Study of the Therapeutic Effects of Intercessory Prayer (STEP): Study design and research methods

Jeffery A. Dusek, PhD,[a] Jane B. Sherwood, RN, BSN,[a] Richard Friedman, PhD,[a] Patricia Myers, BA,[a] Charles F. Bethea, MD,[b] Sidney Levitsky, MD,[c] Peter C. Hill, MD,[d] Manoj K. Jain, MD,[e] Stephen L. Kopecky, MD,[f] Paul S. Mueller, MD,[f] Peter Lam, PhD,[a] Herbert Benson, MD,[a] and Patricia L. Hibberd, MD, PhD[a] ***Boston, Mass, Oklahoma City, Okla, Washington, DC, Memphis, Tenn, and Rochester, Minn***

Background The effect of intercessory prayer (IP) on outcome in cardiac cases has been evaluated previously, but results are controversial. The goals of the Study of the Therapeutic Effects of Intercessory Prayer (STEP) are to evaluate the effects of receipt of additional study IP and awareness of receipt of additional study IP on outcomes in patients undergoing coronary artery bypass graft surgery. STEP is not designed to determine whether God exists or whether God does or does not respond to IP.

Methods STEP is a multicenter, controlled trial of 1802 patients in 6 US hospitals, randomized to 1 of 3 groups. Two groups were informed that they may or may not receive 14 consecutive days of additional IP starting the night before coronary artery bypass graft surgery; Group 1 received IP, Group 2 did not. A third group (Group 3) was informed that they would receive additional IP and did so. Three mainstream religious sites provided daily IP for patients assigned to receive IP. At each hospital, research nurses blinded to patient group assignment reviewed medical records to determine whether complications occurred, on the basis of the Society for Thoracic Surgeons definitions. A blinded nurse auditor from the Coordinating Center reviewed every study patient's data against the medical record before release of study forms.

Results The STEP Data and Safety Monitoring Board reviewed patient safety and outcomes in the first 900 study patients. Patients were enrolled in STEP from January 1998 to November 2000. (Am Heart J 2002;143:577-84.)

The belief that prayer heals the sick is widespread. Recent national surveys indicate that 90% of Americans pray daily[1] and more than 70% believe that prayer can help cure illness.[2,3] Although there are many different forms of prayer, intercessory prayer (IP; or distant healing) is one type of prayer that is organized, regular, and committed to setting time aside with the belief that the prayers are communicating with God. Previous studies indicate that IP has significant beneficial effects in cardiac patients[4,5] and in patients with AIDS.[6] However, methodologic concerns have limited the scientific and medical communities' acceptance of the reported beneficial effects of IP.[7-20]

From the [a]Mind/Body Medical Institute, Beth Israel Deaconess Medical Center, Caregroup, Department of Medicine, Harvard Medical School, [b]Integris Baptist Medical Center, Oklahoma Heart Institute, [c]Beth Israel Deaconess Medical Center, CareGroup, Department of Surgery, Harvard Medical School, [d]Section of Cardiac Surgery, Washington Hospital Center, [e]Department of Infectious Disease, Baptist Medical Hospital, and the [f]Mayo Clinic Rochester, Mayo Physician Alliance for Clinical Trials.

Submitted June 19, 2001; accepted November 30, 2001.

Reprint requests: Jeffery A. Dusek, PhD, Mind/Body Medical Institute, Beth Israel Deaconess Medical Center, LMOB Ste 1A, 110 Francis Ave, Boston, MA 02215. E-mail: jdusek@caregroup.harvard.edu

0002-8703/2002/$35.00 + 0 **4/1/122172**
doi:10.1067/mhj.2002.122172

Evaluation of intercessory prayer as an intervention

There are numerous challenges to the design and conduct of a study of IP. First, because there is no accepted scientific basis for the potential effect of IP on illness, it is difficult or impossible to select a biologically plausible patient outcome to study in a clinical trial. Because the selected outcome may not be relevant to effects of IP, it is difficult to interpret any study result. Second, the timing, amount, and duration of IP that should be provided are unknown, in part because of the lack of biologic basis for the possible effect of IP. Because IP provided in a study may be inadequate to achieve the study outcome, absence of effect could be interpreted as inadequate treatment. Similarly, although it may be appealing to consider whether there is a dose-response relationship between IP and outcome, the lack of hypothesized mechanism for IP does not provide a basis for conducting such an analysis. Third, because it is impossible (and not desirable) to limit prayer provided by family, friends, and others, a study of IP can only evaluate the effects of additional IP, not the effects of prayer in general. Similarly, the intervention can only be described as the IP provided by the intercessors, not as an effect or result of communication with God. Fourth, documenta-

