

fibrillation (VT/VF), post-operative stroke (CVA), and post-operative myocardial infarction (MI).

Methods: We conducted a meta-analysis to assess the effect of peri-operative amiodarone on the incidence of morbidity and mortality. MEDLINE, CINAHL, Cochrane Central Register of Controlled Trials, and EMBASE databases were searched through 5/2003 with the terms *atrial fibrillation, amiodarone and surgery*. Inclusion criteria were randomized controlled double-blind study design and primary outcome designated as incidence of AF/AFL, AF/AFL, VT/VF, CVA, MI, and mortality data were pooled using the DerSimonian-Laird method with a random effects model. Trial heterogeneity was assessed via the Woolf Q statistic, and publication bias was assessed with Kendall's test on standardized effect vs. variance.

Results: Eight randomized controlled double blind placebo trials with a total of 1,527 patients were included in our analysis of the incidence of AF/AFL and mortality. Of these, six trials (1,184 patients) reported data on VT/VF, CVA, and MI. Heterogeneity and publication bias were not detected. Amiodarone significantly decreased the incidence of AF/AFL [odds ratio 0.539, 95% CI (0.428, 0.678), $P < 0.0001$], VT/VF [odds ratio 0.308, 95% CI (0.164, 0.579), $P = 0.0003$], and CVA [odds ratio 0.434, 95% CI (0.203, 0.929), $P = 0.0315$], when compared to placebo. Amiodarone did not significantly decrease the incidence of MI [odds ratio 0.821, 95% CI (0.265, 2.543), $P = 0.732$] and had no impact on mortality [odds ratio 1.043, 95% CI (0.460, 2.370), $P = 0.919$].

Conclusion: Amiodarone significantly reduced not only the incidence of AF/AFL, but also of VT/VF and CVA. This study has important clinical implications and illustrates the need for future prospective studies adequately powered to detect reductions in cardiovascular morbidity and mortality.

POSTER SESSION

1172 Outcomes of Care

Tuesday, March 09, 2004, 3:00 p.m.-5:00 p.m.

Morial Convention Center, Hall G

Presentation Hour: 4:00 p.m.-5:00 p.m.

1172-67

Use of Administrative Databases May Lead to Incorrect Estimates of the Effects of Nonaspirin Nonsteroidal Anti-Inflammatory Drugs on Myocardial Infarction Risk

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Background: Studies using administrative, prescription databases have generally shown no effect of most nonselective non-aspirin nonsteroidal anti-inflammatory drugs (NANSAIDs) on cardiovascular risk. We analyzed data from a study that specifically addressed the biases inherent in using prescription databases to determine the effect of these potential biases.

Methods: In our case-control study of NANSAIDs and first MI, we determined the odds ratio for prescription (Rx) NANSAIDs versus non-users on MI risk as follows: (1) Replicating administrative database studies by: including over-the-counter (OTC) NANSAID users as "non-users," not excluding aspirin (ASA) users, and not adjusting for confounders typically unavailable in administrative databases (smoking, family history, body mass index, education, and physical activity). (2) Analysis #1 after removing OTC NANSAIDs from the "non-user" category. (3) Analysis #2, adding adjustment for the confounders listed above. (4) Analysis #3 plus excluding ASA users.

Results: OTC NANSAIDs accounted for 79% of all NANSAID use. ASA use was 28%. Replication of administrative database analyses led to a null result (table). As we removed each potential bias from our study, the OR moved further from 1.0 and indicated a significant benefit of NANSAIDs in the fully adjusted analysis (#4).

Conclusion: The inability to measure OTC NANSAIDs, exclude ASA users, and adjust for confounding may bias studies of prescription NANSAIDs and MI towards showing no effect.

Effects of Adjustment

Analysis (see text)	Odds Ratio (95% CI)
#1 Replicating Administrative Database Analysis	1.0 (0.7-1.3)
#2	0.9 (0.7-1.1)
#3	0.8 (0.6-1.0)
#4 - Fully adjusted	0.7 (0.5-0.9)

1172-68

Does Statin Therapy Reduce Contrast-Induced Nephropathy? An Analysis From a Large Regional Registry of Contemporary Percutaneous Interventions

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Background: Intravascular administration of contrast media can have nephrotoxic effects particularly in patients with baseline renal insufficiency. Along with lowering serum cholesterol, statins have pleiotropic effects in the vasculature. It is unclear whether statin use has a protective effect against contrast-induced nephropathy (CN).

