Original Article

Intercessory Prayer and Cardiovascular Disease Progression in a Coronary Care Unit Population: A Randomized Controlled Trial

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• *Objective*: To determine the effect of intercessory prayer, a widely practiced complementary therapy, on cardiovascular disease progression after hospital discharge.

• *Patients and Methods*: In this randomized controlled trial conducted between 1997 and 1999, a total of 799 coronary care unit patients were randomized at hospital discharge to the intercessory prayer group or to the control group. Intercessory prayer, ie, prayer by 1 or more persons on behalf of another, was administered at least once a week for 26 weeks by 5 intercessors per patient. The primary end point after 26 weeks was any of the following: death, cardiac arrest, rehospitalization for cardiovascular disease, coronary revascularization, or an emergency department visit for cardiovascular disease. Patients were divided into a high-risk group based on the presence of any of 5 risk factors (age ≥70 years, diabetes mellitus, prior myocardial infarction, cerebrovascular disease, or peripheral vascular disease) or a low-risk group (absence of risk factors) for subsequent primary events.

• *Results*: At 26 weeks, a primary end point had occurred in 25.6% of the intercessory prayer group and 29.3% of the control group (odds ratio [OR], 0.83 [95% confidence interval (CI), 0.60-1.14]; *P*=.25). Among high-risk patients, 31.0% in the prayer group vs 33.3% in the control group (OR, 0.90 [95% CI, 0.60-1.34]; *P*=.60) experienced a primary end point. Among low-risk patients, a primary end point occurred in 17.0% in the prayer group vs 24.1% in the control group (OR, 0.65 [95% CI, 0.20-1.36]; *P*=.12).

• *Conclusions*: As delivered in this study, intercessory prayer had no significant effect on medical outcomes after hospitalization in a coronary care unit.

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CCU = coronary care unit; CHF = congestive heart failure; CI = confidence interval; CV = cardiovascular; ED = emergency department; IP = intercessory prayer; MI = myocardial infarction; OR = odds ratio

Throughout history, medicine and spirituality have been interrelated to varying degrees. At times, medical and spiritual care has been delivered by a single practitioner, a practice that continues today in some cultures. In Western medicine, after the 1600s, science claimed the "body" and relegated the "soul" to spiritual or religious beliefs and practices. Today, we continue to see evidence of this classification as the science of medicine and spiritual beliefs are often considered to be disparate or mutually exclusive. However, medical science alone fails to address a vital element of human experience as up to 98% of hospitalized patients describe a belief in God or some higher power, and 96% acknowledge a personal use of prayer to aid in the healing process.[1,2] In addition, 77% of 203 hospitalized family practice patients thought their physicians should consider their spiritual needs, while, in contrast, 32% of the patients' family physicians discussed spirituality with the patients.[1]

For editorial comment, see page 1189.

In direct contradiction to the exclusion of spirituality from clinical practice are the beliefs of physicians; 99% of 296 family physicians polled in 1996 were convinced of the healing powers of spiritual beliefs, and 75% believed that the prayers of others can promote a patient's recovery.[3] These studies in the family practice literature are most likely high estimates of the number of physicians addressing spirituality with patients and beliefs held by physicians, as other studies have shown far fewer physicians to share their patients' spiritual views. For example, in an American Psychiatric Association survey of psychiatrists, 43% believed in God.[4] Regardless of clinicians' personal biases, patients use spiritual practices in conjunction with their medical care, yet little is known of the effect of these practices on medical outcomes.

The medical community has begun to acknowledge the use of alternative spiritual therapies by patients and to explore the association between spirituality and medicine. Some US medical schools now offer courses in religion, spirituality, and health, and the Association of American

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Medical Colleges Task Force on Communication in Medicine guidelines for medical schools encourage physician query into spiritual beliefs.[5] However, spiritual variables continue to be largely neglected in medical research.[4,6-8] This paucity of research on spirituality is perhaps influenced by the challenges of rigorous study design. Research exploring links between spiritual activity and health outcomes is fraught with methodological difficulties; personal, regional, and cultural variables add further challenges; and confounding factors are difficult to measure.[9]