Table I. Trial design

	Study hypothesis 1: Effect of additional IP	
Study hypothesis 2: Effect of awareness that IP was provided	Group 1: Unaware, IP	Group 2: Unaware, no IP
	Group 3: Aware, IP	Not studied

Study hypothesis 1 evaluates the effects of additional IP in patients unaware of whether they received IP (Group 1 vs Group 2). Study hypothesis 2 evaluates the effect of awareness in patients who received IP (Group 3 vs Group 1).

tion of how and when IP is administered and addition of a specific intention may result in changes from the usual practice of the intercessors. IP provided in a clinical trial may be different from IP usually provided by the intercessors, limiting generalizability of the results. On the basis of these challenges to study design, it is not surprising that previous studies of IP are controversial.

The Study of the Therapeutic Effects of Intercessory Prayer (STEP) is a randomized multiinstitutional clinical trial designed to investigate whether IP improves complication-free recovery after coronary artery bypass grafting (CABG) surgery. This paper describes the study design and methods used in STEP, and our approach to the challenges discussed previously.

Study overview

STEP enrolled 1802 patients who were undergoing nonemergent CABG at 6 US hospitals between January 1998 and November 2000. Patients scheduled for CABG were randomized into 1 of 3 groups (Table I) and were followed for 30 days after surgery. Patients in Group 1 were informed that they may or may not receive IP but did receive IP (unaware, IP). Patients in Group 2 were also informed that they may or may not receive IP but did not receive IP (unaware, no IP). Patients in Group 3 were informed that they would receive IP and did receive it (aware, IP). The STEP Steering Committee (Appendix) and Scientific Advisory Committee considered it unethical to randomize patients to either "being informed that they would not receive IP" or "being informed that they would receive IP, but not have IP provided."

Study objectives

STEP has two primary objectives: 1, to evaluate the effects of additional IP on complications after CABG in patients unaware of whether they would (Group 1) or would not (Group 2) receive IP; and 2, to evaluate the effects of awareness (Group 3) or unawareness (Group 1) that additional IP was being provided on complications after CABG (Table I). The first objective does not attempt to address a biologically plausible hypothesis, but the second may have a biologically plausible basis. Specifically, being "aware of receiving study IP" could evoke the placebo effect or influence outcome with knowledge that "treatment" is being provided.[21] Secondary study objectives are to evaluate the effects of additional IP and awareness that IP was provided on major events after CABG (on the basis of recommendation by the STEP Data and Safety Monitoring Board [DSMB]) and on change in neurocognitive performance. STEP is not designed to evaluate whether God exists, whether God does or does not respond to IP, whether it is possible to evaluate the presence of God in a controlled clinical trial or whether God would withhold treatment from any study group or to put God to the test. STEP focuses only on the effects of additional IP on outcomes after CABG, not on all forms of prayer.

Sample size and study power

STEP planned to enroll 1800 men and women assigned randomly (1:1:1) to the 3 study groups (Table I). Sample size calculations were on the basis of the following assumptions. First, it was anticipated that 50% of patients who did not receive IP would have 1 or more complications (on the basis of Society of Thoracic Surgeons [STS] definitions). This proportion was on the basis of pilot data from 3 study hospitals and is higher than the proportion of patients with complications after CABG reported by STS in 1996.[22] Second, it was anticipated that there would be a 5% loss to follow-up examination or refusal to have CABG. Patients who refused CABG or had an incomplete follow-up examination were conservatively assumed to have had a complication. Finally, because the study was to be monitored by an independent DSMB, the sample size needed to be adjusted for use of an O'Brien Fleming stopping rule[23] for a single interim analysis after 50% of patients had completed their enrollment in STEP. Power calculations were on the basis of 2-tailed 0.025 level tests (conservative Bonferonni correction).[24] With these assumptions, the study has 85% power to detect a difference in the proportion of patients with complications of 10% or more between patients in Group 1 (unaware, IP) versus Group 2 (unaware, no IP), and Group 3 (aware IP) versus Group 1 (unaware, IP).

