UA) or non-ST-segment elevation myocardial infarction (NSTEMI) was cost-effective, with an estimated cost per life-year gained of $8371; for high-risk patients with ST-segment changes at baseline, $3224 per life-year gained.

We examined the joint influence of diabetes and ST-segment changes on the cost-effectiveness of the early invasive strategy. METHODS: Inpatient hospital costs for the 1722 US, non-VA patients for the 6-month trial period were obtained from the UB92 and Medicare cost/charge ratios. Other costs included: physician, outpatient, medication, and productivity costs. Life-expectancy estimates for patients with acute MI/coronary heart disease from the Framingham Heart Study were used for patients who survived the trial with/without experiencing a non-fatal MI. Cost-effectiveness was evaluated in terms of cost per life-year gained. Regression analyses of the net monetary benefit across a range of ceiling ratios were used to obtain cost-effectiveness acceptability curves for subgroups defined by diabetes and ST-change status. RESULTS: Net monetary benefit regression analyses revealed a three-way interaction between diabetes, ST-changes and treatment group which approached significance (p < 0.10) for models based on a ceiling ratio of $14,000–$49,000. Associated cost-effectiveness acceptability curves suggest a probability that the invasive strategy is cost-effective for non-diabetic patients with ST-segment changes of >95% for ceiling ratios $4000 per life-year gained. At a ceiling ratio of $50,000, the probability of cost-effectiveness for diabetic patients without ST-changes is 56%, for diabetic patients with ST-changes, 73%, and for non-diabetic patients without ST-changes, 74%. CONCLUSIONS: In addition to ST-segment changes at presentation, the cost-effectiveness of an invasive strategy for patients with UA or NSTEMI varies by DM status. This analysis demonstrates the usefulness and efficiency of net-benefit regression for the evaluation of cost-effectiveness for different patient subgroups.

EFFECTIVENESS OF AMLODIPINE VS. VALSARTAN UPON BLOOD PRESSURE CHANGE AND CONTROL AMONG HYPERTENSIVE ADULTS

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OBJECTIVES: To compare the effectiveness of two widely prescribed agents, amlodipine and valsartan, in blood pressure lowering and control in a multi-center ambulatory practice setting. METHODS: All adult hypertensive patients were identified from 1998 to 2001 from a large commercially available electronic medical record covering over 360,000 US primary care patients. Study patients were required to have initiated therapy with either amlodipine or valsartan and to have at least one BP measurement within 6 months preceding and 12 months following the index date. Mean change in systolic blood pressure (SBP) and rates of JNC VI BP goal attainment were compared using multivariate statistics. RESULTS: One thousand one hundred seventy-five amlodipine and 512 valsartan patients met criteria. Baseline SBP was 159.5 mmHg for amlodipine; 159.9 for valsartan. Overall, amlodipine was associated with an adjusted mean change of −16.6 mmHg in SBP (95% CI−17.7, −15.5) vs. −13.4 mmHg for valsartan (95% CI−15.1, −11.7; p = 0.002). Approximately 43% of amlodipine patients achieved JNC VI goal vs. 33% in the valsartan treated cohort (p = 0.030). Among patients on complex antihypertensive regimens (2 or more agents), amlodipine was associated with an adjusted mean change of −16.6 mmHg (95% CI−18.5, −14.8) vs. −10.0 mmHg for valsartan (95% CI−12.8, −7.2; p < 0.001). Within this subgroup, JNC VI goal attainment was 43% vs. 36% for amlodipine vs. valsartan (p = 0.095). CONCLUSIONS: In monotherapy and in combination, amlodipine demonstrated both a statistically significant and clinically meaningful improvements in SBP change and JNC VI goal attainments vs. valsartan, particularly among patients on complex antihypertensive regimens. Although these data must be interpreted within the limitations of the observational study design, this study suggests that amlodipine may be used in a variety of therapeutic combinations and among a broad spectrum of hypertensive adults to improve SBP control and goal attainment.