Despite the challenges inherent to studies attempting to integrate scientific and spiritual variables, reported results are affirmative enough to sustain interest in these investigations. Of 212 published studies that have assessed the effects of spiritual factors on health care outcomes, 75% report a positive effect, 17% report no effect, and 7% report a negative effect.[10]

Studies of the effect of intercessory prayer (IP)—prayer by 1 or more persons on behalf of another—on health outcomes are fewer in number. Two large-scale trials have studied the effects of IP on coronary care unit (CCU) hospital course. In 1988, a blinded, controlled study by Byrd[11] assessed the effect of IP in 393 CCU patients and reported a significant prayer benefit. In a priori analyses of the study population, treatment groups differed significantly on only 6 of 26 indicators of hospital course. After a CCU severity score was assigned to each patient, retrospective analysis favored the prayer group ($P<.01$). The study by Harris et al[12] reported in 1999 was the first attempt to replicate Byrd's results. Although they did not achieve significant results using Byrd's method, these researchers reported significant benefit as reflected in CCU outcome scores (based on selected indicators of hospital course) of 446 patients randomized to IP treatment compared with scores of 524 usual-care patients ($P=.04$). It is not clear whether this was an a priori analysis. Because of issues such as blinding, lack of control groups, and failure to obtain informed consent, it is not clear whether these studies of IP support a beneficial link between IP and cardiovascular (CV) outcomes.

Our study, the Healing Effect of Long-distance Prayer, was a multiple-investigator, randomized, double-blind, controlled trial. We sought to improve on the design of earlier studies of IP through the application of standard experimental methods with the hope of obtaining scientific evidence to elucidate the potential role of IP in medical care.

PATIENTS AND METHODS

Study Population

This single-center, randomized, double-blind, controlled trial was conducted at the Mayo Clinic, Rochester, Minn, between July 4, 1997, and October 21, 1999. Male and female patients aged 18 years or older admitted to the Saint Marys Hospital CCU and discharged alive with a CV diagnosis were eligible to participate. The study was approved by the Mayo Clinic Institutional Review Board, and written informed consent was obtained as required by Minnesota Statute 144.335. Of 1965 CCU admissions during the study enrollment period, 799 patients were eligible for the study and chose to participate. Excluded from the study were 1098 patients unwilling or unable to give informed consent, discharged to another hospital or short-term facility, or unavailable for long-term follow-up. Sixty-eight patients refused to participate on the basis of personal beliefs.

Treatment Groups

Patients were randomized within 24 hours of discharge to the control group or to the IP group. All patients received standard CV care as prescribed by their primary physicians. Intercessory prayer treatment was administered by 5 randomly assigned volunteer individual or group intercessors and consisted of prayer at least once a week for 26 weeks. Prayer groups ranged in size from 1 to 65 (median, 1 intercessor). A total of 215 intercessors (individuals or groups) were recruited from local religious groups and community interest meetings. Intercessors prayed for 1 to 100 patients (median, 5 patients; mean, 7.4 patients). After the patients were randomized, in order to create a personal link while still retaining adequate patient anonymity, with Institutional Review Board approval, the assigned patient's first name, age, sex, diagnosis, and general condition were delivered by mail to the intercessors, who immediately initiated IP. Intercessors had no contact with patients, and patients and caregivers were blinded to study assignment.

End Points

Efficacy of treatment was assessed at 26 weeks by occurrence of one of the following primary end points: death, cardiac arrest, coronary revascularization, CV rehospitalization, or emergency department (ED) visit due to CV disease. Death was ascertained from medical records. Cardiac arrest was defined as asystole, ventricular fibrillation, or ventricular tachycardia requiring resuscitation. Revascularization included percutaneous coronary intervention and surgical coronary artery bypass graft procedures. Rehospitalization for CV disease was confirmed by hospital discharge summary with a CV diagnosis. An ED visit for CV disease was based on the ED summary. The Mayo Physician Alliance for Clinical Trials Clinical Events Committee adjudicated 3 equivocal cases.