Eligibility criteria

Participants were men and women aged ≥18 years and nonbelievers and believers of different faith traditions who were scheduled for nonemergent CABG surgery within 14 days of enrollment in 6 US hospitals (Appendix). Participants needed to read or understand English. Patients scheduled for emergent CABG (ie, next available operating room slot), valve replacement, other surgery within 30 days of CABG, minimally invasive CABG (without full sternotomy), stent, angioplasty, or carotid endarterectomy with CABG were ineligible. Additional exclusion criteria included participation in another study within 30 days, CABG scheduled within less than 24 hours, and ongoing chest pain or unstable angina, as defined by their attending surgeon, cardiologist, or private physician. Patients with unstable angina were not approached because the Steering Committee and the Scientific Advisory Committee were concerned about the ethics and feasibility of asking patients in pain to complete a 1-hour to 2-hour baseline interview including baseline medical and psychosocial questionnaires and neurocognitive assessment.

Recruitment and enrollment

Prospective participants, identified in the cardiac catheterization laboratory, preoperative testing area, hospital department or on the surgical schedule (Figure 1), were contacted with permission of their attending surgeon, cardiologist, or primary care physician. Initial contact included screening for study eligibility. Potentially eligible subjects were provided with information about STEP and invited to participate. Patients were informed that they would be randomized to 1 of 3 study groups when they opened a sealed randomization envelope that listed their group assignment. Patients were also informed that, depending on their group assignment, their first name and first initial of their last name might be forwarded to all 3 Christian IP sites (Catholic and Protestant traditions). All patients provided written informed consent before enrolling in STEP. Six hospitals participated in STEP: Integris Baptist Medical Center, Oklahoma City, Okla; Beth Israel Deaconess Medical Center, Boston, Mass; Washington Hospital Center, Washington, DC; Baptist Medical Center, Memphis, Tenn; Mayo Clinic, Rochester, Minn; and St Joseph's Hospital, Tampa, Fla.

Ethics and informed consent

The Institutional Review Board at each of the 6 participating hospitals approved the study protocol and all protocol amendments. Written consent was obtained from subjects after the study objectives, design, intervention and risks, benefits, and alternatives to participation had been explained by trained study staff. Risks to receiving IP were described as minimal because previous studies had not reported serious adverse effects of IP.

Randomization

Random assignments

Random assignments were stratified by hospital, with permuted block sizes of 9, 12, and 15. To avoid errors with more than 1 set of randomization envelopes at each hospital, no additional strata were used. Specially designed software generated the random numbers sequence for each hospital, and assignments were reviewed by a statistician before use.

