Study of the Therapeutic Effects of Intercessory Prayer (STEP) in Cardiac Bypass Patients – A Multi-Center Randomized Trial of Uncertainty and Certainty of Receiving Intercessory Prayer

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Short Title: STEP: Intercessory Prayer and Complications following CABG

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Background: Intercessory prayer is widely believed to influence recovery from illness, but claims of benefits are not supported by well-controlled clinical trials. Prior studies have not addressed whether prayer itself or knowledge/certainty that prayer is being provided may influence outcome. We evaluated whether (1) receiving intercessory prayer or (2) being certain of receiving intercessory prayer was associated with uncomplicated recovery after coronary artery bypass graft (CABG) surgery.

Methods: Patients at 6 US hospitals were randomly assigned to one of 3 groups: 604 received intercessory prayer after being informed they may or may not receive prayer; 597 did not receive intercessory prayer, also after being informed they may or may not receive prayer; and 601 received intercessory prayer after being informed they would receive prayer. Intercessory prayer was provided for 14 days, starting the night before CABG. The primary outcome was presence of any complication within 30 days of CABG. Secondary outcomes were any major event and mortality.

Results: In the two groups uncertain about receiving intercessory prayer, complications occurred in 52% (315/604) of patients who received intercessory prayer versus 51% (304/597) of those who did not (relative risk 1.02, 95% confidence interval 0.92-1.15). Complications occurred in 59% (352/601) of patients certain of receiving intercessory prayer compared with the 52% (315/604) of those uncertain of receiving intercessory prayer (relative risk 1.14, 95% confidence interval 1.02-1.28). Major events and 30-day mortality were similar across the 3 groups.

Conclusions: Intercessory prayer itself had no effect on complication-free recovery from CABG, but certainty of receiving intercessory prayer was associated with a higher incidence of complications.

More than 350,000 Americans and 800,000 people worldwide have coronary artery bypass surgery (CABG) every year.[1] Despite advances in surgical techniques, anesthesia and post-operative care in recent years, approximately 40% have at least one complication within 30 days of CABG.[2] Patients undergoing CABG often report that they are depressed[3] and depression is associated with cardiac events[4] and mortality[5] following CABG. Many patients report using private or family prayer to cope with this stressful experience.[6]

While the effects of private prayer on outcome after CABG are unknown, 4 trials investigated the effects of intercessory prayer in heterogeneous groups of cardiac patients. Results have been mixed – intercessory prayer was beneficial in 2 studies[7-8] and had no effect in 2 studies.[9-10] The studies showing benefit used sub-optimal methods of data analysis, non standard methods of randomization and allocation concealment, and untested outcome measures,[11-14] and those showing no effect had insufficient statistical power to reach this conclusion.[9-10] Despite these concerns, the Cochrane Collaboration[15] and others[16-17] have concluded that further scientific investigation of the possible effects of intercessory prayer is warranted.

We conducted a prospective trial to evaluate whether providing intercessory prayer or knowing that intercessory prayer would be provided influenced outcome after CABG. Patients undergoing CABG were randomized to 1 of 3 groups. Two groups did not know (i.e., were uncertain) whether they would receive intercessory prayer – Group 1 received intercessory prayer and Group 2 did not. The third group (Group 3) was informed (i.e., were certain) that

they would receive intercessory prayer. All patients were followed to determine whether any complication[18] any major event[19] or death occurred within 30 days of CABG.

METHODS

Study Design

The Study of the Therapeutic Effects of intercessory Prayer was a multi-center randomized clinical trial, monitored by an independent Data Safety Monitoring Board. The Institutional Review Board at 6 participating hospitals (Integris Baptist Medical Center, Oklahoma City OK; Beth Israel Deaconess Medical Center, Boston MA; Washington Hospital Center, Washington DC; Baptist Medical Center, Memphis TN; Mayo Clinic, Rochester MN; St. Joseph's Hospital, Tampa FL) approved the protocol, all amendments and procedures for obtaining informed consent. Details of the study design and methods have been published elsewhere.[20]

Patients

Patients scheduled for non-emergent CABG were eligible to participate in the study. Patients were identified in the cardiac catheterization laboratory, pre-operative testing area, or on surgical schedule and were contacted with permission of their surgeon, cardiologist or primary care physician. Inclusion criteria were: age 18 years or older and able to read or understand English. Patients were excluded if they were: scheduled for emergent CABG (next available operating room slot), CABG more than 14 days after enrollment, other planned surgery within 30 days of CABG, minimally invasive CABG, ongoing chest pain, unstable angina or CABG with planned valve replacement, stent, angioplasty or carotid endarterectomy. There were no eligibility criteria relating to religious belief – patients of any or no religious faith were eligible to

participate. Each patient was informed about the study and asked to sign the informed consent document. Enrolled patients were informed that their first name and first initial of their last name might be forwarded to 3 Christian prayer groups. Pre-operatively subjects were asked whether they believed in spiritual healing and whether friends, relatives, and/or members of their religious institution would be praying for them.

Randomization

Randomization assignments (serially numbered, opaque, sealed envelopes)[21] were stratified by center using permuted blocks of size 9, 12 and 15, presented in random order. The envelope message for patients in Groups 1 (Uncertain, Intercessory Prayer) and 2 (Uncertain, No Intercessory Prayer) stated that they "may or may not be prayed for". The message for patients in Group 3 (Certain, Intercessory Prayer) stated that they "will be prayed for". Study staff observed as each patient opened their randomization envelope, but remained unaware of the contents. The enrollment form (patient's first name, first initial of last name, study identification number, dates of randomization and scheduled surgery) was then faxed to the Coordinating Center. Patients were instructed to refrain from notifying study personnel or hospital staff of their treatment assignment.