Randomization and Stratification

Patients were randomized to a study arm by an interactive computer-automated telephone system. Randomiza-

tion stratification factors were sex; age (<65, 65-75, >75 years); diagnosis (myocardial infarction [MI], angina pectoris, congestive heart failure [CHF], or other); and general condition at hospital discharge (guarded, stable, or okay). "Guarded" reflected an above-average risk for complications, "stable" reflected an average risk, and "okay" reflected a low risk. A total of 799 patients were randomized, 400 to the IP arm and 399 to the control arm of the study. Though not prospectively identified in the study protocol, patients were divided into high-risk and low-risk subgroups with use of established parameters to identify high-risk patients for subsequent primary end point outcomes. Factors used to identify patients from the Mayo Clinic CCU database at high risk were aged 70 years or older or had presence of diabetes mellitus, prior MI, or history of cerebrovascular or peripheral vascular disease.[13-15] Four hundred forty-five patients were assigned to high-risk status and 315 to low-risk status for outcomes analysis.

Follow-up

A screening survey was mailed to all participants at the end of the 26-week treatment period, and nonresponders were followed up by telephone, medical records, or death certificate. Follow-up information was available for all 799 patients. Where indicated, outside hospital records were obtained for review. A 12-item modified version of the Medical Outcomes Study Short Form 36 (response rate, 88.2%) assessed quality of life.[16]

Statistical Analysis

We assessed differences in baseline patient characteristics and primary event rates using the χ^2 test for categorical variables and the Wilcoxon rank sum test for continuous variables. We summarized the comparison of the IP vs control groups with respect to CV disease progression using odds ratios (ORs) with 95% confidence intervals (CIs) based on logistic regression models. The study design was based on analysis of the evaluable patient rather than intention to treat. Adjusted ORs considered other variables associated with CV disease progression. The occurrence of any primary event (ie, death, revascularization, rehospitalization, an ED visit, or cardiac arrest) was adjusted for age, dismissal status (ie, guarded, stable, or okay), hypertension, prior MI, and time of randomization. In separate analyses, the occurrence of death was adjusted for age, diagnosis (ie, MI, angina, CHF, or other), hypercholesterolemia, and prior MI. The prayer effect for high-risk and low-risk outcome patients was estimated in a similar fashion.

Event-free survival time was estimated by the Kaplan-Meier method, and differences were assessed via the log-rank test. We analyzed quality-of-life questions with ordinal and binary responses using Wilcoxon rank sum and χ^2 tests, respectively.

An estimated 20% of discharged patients in the control group were expected to experience a progression of CV disease within 26 weeks. Sample sizes of 400 patients in each arm provided greater than 90% power to detect a difference between 20% and 12% rates of progression between the control and IP groups, respectively.

RESULTS

Patient Characteristics

Seven hundred sixty-two patients (383 in the IP group and 379 in the control group) were included in the statistical analyses, based on complete follow-up. We detected no significant differences between the IP group and the control group with respect to demographic characteristics or measures of CV disease at baseline (Table 1). Follow-up was incomplete in 37 cases because of absence of outside hospital records (9 patients); withdrawal of consent (1 patient); inability to locate (10 patients); refusal of follow-up (7 patients); and failure to return the survey form (10 patients).

Treatment Efficacy

The incidence of CV disease progression was not significantly different between the IP group and the control group (25.6% vs 29.3%; OR, 0.83 [95% CI, 0.60-1.14]; *P*=.25) (Table 2). Event rates for each component of CV disease progression were not significantly different between groups (IP vs control, respectively): death, 8.1% vs 9.0%; revascularization, 3.9% vs 6.1%; rehospitalization, 18.5% vs 20.3%; ED visit, 8.4% vs 8.2%; and cardiac arrest, 0.3% vs 0.3% (all *P*>.05) (Table 2).

Event rates for the combined components of death and revascularization (12.0% IP vs 15.0% control) and death, revascularization, and rehospitalization (25.3% IP vs 28.8% control) also were not significantly different between groups (both *P*>.05) (Figure 1).

During analysis for outcomes, no significant benefit of IP on CV disease progression was found in either the low-risk or high-risk group: primary event rate in the low-risk group, 17.0% IP vs 24.1% control (*P*=.12), and in the high-risk group, 31.0% IP vs 33.3% control (*P*=.60) (Table 3). Event-free survival time was not significantly different in the low-risk group (*P*=.06) compared with the high-risk group (*P*=.71) (Figure 2). Although comparison of randomization stratification groups was not prospectively planned in the protocol, no difference was found in the primary end point among the randomization stratification groups of sex, age, diagnosis, or general condition at hospital discharge in the IP group vs the control group.