Methods: We evaluated 29,409 patients who had both baseline pre-procedure and peak

post-procedure serum creatinine measured at the time of their percutaneous coronary intervention (PCI). Baseline demographics and creatinine profile before and after the procedure were compared between patients who received pre-procedure statins and those who did not. CN was defined as increase in serum creatinine of >0.5 mg/dl.

Results: Baseline clinical characteristics were similar between the 2 groups (table). When compared to patients who did not receive pre-procedure statins, patients on pre-procedure statins had a lower incidence of CN (4.9 vs. 6.8, $p < 0.0001$) and a trend towards reduction of nephropathy requiring dialysis (0.4 vs. 0.6, $p = 0.07$). After adjustments for comorbidities, pre-procedure statin use was associated with a significant reduction in CN (OR 0.81, 95% CI 0.72-0.92, $p = 0.0009$).

Conclusions: Pre-procedure statin use is associated with significant reduction in CN after contemporary PCI.

Statin use and CN

Variable	Pre-statins N=11,017	No Pre-statins N=18,392	p-value
Age (mean (SD)), yrs	63.6	63.6	0.78
Female (%)	33.9	35.4	0.008
Baseline Creatinine (mean mg/dl)	1.2	1.2	0.50
Percent with Baseline Creatinine 1.5+mg/dl	12.9	12.6	0.54
Percent with Baseline Creatinine 2.0+mg/dl	4.8	5.0	0.42
Peak Creatinine (mean mg/dl)	1.3	1.3	0.30
Peak Creatinine 1.5+mg/dl	14.5	15.8	0.003
Peak Creatinine 2.0+mg/dl	6.6	7.9	<0.0001
Renal Failure Requiring Dialysis	0.4	0.6	0.07
Contrast Nephropathy	4.9	6.8	<0.0001

1172-69

Early Use of Small Molecule Platelet Glycoprotein IIb/IIIa Inhibitors for All Acute Coronary Syndrome Patients Is Superior to Selective Use of Abciximab for Only Those Requiring Percutaneous Coronary Interventions

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Background: Selective use of medication may be important when several competing therapies are available. Tirofiban and eptifibatid are small molecule platelet GP IIb/IIIa inhibitors with benefit in acute coronary syndromes (ACS), but may not be as effective as abciximab during percutaneous coronary intervention (PCI). However, abciximab does not have proven efficacy in medical management of patients with ACS. No prior study has attempted to balance the competing benefits of a strategy of giving all ACS patients a small molecule versus a strategy of using abciximab only if a patient undergoes PCI.

Methods: A decision analysis examined two treatment options and estimated under what conditions one strategy was superior to another. The two strategies were (1) treat all ACS patients initially with a small molecule GP IIb/IIIa inhibitor or (2) selectively use abciximab only in ACS patients who ultimately undergo PCI. Sensitivity analyses were performed over a wide range of assumptions. The primary outcome was life expectancy, and cost effectiveness and bleeding were a secondary outcomes.

Results: The strategy of general use of a small molecule GP IIb/IIIa inhibitor on presentation with ACS resulted in an average life expectancy of 15.93 years, compared with 15.71 years for selective use (life years savings of 0.22 years). The superiority of the general use strategy persisted over all but extremes in sensitivity analyses. Preliminary cost analyses showed general use as economically attractive, with cost per life year of less than \$50,000 over a wide range of assumptions. There was a similar likelihood of major bleeding for patients with general use v. selective (6.5% v 6.1%).

Conclusion: General use of early GP IIb/IIIa inhibition in all patients presenting with ACS leads to better outcomes than selective use. A selective use strategy may be superior only if a patient is extremely likely to undergo PCI (over 90%) or there is virtually no reduction of events in medically managed patients receiving GP IIb/IIIa inhibition. When faced with these competing strategies, the clinician should consider the significant, cost effective benefits to general use of small molecule platelet GP IIb/IIIa inhibitors in ACS.

1172-70

Tolerability, Safety, and Efficacy of Beta-Blockade in Black Patients With Heart Failure in the Community Setting: Insights From a Large Prospective Beta-Blocker Registry

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Background: Conflicting data exist regarding the tolerability and efficacy of beta-blockade in Black patients with heart failure (HF). In randomized controlled trials bucindolol appeared to worsen clinical outcome in Blacks while carvedilol apparently improved outcome comparably to White patients.

Methods: The Core Heart Failure Registry (COHERE) prospectively evaluated the early and 1-yr tolerability, safety, and efficacy of carvedilol in 4,280 HF patients treated in the community setting.