Intervention

The first name, first initial of last name and an anonymous site code for patients assigned to Group 1 and Group 3 (those to receive intercessory prayer) were placed on the prayer list for 14 consecutive days, starting the night before each patient's scheduled surgery. The same daily updated list was faxed to each of 3 intercessory prayer groups every weekday throughout the

study,[20] and the list was posted in a central location no later than 7:15 PM EST each evening, with intercessory prayer beginning by midnight for patients on the list. The intercessors agreed to add the phrase: "for a successful surgery with a quick, healthy recovery and no complications" to their usual prayers.

Intercessors from 3 Christian groups (2 Catholic (St. Paul's Monastery, St. Paul, Minnesota; Community of Teresian Carmelites, Worcester, Massachusetts) and 1 Protestant (Silent Unity, Lee's Summit, Missouri)) provided study prayer throughout the trial. We were unable to locate other Christian, Jewish, or non-Christian groups that could receive the daily prayer list required for this multi-year study.

Outcome Measures

The primary outcome was presence of any post-operative complications defined by the Society of Thoracic Surgeons Adult Cardiac Surgery Database - within 30 days of CABG.[18] Secondary end-points were the presence of any "major event"– defined by the New York State Cardiac Surgery Reporting System[19] and 30-day mortality. Trained research nurses at each site reviewed medical records of study subjects for presence of complications within 30 days of CABG. All patients discharged alive before post-operative day 30 were called to determine if they had been readmitted to any other hospital within 30 days of surgery. All patients' medical records were independently audited.[20] All investigators, research nurses, interviewers and auditors were blinded to patients' group assignment throughout the study.

Sample Size

We anticipated that approximately 50% of patients in Group 2 (Uncertain, No Intercessory Prayer) would have a complication within 30 days of CABG.[2] On the basis of investigator consensus, we hypothesized that if 40% of patients in Group 1 (Uncertain, Intercessory Prayer), and 30% of patients in Group 3 (Certain, Intercessory Prayer) had any complication within 30 days of CABG, these reductions would be clinically important. We anticipated that 5% of patients would be lost to follow-up during the study period, all of whom would conservatively be assumed to have had a complication for the intent to treat analysis. We calculated our sample size using these adjusted proportions (45%, 55% and 35% respectively), a two-sided alpha level of 0.025 (Bonferroni adjustment[22] for two primary comparisons – Group 1 (Uncertain, Intercessory Prayer) versus Group 2 (Uncertain, No Intercessory Prayer) and Group 3 (Certain, Intercessory Prayer) versus Group 1 (Uncertain, Intercessory Prayer) and a single interim analysis (O'Brien Fleming boundaries[24] for early stopping for efficacy or futility (null hypothesis rejected for $|z| > 3.1495$ and accepted for $|z| < 0.7769$ (EaST, Cytel Software Corporation, Cambridge, MA)). Since we required 572 patients per group to compare Group 1 with Group 2 and 600 per group to compare Group 1 with Group 3, the final sample size was 600 patients per group or 1,800 patients for the study (1:1:1 allocation ratio).

Analysis

Baseline continuous variables were compared using analysis of variance and baseline and outcome categorical variables were compared using the chi-square test. Risk ratios and 95 percent confidence intervals were used for comparison of Group 1 (Uncertain, Intercessory Prayer) versus Group 2 (Uncertain, No Intercessory Prayer) and for Group 3 (Certain,

Intercessory Prayer) versus Group 1 (Uncertain, Intercessory Prayer). A multivariate logistic-regression model (stepwise algorithm) was used to evaluate whether baseline covariates, other than study group, were associated with occurrence of complication and to assess consistency of the unadjusted and final model. Pre-specified covariates were included and variables retained in the final models had a p-value of 0.05 or less. Statistical analyses were performed using SAS 6.12 (Cary, NC) and SPSS 11.0 (Chicago, IL).

RESULTS

Patient Characteristics

Patients were enrolled between January 1998 and November 2000. Of 3,295 eligible patients, 1,493 did not wish to participate and 1,802 patients enrolled (Oklahoma–548; Massachusetts–492; Washington DC–284; Tennessee–256; Minnesota–200; Florida–22) (Figure 1). Intercessory prayer was provided according to the protocol to 1,192/1,205 (99%) of patients randomized to Group 1 and Group 3, over the course of the study period (1,046 days). The overall daily mean of intercessors was 33 (range 10–58). Intercessors reported praying from 30 seconds to several hours, from 1 to 4 times per day.

There were no important differences in baseline or operative characteristics (Table I) across the 3 groups. These characteristics are similar to those reported by the Society of Thoracic Surgeons Adult Cardiac Surgery Database,[24] the New York State Cardiac Surgery Reporting System,[25] and both characteristics and our 45% refusal rate are comparable to the Bypass Angioplasty Revascularization Investigation.[26]

Similar proportions in Group 1 (68.2% (412/604)), Group 2 (63.0% (376/597)) and Group 3 (64.4% (387/601)) strongly agreed with the statement, "I believe in spiritual healing." Almost all subjects believed that friends, relatives, and/or members of their religious institution would be praying for them –Group 1 (95.0% (574/604)), Group 2 (96.8% (579/597)) and Group 3 (96.0% (577/601)).

Interim Analysis Results

The independent Data Safety Monitoring Board (DSMB) reviewed the interim data. An independent statistician provided blinded, then unblinded, interim results to the DSMB members. Similar proportions of patients in Group 1 (51% (151/299)) and Group 2 (51% (155/304)) had at least 1 complication (p=0.905). Sixty three percent (186/297) patients in Group 3 had a complication (compared to 51% patients in Group 1 (p=0.003), which did not reach the interim boundary. Without evidence of early efficacy and in the absence of concerns about safety, the DSMB advised that the trial be completed as planned.