Table 1. **Baseline Patient Information***

	Control group (n=399)	IP group (n=400)	*P* value
Stratification factors			
No. of patients with complete follow-up	379	383	
Male	235 (62.0)	241 (62.9)	.79
Age (y)			.98
<65	165 (43.5)	167 (43.6)	
65-75	109 (28.8)	108 (28.2)	
>75	105 (27.7)	108 (28.2)	
Diagnosis			.97
MI	193 (50.9)	192 (50.1)	
Angina	58 (15.3)	63 (16.4)	
CHF	32 (8.4)	34 (8.9)	
Other	96 (25.3)	94 (24.5)	
General condition			.99
Guarded	92 (24.3)	91 (23.8)	
Stable	282 (74.4)	287 (74.9)	
Okay	5 (1.3)	5 (1.3)	
Demographic characteristics			
No. of evaluable patients	378	382	
Diabetes	43 (11.4)	49 (12.8)	.54
Family history of CAD	67 (17.7)	58 (15.2)	.34
Hypercholesterolemia	126 (33.3)	122 (31.9)	.68
Hypertension	132 (34.9)	120 (31.4)	.30
Smoking status			.68
Never smoked	224 (59.3)	227 (59.4)	
Former smoker	94 (24.9)	87 (22.8)	
Current smoker	60 (15.9)	68 (17.8)	
Prior MI	66 (17.5)	64 (16.8)	.80
Presentation characteristics			
No. of evaluable patients	253	236	
Killip class >1	56 (22.1)	52 (22.0)	.98
Ejection fraction measured	191 (75.5)	188 (79.7)	.29
Mean ± SD	48±15.0	47.1±14.3	

*Values are number (percentage) unless indicated otherwise. CAD = coronary artery disease; CHF = congestive heart failure; IP = intercessory prayer; MI = myocardial infarction.

Quality of Life

Analysis of the individual modified Short Form 36 questions did not reveal statistically significant differences in perceived quality of life between groups.

DISCUSSION

In the medical community, randomized controlled trials are the "gold standard" to establish treatment effect. It was our aim to design a trial to examine the possible effect of IP on health outcomes of CCU patients. In our study design, IP is analogous to a trial medication; unlike a trial medication, however, the most effective administration timing, dosage, and form of IP are not established.

A double-blind trial design was used to isolate the effect of prayer from the benefits of patient beliefs and the charismatic component of prayer. On the basis of data suggesting that few hospitalized patients are unreceptive to prayer,[1] we sought to minimize selection bias by using randomization and double-blind design. While Byrd's study[11] has been criticized for possible selection bias favoring subjects receptive to prayer, our study design assumed that both groups reflected similar mixes of beliefs regarding spirituality and prayer. Unlike the 1999 study by Harris et al,[12] which sought to avoid selection bias by not informing patients of study involvement and waiving the requirement for patient consent, our study required informed patient consent and provided the opportunity for study withdrawal.

Placebo-controlled trials of IP as a therapeutic modality are difficult to implement, as any patient in either group could be influenced by their personal beliefs or prayer and could also be the recipient of prayer from sources not

Table 2. **Events Information***

	Control group (n=399)	IP group (n=400)	*P* value
No. of patients with complete follow-up	379	383	…
Primary events at 6 mo			
Any	111 (29.3)	98 (25.6)	.25
Death	34 (9.0)	31 (8.1)	.66
Revascularization	23 (6.1)	15 (3.9)	.17
Rehospitalization	77 (20.3)	71 (18.5)	.54
ED visit	31 (8.2)	32 (8.4)	.93
Cardiac arrest	1 (0.3)	1 (0.3)	.99
Any event			
Observed	111 (29.3)	98 (25.6)	.25
Odds ratio (95% CI)	0.83 (0.60-1.14)		.25
Adjusted†	…	…	…
Odds ratio (95% CI)	0.82 (0.59-1.14)		.25
Death			
Observed	34 (9.0)	31 (8.1)	.66
Odds ratio (95% CI)	0.89 (0.54-1.49)		.66
Adjusted‡	…	…	…
Odds ratio (95% CI)	0.84 (0.50-1.42)		.52

*Values are number (percentage) unless indicated otherwise. CHF = congestive heart failure; CI = confidence interval; ED = emergency department; IP = intercessory prayer; MI = myocardial infarction. Ellipses indicate data not applicable.