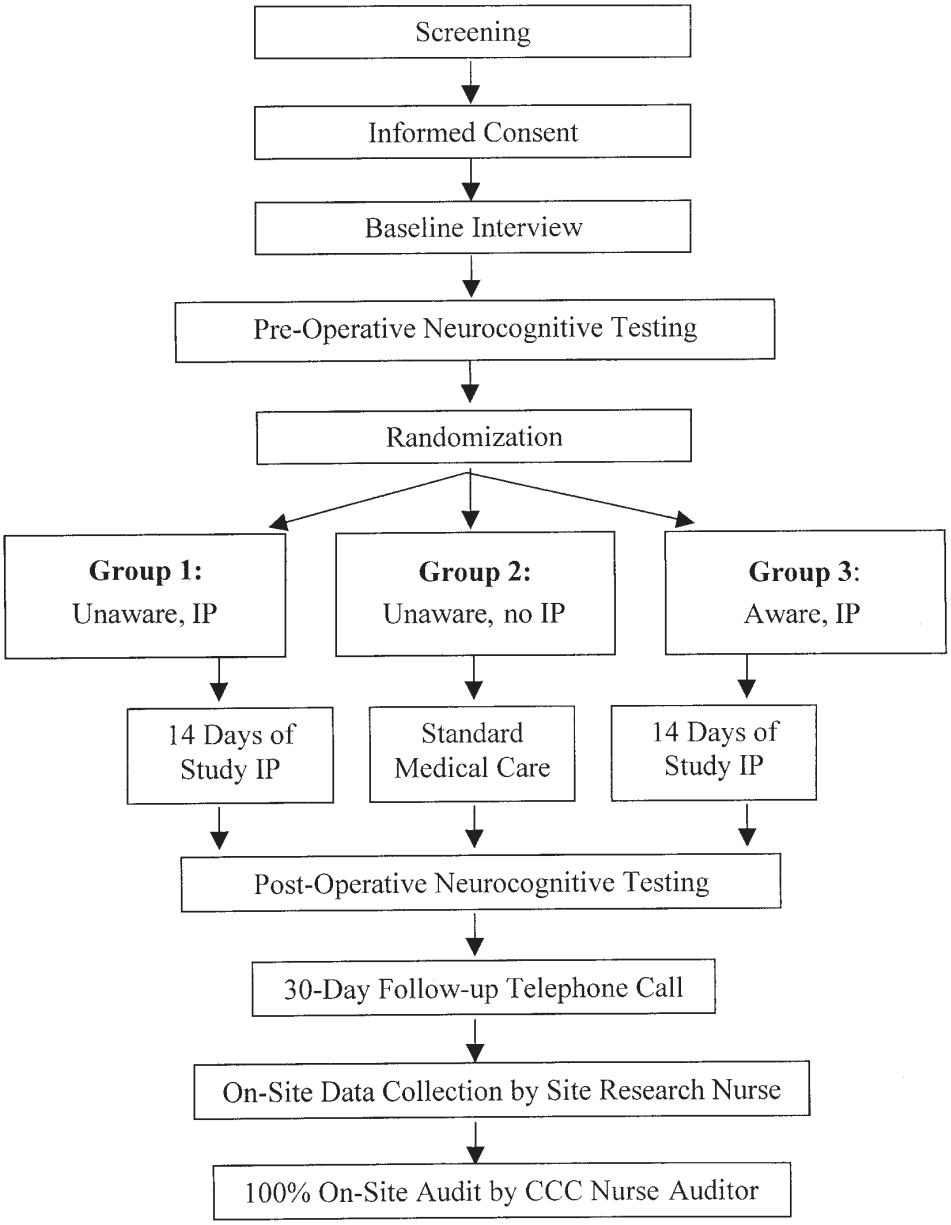
Randomization packets

STEP Clinical Coordinating Center (CCC) personnel prepared each patient randomization packet that included a sealed randomization envelope containing information about the patient group assignment. Each sealed packet had an external preprinted study identification number and an area for the patient to sign and date the packet before they opened it. Patients randomized to Group 1 and Group 2 found a note inside the packet stating they "may or may not be prayed for," and patients randomized to Group 3 found a note stating that they "will be prayed for." To minimize errors, the randomization packets were prepared in batches, with all "may or may not be prayed for" packets being prepared at a different time than the "will be prayed for" packets. A clinical data manager supervised the packet preparation, and contents of a randomly selected 10% of the packets were opened to check assignments against the study ID number (99% accuracy). The accuracy of the randomization process was checked during site visits. The CCC auditor checked that there was a signed copy of the informed consent form in the patient study binder and that the signature on the randomization packet matched the patient signature on the consent form.

Randomization procedures

After ensuring that a patient met all eligibility criteria, including provision of informed consent, a trained study interviewer collected baseline medical, psychosocial, and neurocognitive data. The interviewer gave the patient the randomization packet with instructions to open the sealed randomization envelope but not to inform the interviewer of the group assignment. After the patient was observed opening the randomization envelope, the interviewer sent an enrollment form by facsimile to the Mind/Body Medical Institute CCC. The enrollment form listed the patient first name, first initial of last name, study identification number, and dates of randomization and scheduled surgery. Facsimiles were transmitted to the

Figure 1. Flow chart of Study



CCC, STEP Clinical Coordinating Center.

CCC no later than 7:10 PM Eastern Standard Time (EST) the evening before the scheduled surgery date. The interviewer contacted the CCC to ensure that the enrollment information had been received.