Final Analysis Results

Effect of Intercessory Prayer on Outcomes (Group 1 vs. Group 2)

Any complication: 52% (315/604) in Group 1 and 51% (304/597) in Group 2 had at least 1 complication (relative risk 1.02, 95% confidence interval (CI) 0.92–1.15, p=0.67) (Figure 2). These proportions include 25 patients who had missing data– 21 did not have CABG (Group 1: 11, Group 2: 10) and 4 had no complication prior to being lost to follow-up before day 30 (Group 1: 2, Group 2: 2) – all 25 assumed *a priori* to have had a complication. In a "modified intent to treat" analysis (excluding these 25 patients), the results were similar: 51% (302/591) in

Group 1 and 50% (292/585) in Group 2 had at least 1 complication (relative risk 1.02, 95% CI 0.91–1.15, p=0.68). The proportion of patients with at least 1 complication varied from 40% to 65% across the 6 hospitals. Details of the complications are shown in Table II (see AHJ website for individual complications). There were no differences between Group 1 and Group 2 in planned subgroup analyses (Figure 3a).

***Any major event**:* 18% (109/604) in Group 1 versus 13% (80/597) in Group 2 (relative risk 1.18, 95% CI 1.03-1.35, p=0.027) had at least 1 major event within 30 days of CABG. These proportions include 36 patients who had missing data – 21 did not have CABG (Group 1: 11, Group 2: 10) and 15 had no complication prior to being lost to follow-up (Group 1: 8 and Group 2: 7), all 36 patients were assumed to have had a major event for the intent-to treat analysis. After excluding these 36 patients in the modified intent to treat analysis, 15% (90/585) in Group 1 and 11% (63/580) in Group 2 had a major event (relative risk 1.20, 95% CI 1.04–1.39, p=0.022).

Mortality: Three percent (16/604) of patients in Group 1 and 2% (14/597) in Group 2 died within 30 days of CABG. The relative risk was 1.06 (95% CI 0.76–1.49, p=0.74).

Effect of Certainty of Receiving Intercessory Prayer on Outcomes (Group 3 vs. Group 1)

Any complication: In Group 3, 59% (352/601) had at least 1 complication, compared to 52% (315/604) in Group 1 (relative risk 1.14, 95% CI 1.02–1.28, p=0.025). These proportions included 25 patients who did not have CABG (Group 3: 6 and Group 1: 11) or who no complication prior to being lost to follow-up before day 30 (Group 3: 6, Group 1: 2). The results of the modified intent to treat analysis excluding the 25 patients were almost identical: in Group

3, 58% (340/589) had at least 1 complication versus 51% (302/591) in Group 1 (relative risk 1.14, 95% CI 1.02–1.29, p=0.022). Although not a preplanned analysis, significantly more patients with new onset atrial fibrillation/flutter (AF) in Group 3 (192/601:32%) versus Group 1 (145/604:24%) (relative risk 1.21, 95% CI 1.08–1.36, p=0.0022). Patients in Group 3 were consistently more likely to have a complication than those in Group 1 across the planned subgroup analyses (Figure 3b).

Any major event*:* 14% (85/601) in Group 3 had a major event versus 18% (109/604) in Group 1 (relative risk 0.86, 95% CI 0.72–1.02, p=0.065). These proportions include 33 patients who had missing data– 17 did not have CABG (Group 3: 6, Group 1: 11) and 16 patients had no complication prior to being lost to follow-up before day 30 (Group 3: 8, Group 1: 8). The modified intent to treat analysis (excluding these 33 patients) yielded similar results: 12% (71/587) in Group 3 and 15% (90/585) in Group 1 had a major event (relative risk 0.86, 95% CI 0.72–1.04, p=0.10).

Mortality: Two percent (13/601) in Group 3 and 3 percent (16/604) in Group 1 and died within 30 days of CABG. The relative risk was 0.90 (95% CI 0.60–1.35, p=0.58).

Predictors of Occurrence of Any Complication

The independent predictors of occurrence of any complication within 30 days of CABG are listed in Table III. Neither social nor religious variables were associated with occurrence of any complication.

DISCUSSION

Our study had 2 main findings. First, intercessory prayer itself had no effect on whether complications occurred after CABG. Second, patients who were certain that intercessors would pray for them had a higher rate of complications than patients who were uncertain but did receive intercessory prayer.

While our study population appears similar and representative of CABG patients in the US,[26] the proportion of patients in all 3 study groups who developed complications or major events was higher in our study population than reported elsewhere. These higher rates are likely attributable to our 100% audit of all case report forms against information in the medical record to ensure consistent and complete reporting of complications and major events after CABG. We do not believe there was differential reporting by treatment group because the independent auditor and site research nurses, who completed the case report forms, were unaware of patients' assignment.

Our findings are not consistent with prior studies showing that intercessory prayer had a beneficial effect on outcomes in cardiac patients.[7-8] Possible explanations for the lack of effect of intercessory prayer itself include the following. First, intercessory prayer may not be effective in reducing complications after CABG. Second, the magnitude of the reduction could be smaller than the 10% that our study was powered to detect. Third, the occurrence of any complication within 30 days of surgery may not be appropriate or relevant to the effects of intercessory prayer.

We have no clear explanation for the observed excess of complications in patients who were certain that intercessors would pray for them (Group 3). While post-operative atrial

fibrillation/flutter was responsible for much of the excess of complications in the Group 3 patients, this outcome is only one of the complications that contributed to the composite outcome[27] and the excess may be a chance finding. Although there was a borderline excess of major complications (secondary outcome) in patients in Group 1, this excess may also be well due to chance.