METHODOLOGY ISSUES

AN ECONOMETRIC APPROACH TO GENERATING POPULATION COST ESTIMATES FOR EVENT-TIME DATA: AN EXAMPLE USING RENAL TRANSPLANT GRAFT FAILURE DATA

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OBJECTIVES: Generation of population cost estimates for event-time data requires a sophisticated approach to account for the probability of incurring the event over time. This research investigated the relationship of donor and recipient factors with all-cause renal graft failure and estimates of the cost of failure from a Medicare perspective. METHODS: A two-part econometric approach was used to determine Medicare claims attributable to all-cause graft failure (including deaths). First, type-specific hazard functions were estimated with Cox proportional hazards models. Using data from USRDS for primary renal transplants in adults between 1993-1998, we developed separate predictive models for transplants from living and cadaveric donors after identifying covariates associated with graft loss. Models were stratified by transplant year and included donor and recipient characteristics plus clinical variables including immunosuppression therapies. Next, the log-transformed costs for patients who experienced the event were modeled against the covariates to estimate costs specifically associated with failure at a given time point. For patients who did not experience the event, predicted costs were generated based on the model coefficients and individual covariates. Retransformation of the log costs included an adjustment using residual smearing. The expected Medicare claims associated with graft failure were calculated by combining the estimated cumulative hazards of graft failure with the smeared estimate of the claims associated with the event. RESULTS: For living donor transplants (N = 5831), expected Medicare claims attributed to renal transplant graft failure were approximately $13,073 ± $5831, the expected Medicare claims were $8,933; range $560–$191,169) at 3 years post-transplant. For cadaveric donor transplants (N = 22,941), the expected Medicare claims were approximately $15,075 ± $13,149 (median = $11,540; range = $699–$214,184). CONCLUSIONS: These estimates provide groundwork for population-based studies to address the cost-effectiveness of various treatments to delay or prevent graft loss. The method allows policymakers to assess population costs after taking into account the probability of event occurrence.

COMPARISON OF PATIENT SELF-REPORTED HEALTHCARE RESOURCE UTILIZATION TO ELECTRONIC RECORD DATA: LESSONS LEARNED FROM A STUDY OF HERPES ZOSTER PATIENTS

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Healthcare resource utilization (HCRU) may be evaluated through patient interviews in multicenter clinical trials but the accuracy of self-reported data should be assessed. OBJECTIVE: This study evaluated the consistency between electronic record data and patient self-reported HCRU for herpes zoster (HZ) through telephone interviews. METHODS: HZ patients (N = 116) were recruited from a managed care organization in Boston. HZ-related hospitalizations, Emergency Department (ED) visits, outpatient visits and telephone calls were compared separately, with further differentiation among outpatient contacts with primary care providers and specialists. Medication use comparisons were made for analgesics, antivirals and other prescription medications. Judgments of consistency were based on intraclass correlation coefficients (ICC) unless data were sparse. RESULTS: Two patients with HZ hospitalizations were found in the electronic records versus three in the questionnaire. Four patients with ED visits were found in the electronic records versus 34 in the questionnaire. The ICC for outpatient visits was 0.46 (CI 0.06–0.85; ICC electronic records = 268, nHSEQ = 265). The ICC for telephone calls was 0.51 (CI 0.06–0.96; nHSEQ = 87, nHSEQ = 110). By outpatient provider type, the ICC ranged from 0.27 for primary care visits to 0.84 for specialist visits. ICCs of 0.55, 0.64 and 0.56 were found for pain medications, antiviral medications, and other medications, respectively. CONCLUSION: Patient self-reported HCRU reasonably (ICC ≥ 0.4), but imperfectly matched the electronic records across most categories, with no systematic bias observed. Patient misclassification of urgent care visits as ED visits may account for some of the observed discrepancies between ED and primary care visits. This study, which represents one of the first efforts to evaluate the design of a patient self-report HCRU questionnaire for use in clinical trials, identified limitations to comparisons between the two types of data sources and offers insight into potential improvements for the design and validation of such questionnaires.

THE IMPACT OF REQUIRING A FIXED PERIOD OF ELIGIBILITY IN ECONOMIC AND EPIDEMIOLOGICAL STUDIES THAT UTILIZE LONGITUDINAL DATA

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OBJECTIVES: In economic and epidemiologic studies utilizing longitudinal data, researchers often require a fixed follow-up period. By allowing differential follow-up, researchers can eliminate one source of selection bias. Our objective was to compare analyses of two study populations from the General Practice Research Database (GPRD) differing only in length of follow-up time. METHODS: Study population 1 (SP1; n = 28,643) included patients with a given condition first diagnosed between June 1988 and February 1999. Study population 2 (SP2; n = 21,289) included only those patients in SP1 with at least a year of follow-up. Comorbid conditions, resource use, and reasons for loss to follow-up were