Intercessory prayer groups and intervention

Site selection

To participate in STEP, IP sites needed to meet specific criteria. First, IP sites were required to receive the daily prayer list by facsimile and to post the list in a central location no later than 7:15 PM EST each evening. Second, each IP site was required to have at least 1 IP for patients on the prayer list by midnight each evening, so that IP would be provided the evening before the scheduled surgery. Three Christian sites (St Paul's Monastery, St Paul, Minn; Silent Unity, Lee's Summit, Mo; and the Community of Teresian Carmelites, Worcester, Mass) met the criteria and provided IP throughout the trial. Unfortunately, ap-

proached representatives from other Christian, Jewish, and nonChristian groups were unable to meet IP site criteria.

Duration of intercessory prayer intervention

The goal of STEP was to provide IP to those randomized to receive IP during the period that complications were most likely to occur—during postoperative recovery in the hospital. Because 95% of patients who underwent CABG in the 1996 STS database were discharged within 14 days of CABG,[25,26] patients who were assigned to receive study IP received 14 consecutive days of IP, commencing the night before scheduled CABG. Although provision of IP for the duration of each hospitalization was considered, the logistics of doing so accurately were prohibitive because personnel at the hospitals, CCC, and IP sites would be required to update information at night, on weekends, and on holidays throughout the multiyear study. Duration of IP represented a balance between likely length of stay and a logistically feasible approach to its accurate administration. We recognize the limitations of the lack of an individualized approach to the duration of study IP.

Intercessory prayer site notification

After discussion with the IP sites participating in the study, intercessors agreed that the patient first name, first initial of the last name, and a site code for each participating hospital was sufficient. Institutional Review Boards, which require that only nonidentifying information be provided to the IP sites, approved release of this information to the IP sites. Thus, prayer lists included the first name, first initial of last name, and site code for patients randomized to receive study IP (on the basis of their individual 14-day intervention period, starting the night before scheduled surgery). Daily prayer lists were generated at the CCC, and the identical prayer list was sent to each IP site by facsimile every Monday through Thursday by 7:15 PM EST. The Monday prayer list was viewed by intercessors during a 24-hour period (eg, from Monday 7:15 PM EST to Tuesday 7:15 PM EST). This routine was repeated on Tuesday through Thursday evenings. On Friday evenings, each IP site received 3 prayer lists: 1 for Friday/Saturday, 1 for Saturday/Sunday, and 1 for Sunday/Monday. The designated coordinator at each IP site informed the CCC if the daily facsimile was not received and posted the appropriate prayer list at 7:15 PM EST each week and weekend day.

Hospitals were asked to notify the CCC if any surgery had been postponed by more than 7 days. If the CCC was notified and the postponement was for a patient randomized to receive IP, then they were removed from the prayer list until the night before their new surgery date. Because these patients had already received at least 1 day of IP, the second time that they were placed on the list, they received 7 additional days of IP.

Content of intercessory prayer intervention

We recognize that the information provided to the intercessors was limited. Typically, patients and families interact directly with the intercessors, providing them with the complete name, location, age, diagnosis, updates on condition, and even photographs. In STEP, intercessors received no feedback about the patient's recovery and had no contact with the patient or family because the CCC notified the intercessors of each patient for whom they were to pray. We recognize that our modifications of the way in which IP is provided in STEP may limit the conclusions about effects of IP.

We anticipated that almost all patients in STEP would receive some form of non-study prayer from family, friends, or church members, but no Study IP was provided at our participating hospitals. Our study focuses only on the effects of additional IP provided by the study intercessors. All patients were contacted by telephone at least 30 days after CABG as described subsequently. During this call, patients were asked whether they were aware of prayers from family or friends during their recent CABG hospitalization and whether they believed they had received study IP during their hospitalization.

Documentation of intercessory prayer intervention

Before the start of the trial, members of each IP site were trained in the procedures for provision of study IP. The intercessors were asked to only pray for patients named on the prayer list (ie, refrain from praying for all patients participating in the trial) and to stop praying for a patient once the name was removed from the prayer list. Two IP sites prayed collectively (eg, during a Mass) and individually, whereas members of the third site only prayed individually. Intercessors used their usual method of prayer and were asked to include the intention "for a successful surgery with a quick, healthy recovery and no complications." The intention, printed at the top of each daily prayer list, was included when intercessors prayed collectively or individually.