Our study had limitations: we placed constraints on how intercessory prayer was provided in this study. Although the intercessors were motivated to participate in the trial, they received limited information without feedback on the patient's condition; did not know or have any communication with patients or their families; used a standard study intention during their prayers; and prayed for patients in Groups 1 and 3 for a study-specific 14 days (anticipated maximum duration of inpatient stay for at least 95% of subjects). Prior to the start of this study, intercessors reported that they usually receive information about the patient's age, gender and progress reports on their medical condition; converse with family members or the patient (not by fax from a third party); use individualized prayers of their own choosing; and pray for a variable time period based on patient or family request. Our rationale for altering the way in which intercessory prayer is routinely provided was to enable us to standardize the initiation and duration of intercessory prayer, to assess compliance with provision of study prayer, and to direct the intercessors away from praying for everyone in the trial (by focusing on praying for those assigned to Groups 1 and 3). The strict study instructions for providing intercessory prayer do not permit us to explore relationships between presence or absence of complications and the amount, duration and timing of intercessory prayer.

We did not request that subjects alter any plans for family, friends and/or members of their religious institutions to pray for them, as to do so would have been unethical and impractical. At enrollment, most subjects did expect to receive prayers from others regardless of their participation in the study. We also recognize that subjects may have prayed for themselves. Thus our study subjects may have been exposed to a large amount of non-study prayer and this could have made it more difficult to detect the effects of prayer provided by the intercessors.

The finding that intercessory prayer, as provided in this study, had no effect on complication-free recovery from CABG may be due to the study limitations. Understanding why certainty of receiving intercessory prayer was associated with a higher incidence of complications will require additional study.

Private or family prayer is widely believed to influence recovery from illness and the results of this study do not challenge this belief. Our study focused only on intercessory prayer as provided in this trial and was never intended to and cannot address a large number of religious questions, such as whether God exists or whether God answers intercessory prayers or whether prayers from one religious group work in the same way as prayers from other groups.

REFERENCES

1 Kozak LJ, Owings MF, Hall MJ. National Hospital Discharge Survey: 2002 annual summary with detailed diagnosis and procedure data. Vital Health Stat 13. 2005;158:1-199.

2 1997 Society of Thoracic Surgeons Adult Cardiac Surgery Database Website. Available at: http://www.sts.org/doc/2988. Accessed: 12/20/2004.

3 McKhann GM, Borowicz LM, Golsborough MA, et al. Depression and cognitive decline after coronary artery bypass grafting. Lancet 1997;349:1282-4.

4 Connerney I, Shapiro PA, McLaughlin JS, et al. Relation between depression after coronary artery bypass surgery and 12-month outcome: a prospective study. Lancet 2001;358: 1766-71.

5 Blumenthal JA, Lett HS, Babyak MA, et al. Depression as a risk factor for mortality after coronary artery bypass surgery. Lancet 2003;362: 604-9.

6 Ai AL, Peterson C, Bolling SF, et al. Private prayer and optimism in middle-aged and older patients awaiting cardiac surgery. Gerontologist 2002;42:70-81.

7 Byrd RC. Positive therapeutic effects of intercessory prayer in a coronary care unit population. South Med J 1988;81:826-9.

8 Harris WS, Gowda M, Kolb JW, et al. A randomized, controlled trial of the effects of remote intercessory prayer on outcomes in patients to the coronary care unit. Arch Intern Med 1999;159:2273-8.

9 Krucoff MW, Crater SW, Green CL, et al. Integrative noetic therapies as adjuncts to percutaneous intervention during unstable coronary syndromes: Monitoring and Actualization of Noetic Training (MANTRA) feasibility pilot. Am Heart J 2001;142:760-9.

10 Aviles JM, Whelan SE, Hernke DA, et al. Intercessory prayer and cardiovascular disease progression in a coronary care unit population: A randomized controlled trial. Mayo Clin Proc 2001;76:1192-8.

11 Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. Lancet 2001;357(9263):1191-4.

12 Cohen CB, Wheeler SE, Scott DA, et al. Prayer as therapy. A challenge to both religious belief and professional ethics. The Anglican Working Group in Bioethics. Hastings Cent Rep 2000; 30:40-7.

13 Halperin EC. Should academic medical centers conduct clinical trials of the efficacy of intercessory prayer? Acad Med 2001; 6:791-7.

14 Chibnall JT, Jeral JM, Cerullo, MA. Experiments on distant intercessory prayer God, science, and the lesson of Massah. Ann Intern Med 2001;161:2529-36.

15 Roberts L, Ahmed I, Hall S. Intercessory prayer for the alleviation of ill health. Cochrane Database Syst Rev 2000; (2):CD000368.

16 Astin JA, Harkness E, Ernst E. The efficacy of "distant healing": a systematic review of randomized trials. Ann Intern Med 2000; 132:903-10.

17 Abbot NC. Healing as a therapy for human disease: a systematic review. J Altern Complement Med 2000; 6:159-69.

18 Society of Thoracic Surgeons Adult Cardiac Surgery Database Website. Available at: http://www.sts.org/database/corefullspecs235.pdf. Accessed on 12/20/2004.

19 New York State Cardiac Surgery Reporting System. Available at: http://www.sts.org/outcomes/ny/csrs197.pdf. Accessed on 12/20/2004.

20 Dusek JA, Sherwood JB, Friedman R, et al. Study of the Therapeutic Effects of Intercessory Prayer (STEP): Study design and research methods. Am Heart J 2002;143-577-84.

21 Schulz KF, Grimes DA. Allocation concealment in randomised trials: defending against deciphering. Lancet 2002;359(9306):614-8.