Results: Prior to initiation of carvedilol, Black patients (n=523) differed from White patients (n=3,433) in demonstrating more severe symptoms (NYHA Class III/IV, 44.3% vs 35.3%, $p < 0.001$), more diabetes (37.1% vs 30.3%, $p = 0.002$), less history of ischemic

heart disease (prior myocardial infarction, 22.9% vs 44.2%, $p<0.001$), and more history of hypertension (79.2% vs 55.1%, $p<0.001$). Slightly higher resting heart rates and blood pressures were also observed in Blacks. While the reported HF etiology was predominantly hypertensive in Blacks and ischemic in Whites, the proportion of patients with preserved left ventricular function did not differ between the two groups, as 16.5% of Whites and 16.7% of Blacks had left ventricular ejection fractions $>40\%$ ($p=0.93$). Physician assessment of carvedilol titration demonstrated excellent tolerability in both groups, with no problem or mildly difficult assessments recorded for 86.2% of Black patients vs 81.8% of White patients, $p=0.02$. There was no difference in distribution of carvedilol dose by race, with most patients achieving a dose of at least 6.25 mg bid. Compared to the 12 months prior to carvedilol initiation, hospitalization rates for all-causes, cardiovascular reasons other than HF, and HF were reduced in both groups during carvedilol treatment. The incidence of death per 1,000 person-years was similar in Blacks (71.0) and Whites (73.6), and the hazard ratio was 1.01 (95% CI 0.68 to 1.49; $p=0.96$).

Conclusions: In the community setting of COHERE, carvedilol was well tolerated in Blacks who, despite different baseline characteristics and risk factors for HF, also demonstrated safety and efficacy comparable to that seen in White patients.

1172-71 Practical Predictors of Clinical Outcomes in Patients Initiating Beta-Blockers for Heart Failure: Findings of a Community-Based Registry

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Background: Increased morbidity and mortality in heart failure (HF) patients has been related to risk factors derived from populations in clinical trials, at hospital discharge, or in localized geographic/socioeconomic strata, and were identified before wide use of beta-blockers for HF.

Methods: The Coreg Heart Failure Registry (COHERE) observed 4,280 unselected HF patients during 1-yr follow-up after initiating carvedilol in a community setting. Patients entered the registry regardless of ejection fraction (EF). Significant risk factors for the composite of death, hospitalization for HF and hospitalization for cardiovascular (CV) reasons other than HF were identified by age-, sex-, and race-adjusted analyses. Independent risk factors were identified from a multivariable analysis adjusted for all factors simultaneously.

Results: Over this period 7% of patients died, 11% were hospitalized for HF, 12% were hospitalized for other CV reasons, and 27% had any of these events. Key findings of the multivariate analysis are shown in the table.

Variable	Odds Ratio	95% Confidence Limits	P
NYHA class (IV vs I)	3.56	2.23 - 5.68	<0.001
NYHA class (III vs I)	2.85	2.08 - 3.91	<0.001
HF Hospitalization prior yr	1.92	1.63 - 2.25	<0.001
NYHA class (II vs I)	1.66	1.22 - 2.26	<0.001
History of angina	1.38	1.17 - 1.63	<0.001
HF duration (> 2yr vs < 6 mos)	1.28	1.06 - 1.54	0.009
History of diabetes	1.22	1.04 - 1.43	0.013
History of acute MI	1.20	1.01 - 1.43	0.039
MD (non-cardiologist vs cardiologist)	1.12	0.94 - 1.33	0.216
Sex (males vs females)	1.05	0.89 - 1.23	0.555
Age (per 1 yr increase)	1.01	1.00 - 1.01	0.171
Race (Black vs Caucasian)	1.00	0.78 - 1.28	0.992
MD (yrs since graduation 19-24 vs <13 yr)	0.82	0.68 - 1.00	0.055
MD (yrs since graduation 13-18 vs <13 yr)	0.76	0.62 - 0.94	0.011
Insurance (commercial vs Medicare/Medicaid)	0.76	0.60 - 0.95	0.017
MD (yrs since graduation >24 vs <13 yr)	0.71	0.58 - 0.87	<0.001
HF cause (Idiopathic vs CAD)	0.71	0.55 - 0.91	0.007
HF cause (HTN vs CAD)	0.69	0.53 - 0.89	0.004

CAD = coronary artery disease; HTN = hypertension

Although EF and blood pressure were significant predictors when adjusted for age, sex, and race, the relationship did not persist when simultaneously adjusted for other co-variables.

Conclusions: Simple historical information identifies community HF patients at increased risk for death or hospitalization in the year after initiating carvedilol. In this population not selected by EF, these historical factors appear to better predict risk than did EF.