At 2 IP sites, intercessors initialed the prayer list after completing their IP, and the initialed prayer lists were sent by facsimile to the CCC weekly throughout the study. The coordinator (head of the order) of the third IP site signed a letter stating the number of active intercessors who participated in the study during the previous 12 months. Study staff conducted annual site visits to all IP sites to evaluate compliance and provide retraining as needed. Representatives of the IP sites were contacted by phone on a regular basis to review study progress.

Primary and secondary end points

The primary endpoint in STEP was the presence of any complication (on the basis of the STS definition of com-

Table II. Complications and major events

Complications (primary end point); *Major events (secondary end point)
- Operative complications
  - Reoperation due to bleeding*
  - Reoperation due to graft occlusion
  - Reoperation/other cardiac
  - Reoperation/other noncardiac
  - Perioperative myocardial infarction*
  - Other operative complication
- Infectious complications
  - Superficial sternal infection
  - Deep sternal infection*
  - Thoracotomy site infection
  - Harvest site (leg) infection
  - Intra-aortic balloon pump site infection
  - Sepsis*
  - Urinary tract infection
  - Pneumonia
  - Other infectious complication
- Neurologic complications
  - Stroke–permanent*
  - Stroke–transient*
  - Continually unresponsive in coma >24 hours
- Pulmonary complication
  - On ventilator ≥24 hours* (≥72 hours for major event)
  - Radiologic evidence of pulmonary edema
  - Radiologic evidence of congestive heart failure
  - Radiologic evidence of pulmonary embolism
  - Radiologic evidence of acute respiratory distress syndrome
- Renal complication
  - New onset of renal failure
  - New onset of need for dialysis*
- Cardiac complication
  - New onset atrial fibrillation/atrial flutter
  - High grade ectopy
  - Cardiopulmonary resuscitation for cardiac arrest
- Vascular complication
  - Aortic dissection
  - Iliac-femoral dissection
  - Acute limb ischemia
- Other complications
  - Heart block requiring permanent pacemaker
  - Anticoagulant complication
  - Gastrointestinal complication*
  - Treatment for tamponade
  - Readmission to hospital within 30 days of CABG

Patients had a "complication" if any of the 36 complications that made up the primary end point were present within 30 days of CABG (based on Society for Thoracic Surgeons definitions). Patients had a "major event" if any of the 9 end points (shown with asterisk) were present within 30 days of CABG (based on New York State Department of Health Cardiac Surgery Reporting System definitions).

plication) within 30 days of CABG (Table II). This end point was chosen because it is widely collected by many hospitals as a clinically important outcome after CABG and is used to evaluate risk factors for adverse outcomes after CABG.[27] We recognize that it may not be the optimal endpoint to evaluate effects of IP after CABG.

Approximately 30 days after CABG, the site interviewer called each patient at their discharge location to determine whether they had been readmitted to any hospital since discharge. The interviewer asked for written permission to obtain and review medical records for all subsequent admissions. The research nurse reviewed all medical records for complications occuring within 30 days of CABG.

All medical records were independently audited during approximately 10 site visits to each hospital center. Discrepancies between abstracted data and the medical record were resolved with consensus of the auditor and the site research nurse, with STEP study definitions. All research nurses, CCC personal and auditors were blinded to the patient group assignment throughout the trial.

Secondary endpoints included the presence of a major event (as defined by the New York State Department of Health Cardiac Surgery Reporting System[28]) and changes in neurocognitive performance. Patients who completed preoperative neurocognitive testing were asked to complete postoperative testing no sooner than 24 hours after discharge from intensive care unit and before hospital discharge (3 to 5 days after surgery).

Data and safety monitoring board

Halfway through the trial, an independent DSMB is scheduled to review safety and efficacy of the studied IP intervention. As described previously, the O'Brien Fleming stopping rule[23] will be used in determination of whether to terminate STEP early on the basis of concerns for patient safety or demonstrated efficacy of IP or awareness of receiving IP.