22 Dunn OJ. Multiple comparisons among means. J Am Stat Assoc 1961; 56:52-64.

23 O'Brien PC, Fleming TR. A multiple testing procedure for clinical trials. Biometrics 1979; 35:549-56.

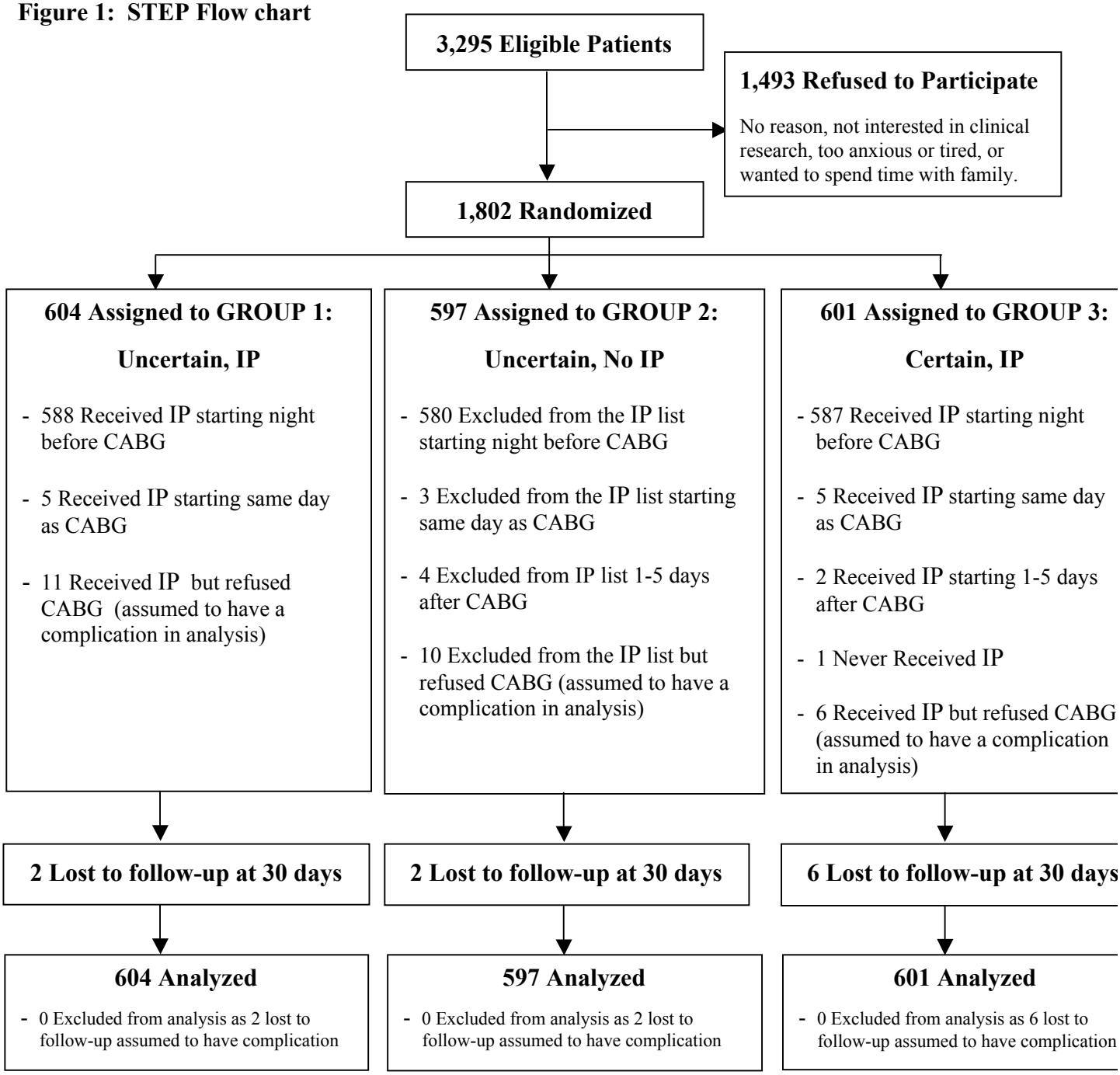
24 Grover Fl, Shroyer LW, Hammermeister K, et al. A decade's experience with quality improvement in cardiac surgery using the Veterans Affairs and Society of Thoracic Surgeons national databases. Ann Surg. 2001;234:464-72.

25 New York State Department of Health Cardiac Services Program 1997 CSRS Data: Dated February 22, 2002.

26 Brooks MM, Jones RH, Bach RG, et al. Predictors of mortality and mortality from cardiac causes in the bypass angioplasty revascularization investigation (BARI) randomized trial and registry. For the BARI Investigators. Circulation 2000;101:2682-9.

27 Lauer MA, Topol EJ. Clinical trials--multiple treatments, multiple end points, and multiple lessons. JAMA 2003;289(19):2575-7.

Figure 1: STEP Flow chart



Legend: IP= Intercessory Prayer, CABG= Coronary Artery Bypass Graft Surgery.