1172-72 Combination Evidence-Based Therapy Improves Survival After Percutaneous Coronary Intervention

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Introduction: The impact of combination "evidence-based" therapy (ASA, beta-blockers, ace inhibitors, and statin use) on long-term survival of patients undergoing percutaneous coronary intervention (PCI) is uncertain.

Hypothesis: We hypothesized that post-PCI patients with higher rates of use of evidence-based therapy would have lower mortality rates.

Methods: We collected clinical and angiographic data on consecutive PCIs from July 1997 to October 2001. An additive evidence-based therapy score (0-4) was calculated by applying 1 point each to hospital discharge on ASA, beta-blockers, ace inhibitors and statins. Follow-up long-term survival was obtained by telephone contact and/or searching the Social Security Death Index. Using a Cox proportional hazards model, we assessed the impact of the score on survival after adjusting for age, sex, cardiac risk factors (e.g., diabetes(DM), hypertension, congestive heart failure, ejection fraction, extent of coronary disease, renal insufficiency, hx of bypass surgery/PCI/acute myocardial infarction(MI), clinical priority and procedural factors (e.g., stent, gIIB/IIIa use).

Results: 2311 patients underwent 3231 PCIs with a mean-follow-up of 344 +/- 225 days. Mean age was 63 +/- 12 years; 752 (33%) were women, 609 (26%) had DM, 487 (19%) had recent MI. Most (78%) received stents. 211 (9%) patients were discharged on 0-1 evidence-based therapies (i.e., score of 0-1) and 570 (25%) were discharged on all 4 evidence-based therapies. After multivariate adjustment, the evidence-based therapy score remained an independent predictor of improved survival (HR per 1 unit increase in evidence-based therapy score, 0.78; 95% ci, 0.66-0.92; $p=0.003$). Other significant factors included: advanced age, congestive heart failure, ejection fraction, left main disease, multivessel PCI, renal insufficiency, and post-PCI QWMI.

Conclusion: The use of combination evidence-based therapy as assessed by an additive score is independently associated with improved survival after PCI. Evidence-based therapy use should be strongly encouraged and implemented in these patients.

1172-73 First Postoperative Day Prognosis Score in Patients Undergoing Cardiac Surgery Based on Pre-, Peri-, and Postoperative Variables

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Background: We have several prognosis models for heart surgery (HS). However, these scores were based on preoperative variables, our model have used both, preoperative and first postoperative day (FPOD). Objectives: To create a predictive score of in-hospital mortality in patients (pts) undergoing HS and admitted to a public and private surgical intensive care unit (SICU), analyzing pre-, perioperative and FPOD variables. Case series and methods: Classical cohort of data (1,458 pts) consecutively collected from June 2000 to February 2003. All 46 variables were previously defined according to the major prognostic index found in the literature. The statistical analysis comprised: univariate analysis with the chi-square test, Student t test, Mann-Whitney and Pearson tests, followed by logistic regression and stepwise (likelihood ratio), with the linear trend test and ROC curve. Results: The score, shown in the attached table, provides the following risk prediction: 0 to 4 - low risk; 5 to 9 - medium; and 10 to 14 - high. The results had significance ($p<0.0001$) and linear trend ($p<0.0001$). The area under the ROC curve was 0.84. Conclusions: The score shows the strength of the variables on the FPOD, such as worse PO2/ FIO2 < 100, epinephrine > 0,1 or norepinephrine > 0,1, and mechanical ventilation duration > 12 h, probably related to perioperative factors, such as type of anesthesia, host response, hemodynamic profile, use or nonuse of corticosteroids.

95% CI for OR

Characteristics	OR	Lower	Upper	Score
Age 64 to 74years	2,05	1,16	3,63	+1
Age >75 years	4,79	2,60	8,83	+2
Left atrium>45mm	2,58	1,53	4,37	+1
Creatinine>2mg/dl	4,84	1,87	12,48	+2
Extracorporeal circulation>180min	4,93	1,99	12,18	+2
Worse FPOD PO2/FiO2 < 100	9,47	3,18	28,23	+3
FPOD Epinephrine > 0.1 or Nor > 0.1 mcg/kg/min	6,78	3,99	11,53	+3
FPOD duration of mechanical ventilation > 12 h	2,24	1,34	3,72	+1

1172-74 Pulmonary Hypertension Is Strongly Associated With Mortality in Sickle Cell Disease: Comparison of Echocardiographic Outcome Predictors

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Background: The development of pulmonary hypertension (PH) has been reported in most hemolytic anemias and preliminary reports have suggested its prognostic value in sickle cell disease (SSD). We, therefore, assessed the predictive values of transthoracic