Data analysis

For the primary analysis, a χ^2 test will be used to compare the proportion of patients with complications within 30 days of CABG in Group 1 (unaware, IP) versus Group 2 (unaware, no IP), and between Group 3 (aware, IP) and Group 1 (unaware, IP), with a 2-sided level of significance of 0.025, adjusted for interim analyses. Both main hypotheses will be tested with an intent-to-treat analysis as described previously. Exploratory subgroup analysis, by prognostic factors identified by multiple regression model, will be assessed to ascertain the consistency of the primary outcome. A χ^2 test will be used to compare proportions of patients across the same study groups who have a major event[28] within 30 days of CABG (Table II). Again, patients who do not have CABG or who are lost to follow-up examination will be defined as having had a major event. Another secondary endpoint is change in neurocognitive performance,[29] including data from anxiety[30] and depression[31] questionnaires. Groups will be compared with analysis of variance, stratified by hospital.

Organizational structure

STEP is governed by a Steering Committee (study principal investigator, CCC principal investigator, STEP project director/CCC coprincipal investigator, and 2 coinvestigators). There is complete separation of CCC and site staff. A DSMB appointed by the study principal investigator will monitor the study.

Conclusion

STEP is the first multicenter randomized controlled trial to examine the effect of additional IP on complications after nonemergent CABG. The sample size of 1802 patients allows for the examination of 2 hypotheses simultaneously: effect of additional study IP and effect of awareness about receipt of study IP on complications after CABG. Other significant features of STEP include: 1, use of Institutional Review Board approved consent process; 2, use of single study outcome (on the basis of STS definition); 3, blinded 100% audit of medical records by CCC personnel to ensure accuracy of study outcomes; and 4, independent monitoring by a DSMB. Patients were enrolled in the study from January 1998 to November 2000.

STEP is supported by the John Templeton Foundation. The Baptist Medical Hospital site was supported by the Baptist Memorial Health Care Corporation.

References

1. Gallup G Jr. Poll releases: as nation observes national day of prayer, 9 in 10 pray—3 in 4 daily. Gallup Organization Web site. Available at: http://www.gallup.com/poll/releases/pr990506.asp. Accessed February 14, 2002.
2. CBS News Poll [transcript]. "CBS News." CBS television. April 20-22, 1998.
3. Yankelovich Partners, Inc. [transcript]. TIME/CNN. June 12-13, 1996.
4. Byrd RC. Positive therapeutic effects of intercessory prayer in a coronary care unit population. South Med J 1988;81:826-9.
5. 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.
6. Sicher F, Targ E, Moore D, et al. A randomized double-blind study of the effect of distant healing in a population with advanced AIDS—report of a small scale study. West J Med 1998;169:356-63.
7. Astin JA, Harkness E, Ernst E. The efficacy of "distant healing": a systematic review of randomized trials. Ann Intern Med 2000;132: 903-10.
8. Sloan RP, Bagiella E, Powell T. Religion, spirituality, and medicine. Lancet 1999;353:664-7.
9. Sloan RP, Bagiella E. Data without a prayer [letter]. Arch Intern Med 2000;
160:1870.
10. Karis R, Karis D. Intercessory prayer [letter]. Arch Intern Med 2000; 160:1870.
11. Goldstein J. Waving informed consent for research on spiritual matters [letter]. Arch Intern Med 2000;160:1870-1.
12. Van der Does W. A randomized, controlled trial of prayer [letter]. Arch Intern Med 2000;160:1871-2.
13. Sandweiss DA. P value out of control [letter]. Arch Intern Med 2000;160:1872.
14. Hamm RM. No effect of intercessory prayer has been proven [letter]. Arch Intern Med. 2000;160:1872-3.
15. Price JM. Does prayer really set one apart? [letter]. Arch Intern Med 2000;160:1873.
16. Pande PN. Does prayer need testing? [letter]. Arch Intern Med 2000;160:1873-4.
17. Hammerschmidt DE. Ethical and practical problems in studying prayer [letter]. Arch Intern Med 2000;160:1874.
18. Waterhouse WC. Is it prayer, or is it parity? [letter]. Arch Intern Med 2000;160:1875.
19. Hoover DR, Margolich JB. Questions on the design and findings of a randomized, controlled trial of the effects of remote, intercessory prayer on outcomes in patients admitted to the coronary care unit [letter]. Arch Intern Med 2000;160:1875-6.
20. Smith JG, Fisher R. The effect of remote intercessory prayer on clinical outcomes [letter]. Arch Intern Med 2000;160:1876.
21. Benson H, Friedman R. Harnessing the power of the placebo effect and renaming it "remembered wellness." Annu Rev Med 1996;47: 193-9.
22. STS 1996 Database Web site. Available at: http://www.ctsnet.org/doc/2243. Accessed February 14, 2002.
23. O'Brien PC. Procedures for comparing samples with multiple endpoints in clinical trials. Biometrics 1984;40:1079-87.
24. Dunn OJ. Multiple comparisons among means. J Amer Stat Assoc 1961;56:52-64.
25. STS 1996 Database Web site. Available at: http://www.ctsnet.org/image/5425. Accessed February 14, 2002.
26. STS 1996 Database Web site. Available at: http://www.ctsnet.org/image/5512. Accessed February 14, 2002.
27. Grossi EA, Groh MA, Lefrak EA, et al. Results of a prospective multicenter study on port-access coronary bypass grafting. Ann Thorac Surg 1999;68:1475-7.
28. New York State Department of Health Cardiac Surgery Reporting System Web site. Available at: http://www.sts.org/outcomes/ny/csrs197/pdf. Accessed February 14, 2002.
29. Murkin JM, Newman SP, Stump DA, et al. Statement of concensus on assessment of neurobehavioral outcomes after cardiac surgery. Ann Thorac Surg 1995;59:1289-95.
30. Spielberger CD, Gorsuch RL, Lushene RE. Manual for the State-Trait Anxiety Inventory. Palo-Alto: Consulting Psychologists Press; 1970.
31. Beck AT, Steer RA, Brown GK. Manual for the Beck Depression Inventory. 2nd ed. San Antonio: The Psychological Corporation; 1996.