Table I: Selected Baseline and Operative Characteristics

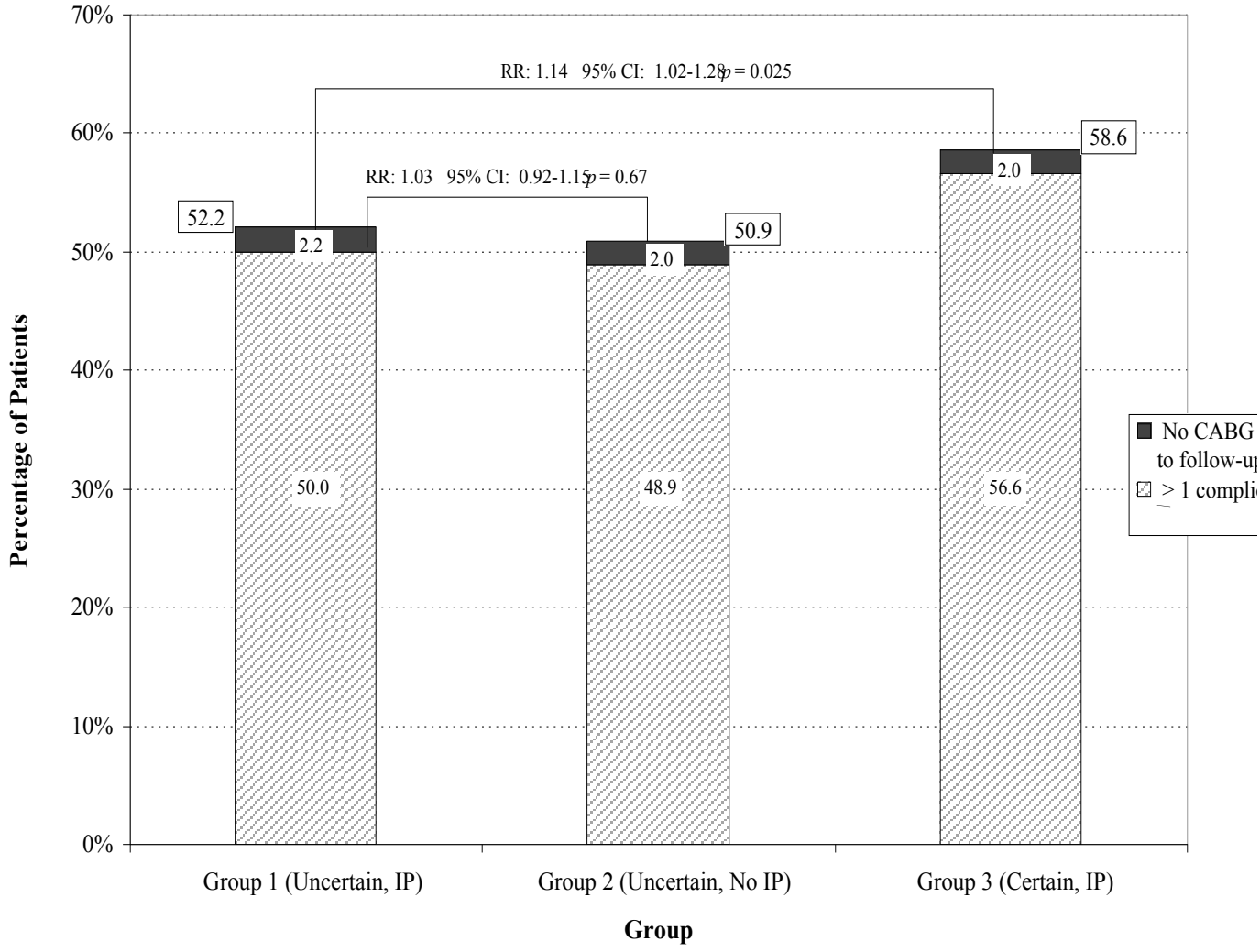
	Group 1: Uncertain, IP (n=604)	Group 2: Uncertain, No IP (n=597)	Group 3: Certain, II (n=601)
Demographics			
Mean age in years (± SD)	64.2 (± 10.3)	63.4 (± 11.2)	64.2 (± 10.5)
Male – no. (%)	410 (68)	432 (72)	441 (73)
Self identified Caucasian – no. (%)	550 (91)	519 (87)	547 (91)
Current Smoker – no. (%)	79 (13)	94 (16)	84 (14)
Ever smoked – no. (%)	317 (52)	297 (50)	333 (55)
High school education or less – no. (%)	326 (54)	296 (50)	333 (55)
Cardiovascular History			
Hypertension – no. (%)	446 (74)	425 (71)	452 (75)
Diabetes Mellitus – no. (%)	204 (34)	177 (30)	207 (34)
Myocardial Infarction (MI) – no. (%)	299 (50)	277 (46)	288 (48)
Congestive Heart Failure (CHF) – no. (%)	98 (16)	81 (14)	88 (15)
Chronic Obstructive Pulmonary Disease (COPD) – no. (%)	61 (10)	54 (9)	78 (13)
Peripheral Vascular Disease (PVD) – no. (%)	80 (13)	85 (14)	63 (10)
Cerebrovascular Accident (CVA) – no. (%)	49 (8)	49 (8)	53 (9)
Untreated Carotid Stenosis (UCS) – no. (%)	35 (6)	28 (5)	41 (7)
Renal failure – no. (%)	20 (3)	12 (2)	23 (4)
Immunosuppressive therapy – no. (%)	33 (5)	24 (4)	35 (6)
Prior Coronary Artery Bypass Grafting (CABG) – no. (%)	46 (8)	41 (7)	47 (8)
Current Cardiovascular			
Mean Ejection Fraction (± SD)	51.7 (± 14.1)	51.8 (± 13.7)	53.3 (± 13.3)
Mean Body Surface Area (± SD)	1.98 (± 0.23)	1.99 (± 0.23)	2.01 (± 0.22)
Beta-Blockers within 30 days of CABG– no. (%)	327 (54)	315 (53)	308 (51)

Table I: Selected Baseline and Operative Characteristics (cont)

	Group 1: Uncertain, IP (n=604)	Group 2: Uncertain, No IP (n=597)	Group 3: Certain, II (n=601)
Religious			
Any religious affiliation – no. (%)	485 (80)	472 (79)	475 (79)
Religious denomination – no. (%)			
Protestant	348 (58)	360 (60)	363 (60)
Catholic	165 (27)	155 (26)	160 (27)
Jewish	17 (3)	16 (3)	15 (3)
Other	20 (3)	19 (3)	20.(3)
None	12 (2)	17 (3)	5 (1)
Missing	42 (7)	30 (5)	38 (6)
Operative			
Mean cross clamp time in minutes (± SD)	63.5 (± 30.6)	66.6 (± 34.0)	65.7 (± 33.8)
Mean cardiopulmonary bypass duration time in minutes (± SD)	94.9 (± 38.3)	98.0 (± 41.6)	97.3 (± 41.3)
Off-pump CABG – no. (%)	80 (13)	80 (13)	66 (11)
Number of major vessels/branches bypassed – no. (%)			
0 Vessels***	11 (2)	11 (2)	7 (1)
1 Vessel	42 (7)	44 (7)	36 (6)
2 Vessels	202 (33)	182 (31)	189 (31)
3 Vessels	349 (58)	360 (60)	369 (61)

Legend: *=161 patients were excluded because their pre-operative ejection fraction was not reported as a percent. **=266 patients were excluded because they had an off-pump procedure. ***= 27 patients did not have CABG, 1 patient had valve replacement only, and operative data could not be retrieved on 1 patient who had CABG at a non-study hospital, IP= Intercessory Prayer.

