Enrollment Disparities on the Basis of Age and Chronic Disease Burden in Cardiovascular Clinical Trials: Are Patients’ Decisions the Reason?

Anand Parekh, Neil R. Powe, Joel B. Braunstein, Johns Hopkins Medical Institutions, Baltimore, MD

Background: Randomized controlled trials have been criticized for enrolling select groups of patients, while excluding those most representative of the population under study. In cardiovascular disease, this concern implies inadequate representation of patients who are older and have multiple comorbidities. We determined willingness to participate (WTP) in a cardiovascular clinical trial among a community-based sample of patients with these characteristics.

Methods: We approached 1440 randomly selected individuals from 13 Maryland-based outpatient cardiology and internal medicine clinics to complete a brief self-administered survey, which contained a 1-page description of an efficacy trial of a new drug for prevention of myocardial infarction. We measured WTP on a 5-point Likert response scale (+ response = Very likely/likely). Patients provided demographic and socioeconomic information, along with a report of their comorbidity burden, measured by presence of conditions included in the Deyo-Charlson case-mix severity index.

Results: Of 1132 patients eligible, 789 (70%) patients responded. Respondents were mean aged 54 ± 16 (range 18-89) years, 51% female, and 35% black, with a median of 2 comorbidities (range 0-11). Older-aged patients (≥ 75 years) (n = 79) were less WTP than younger patients (19% vs. 36%, p = 0.01). Patients with more extensive comorbidity, however, were no less WTP than those with less extensive comorbidity (WTP = 29% if no comorbidity, 34% if 1 comorbidity, 35% if 2-4 comorbidities, 39% if 5-7 comorbidities, p = 0.43). In multivariable logistic regression, after adjusting for race, gender, income, and education, older age was associated with a 66% lower likelihood of WTP (OR, 95% CI = 0.35, 0.19-0.64; p = 0.001), while each categorical increase in comorbidity was associated with a 19% higher likelihood of WTP (1.19, 1.00-1.42; p = 0.05).

Conclusion: While older age is independently associated with lower WTP in cardiovascular clinical trials, more extensive comorbidity is not. These findings warrant consideration in the design of future trials, which seek to adequately enroll cardiac patients who are most representative of those encountered in routine clinical practice.

11:30 a.m.

Poster Session 6 - Special Topics

Tuesday, March 09, 2004, Noon-2:00 p.m.
Morial Convention Center, Hall G
Presentation Hour: 1:00 p.m.-2:00 p.m.

Poster Session 5

1153 Patient and Physician Factors Important to Successful Care

Mien Gupta, Blanche Aaron, Janice Burtcher, Nicoletta Bonafede, David Borts, Brampton Research Associates, Brampton, ON, Canada, William Osler Health Centre, Brampton, ON, Canada

Background: Little is known about patient attitudes towards informed consent and participation in cardiovascular clinical trials (CT). We surveyed 430 consecutive participants in 8 large in-patient (IP) and out-patient (OP) trials between 1998-2002 through a mailed survey sent out over 3 months.

Results: Of 430 participants, 37 (8.6%) died prior to study completion, and 242 (56.1%) responded to the survey (69% male). Similar proportions had participated in IP and OP CT (46.6% vs. 53.3%). The majority were 50-69 years old (59.8%), with 35.7% > age 69, with no difference in age distribution between genders. The majority had a high school (38.7%) or university degree (28.5%) and were unemployed or retired (66.9%). Most patients had read the study consent form (87.6%), and 3.5% found the consent form too difficult to understand. Women were more likely to feel pressured to join their CT than men (16.2% vs. 5.5%, p = 0.024). Side effects attributed to study drug were common among women (27.5% vs. 11.9%, p < 0.005), but early drug termination was similar between genders (7.3% vs. 6.5%). The majority (74.4%) were willing to participate in future CT. Other differences noted:

% IP Participants % OP Participants p
Understood consent form 68.0 89.0 0.0002
Received copy of consent 49.1 70.5 0.0023
Felt pressure to join study 15.4 3.1 0.003
GP aware of participation 47.6 79.5 < 0.0001
Would participate again 65.5 82.2 0.003

Conclusions: CT participants are satisfied with informed consent and are willing to participate in future trials. Women are more likely to feel pressured into joining, and to experience study-related side effects. The consent process is sub-optimal for participants of in-patient clinical trials, and warrants further investigation.

1153-68 Do Patients With Heart Failure Have a Medically Accurate Mental Image of Their Illness (also known as Illness Representation)?

Nancy M. Albert, The Cleveland Clinic Foundation, Cleveland, OH

Background: HF self-care behaviors modulate symptoms, morbidity and prognosis but adherence is inconsistent. Mental image of an illness or illness representation (REP) influences coping and behavior. Attributes of REP that influence behavior in other chronic conditions are identity (label, silent processes, symptoms), time-line (duration), consequences (prognosis) and control (self-care actions). Medically inaccurate HF-REP may negatively impact self-care adherence. There are no published reports of the medical accuracy of patients’ HF-REP. Methods: 104 chronic systolic HF patients completed a 33-item Likert scale of HF-REP statements. Patient sum score (range 33-132) determined the level of HF-REP medical accuracy and item mean score (range 1-4) specified items of low and high medical accuracy. Demographic and medical history data were used to determine predictors of medically accurate HF-REP. Instrument Cronbach’s alpha was 0.8535; validity testing completed. Results: Mean age was 61.8 ± 13.13; 66% of patients had HF for > 2 years. Mean sum score was 98.8, reflecting medically accurate HF-REP. Thirty patients (28%) scored in the mixed medically accurate-inaccurate range (72-93).