Appendix

Steering Committee

Herbert Benson, MD (Principal Investigator [PI]); Patricia L. Hibberd, MD, PhD, (CCC PI); Jeffery A. Dusek, PhD (STEP Project Director/CCC Co-PI); Jane S. Sherwood, RN, BSN (Co-investigator); Patricia Myers (former Co-investigator); and Richard Friedman, PhD (Co-PI [deceased]).

Site investigators and study center personnel

Integris Baptist Medical Center, Oklahoma City, Okla: Charles F. Bethea, MD (PI), Reverend William F. Carpenter (Co-PI); Sue Rollins, RN; Marva Davis; Suzanne Zachary, RN; Robert Browning; Travis Kanaly.

Beth Israel Deaconess Medical Center, Boston Mass: Sidney Levitsky, MD (PI); Kathleen Sussek, RN; Lori Thibeault; Kendra Ward; Carol Collins; Amy Ojena.

Washington Hospital Center, Washington, DC: Peter C. Hill, MD (PI); Reverend Donald Clem (Co-PI); Jan Harrison, RN; Dancia Langley; Corey Evans.

Baptist Medical Center, Memphis Tenn: Manoj K. Jain, MD (PI); Reverend David L. Drummel (Co-PI); Wyvonnia Harris, RN; Raymond Baser; Hunter Welles.

Mayo Clinic, Rochester Minn: Stephen L. Kopecky, MD (PI); Paul S. Mueller, MD (PI); Father Dean Marek (Co-PI); Kathy Kenny, RN; Cindy Andrist; Brandon Messmer.

St. Joseph's Hospital, Tampa Fla: Dennis Pupello, MD (PI); Sister Pat Shirley (Co-PI); Brenda McFadden, RN; Vicki Kenyon, RN; Nadine Belham, RN; Linda Tyre, RN.

Clinical Coordinating Center

Patricia L. Hibberd, MD, PhD (PI); Jeffery A. Dusek, PhD (Co-PI); Kathryn C. Dusek, BA; Jane S. Sherwood, RN.

Data and Safety Monitoring Board

Thomas J. Ryan, MD (Chair); Marian R. Fisher, PhD; David H. Adams, MD; David S. Krantz, PhD; Father Robert S. Smith.