Figure 2: Presence of Any Complication (Society of Thoracic Surgeons Adult Cardiac Surgery Database Definitions)



Legend: IP= Intercessory Prayer, CABG= Coronary Artery Bypass Graft Surgery, ITT = Intent to Treat, RR= Relative Risk, CI= Confidence Interval

Table II: Details of Complications following CABG (Society of Thoracic Surgeons Adult Cardiac Surgery Database Definitions)

	Group 1: Uncertain, IP (n=604) no. (%)	Group 2: Uncertain, No IP (n=597) no. (%)	Group 3: Certain, IP (n=601) no. (%)
ANY STS COMPLICATION	**315 (52.5)**	**304 (50.9)**	**352 (58.6)**
TYPES OF COMPLICATIONS			
Any Operative Complication	58 (9.6)	39 (6.5)	44 (7.3)
Any Infectious Complication	84 (13.9)	66 (11.1)	82 (13.6)
Any Neurologic Complication	20 (3.3)	19 (3.2)	26 (4.3)
Any Pulmonary Complication	140 (23.2)	131 (21.9)	163 (27.1)
Any Renal Complication	21 (3.5)	19 (3.2)	18 (3.0)
Any Cardiac Complication	158 (26.2)	187 (31.3)	197 (32.8)
Any Vascular Complication	6 (1.0)	2 (0.3)	4 (0.7)
Other complication	38 (6.3)	33 (5.5)	28 (4.7)
Readmitted within 30 days	57 (9.4)	59 (9.9)	54 (9.0)
Mortality within 30 days	16 (2.6)	14 (2.4)	13 (2.2)
No CABG	11 (1.8)	10 (1.7)	6 (1.0)
Uncomplicated prior to loss to follow-up	2 (0.3)	2 (0.3)	6 (1.0)

Legend: Types of complications total more 100% because patients may have had more than 1 type of complication.

Figure 3a: Complications (Society of Thoracic Surgeons Adult Cardiac Surgery Database Definitions) in Subgroup Analyses Group 1 vs. Group 2

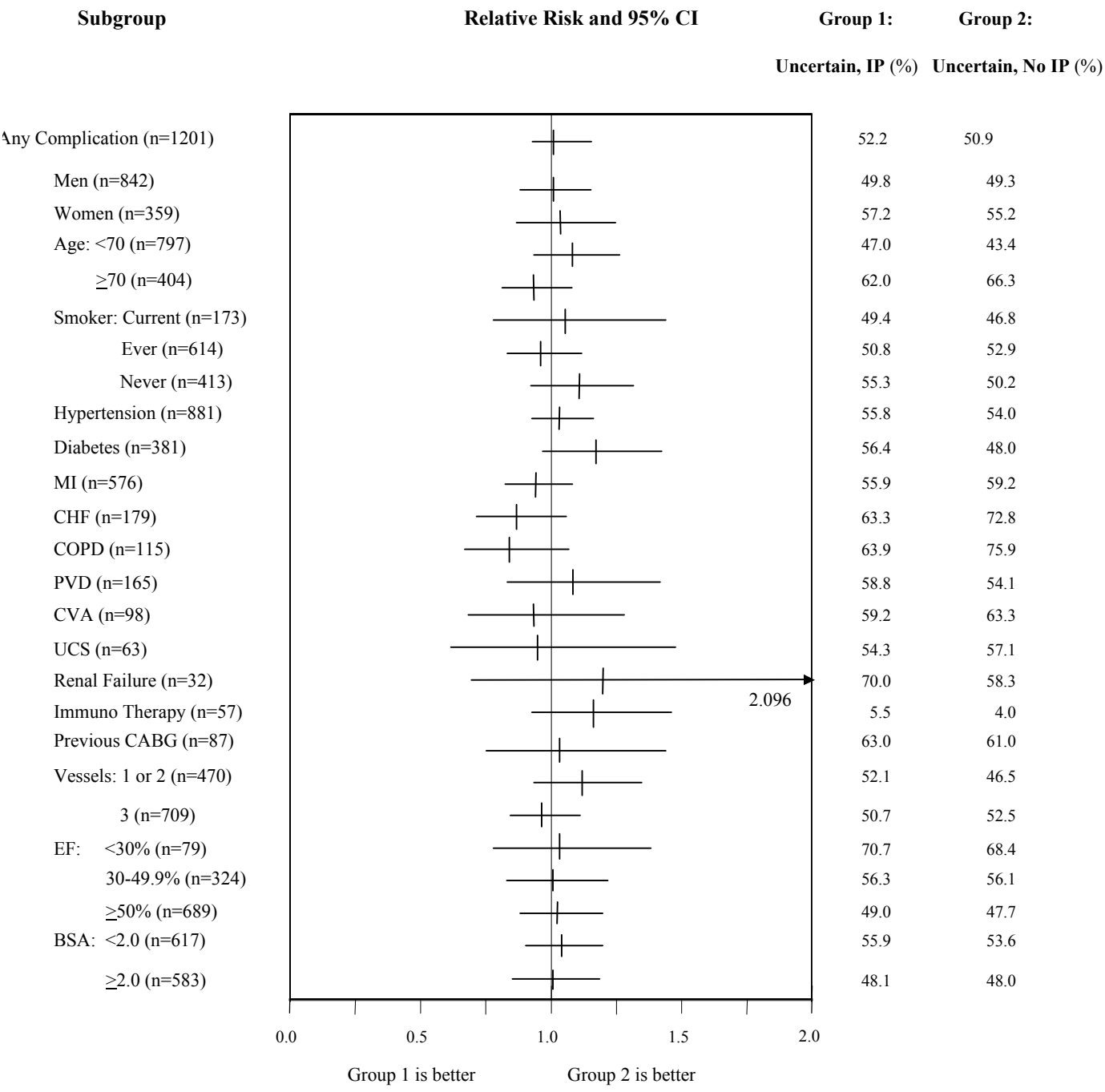


Figure 3b: Complications (Society of Thoracic Surgeons Adult Cardiac Surgery Database Definitions) in Subgroup Analyses Group 3 vs. Group 1

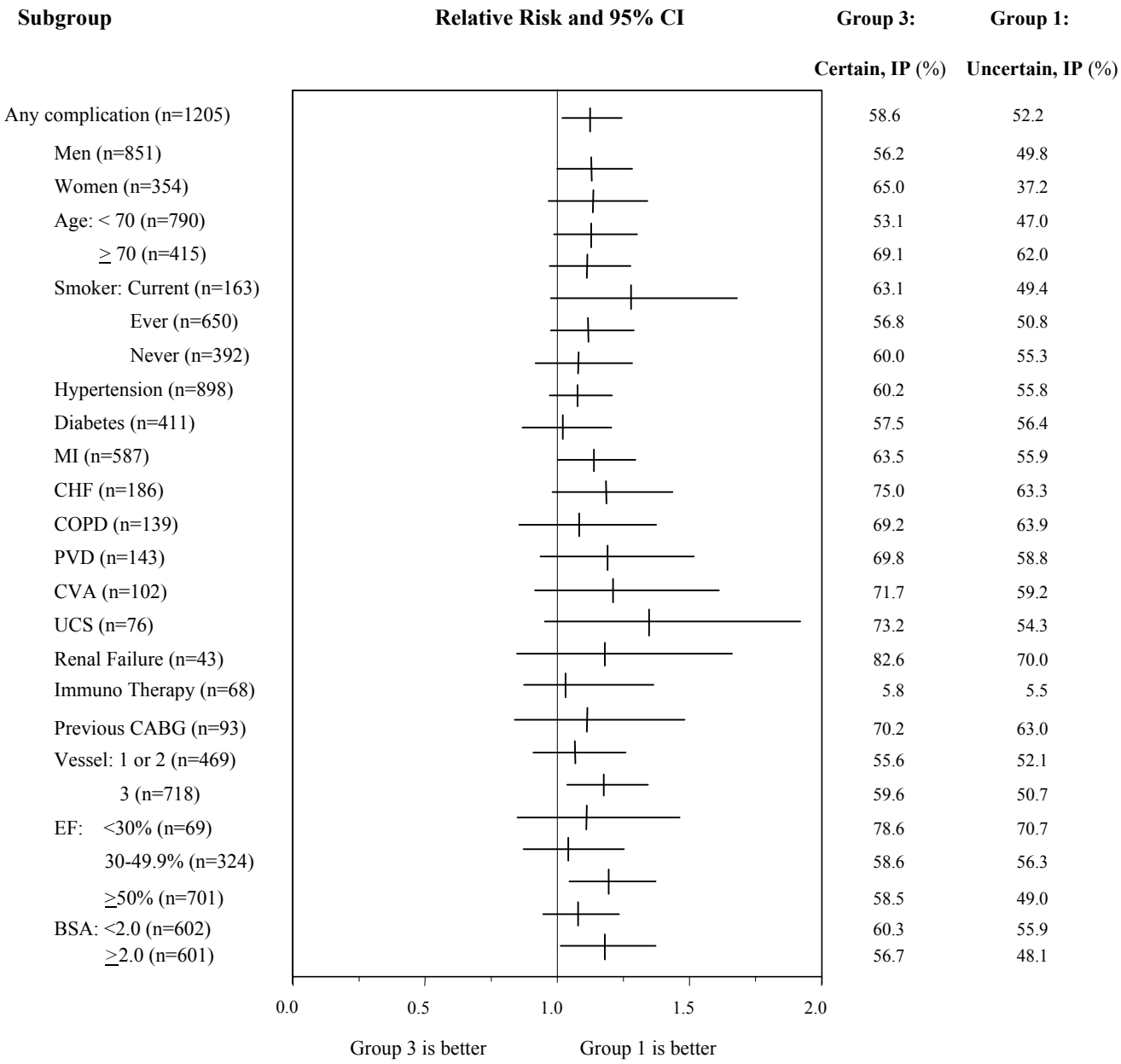


Figure 3 Legend: IP= Intercessory Prayer, CI= Confidence Interval, MI =Myocardial Infraction, CHF= Congestive Heart Failure, COPD= Chronic Obstructive Pulmonary Disease, PVD= Peripheral Vascular Disease, CVA= Cerebrovascular Accident. UCS= Untreated Carotid Stenosis, Immuno Therapy =Immunosuppressive Therapy, EF= Ejection Fraction, BSA= Body Surface Area. Relative risk estimates appearing to the right of the vertical line at 1.0 indicate a higher estimate for the specific group on that side of 1.0 compared to the specific group on the left side. Confidence intervals overlapping the vertical 1.0 line indicate the observed relative risks are similar.

Table III: Independent Predictors of Complications following CABG (Society of Thoracic Surgeons Adult Cardiac Surgery Database Definitions)

Variable Associated with Having a Complication	Relative Risk	95% Confidence Interval
Certain of Receiving Intercessory Prayer	1.27	1.03 – 1.57
Older Age	1.04	1.03 – 1.05
Prior Myocardial Infarction	1.45	1.18 – 1.77
History of Chronic Obstructive Pulmonary Disease	1.61	1.14 – 2.27
History of Congestive Heart Failure	1.67	1.23 – 2.26
History of Hypertension	1.39	1.11 – 1.74

Legend: IP= Intercessory Prayer. Model includes 1,684 patients (93% of total) with a complete data and no missing values.