†Adjusted for age, dismissal status (guarded, stable, or okay), hypertension, prior MI, and time of randomization.

‡Adjusted for age, diagnosis (MI, angina, CHF, or other), hypercholesterolemia, and prior MI.

included in the study. Unlike standard medical therapy, IP rendered to a patient outside the confines of a study is difficult to track. Both Byrd and Harris et al acknowledged that IP occurred outside the design of their studies; rather than attempting to control for this, they described their studies as examinations of "supplemental" IP. At our institution, approximately 87% of patients cite a religious affiliation, and for this reason, most patients in our study likely used personal prayer, received IP, or both. In addition, an increased awareness of prayer and spirituality in CCU nurses' delivery of care may have contributed to a Hawthorne effect by suggesting that prayer is a positive adjunct therapy. In Byrd's study, IP treatment was administered only during hospitalization; in the study by Harris et al, IP extended to 28 days from randomization. However, in an attempt to minimize the effect of IP external to the study, our 26-week period of prayer treatment began at hospital discharge, a time at which outside prayer might be expected to wane.

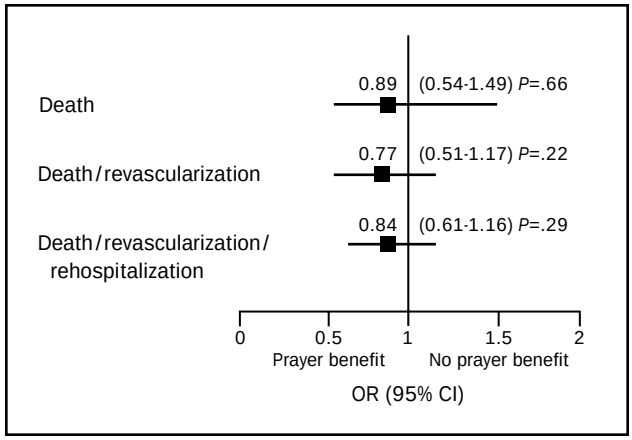

Figure 1. Effect of prayer on combined components of primary end points. CI = confidence interval; OR = odds ratio.

The study treatment, IP, has not been well characterized. Studies of the effect of meditative prayer have found a positive "relaxation response" to many forms of prayer and report that meditative prayer yields "better results" when it is not associated with requests for specific outcomes.[17,18] A difference in the effects of various forms of IP, however, has not been characterized. Unlike previous studies of IP, our study did not specify the form or content of the prayers to be offered; intercessors were asked only to pray at least weekly for an assigned patient for 26 weeks. We did not consider it appropriate in the case of IP to mandate prayer content or to write it down. However, we acknowledge that the limited prayer requirement may represent a weakness in

Table 3. **Event Information by Low vs High Risk***

	Control group (n=399)	IP group (n=400)	*P* value
No. of evaluable patients	378	382	
Low risk			
No. of patients	162	153	
Any primary event	39 (24.1)	26 (17.0)	.12
Odds ratio (95% CI)	0.65 (0.20-1.36)		
Death	13 (8.0)	7 (4.6)	.22
Odds ratio (95% CI)	0.55 (0.20-1.38)		
High risk			
No. of patients	216	229	
Any primary event	72 (33.3)	71 (31.0)	.60
Odds ratio (95% CI)	0.90 (0.60-1.34)		
Death	21 (9.7)	23 (10.0)	.91
Odds ratio (95% CI)	1.04 (0.56-1.94)		

*Results based on patients with information available on all risk factors. High risk was defined as presence of any of the following: age ≥70 years, diabetes mellitus, prior MI, cerebrovascular disease, or peripheral vascular disease. Low risk was defined by absence of all the preceding risk factors. Values are number (percentage) unless indicated otherwise. CI = confidence interval; IP = intercessory prayer; MI = myocardial infarction.

study design. The dose and frequency of prayer needed to achieve the desired effect are unknown, and an increased frequency of prayer may be likened to administration of a drug more than once a week. By randomizing intercessor-patient assignments, we assumed that each patient received a random sample of 5 intercessors' prayer schedules, "doses," forms, and contents. Although intercessors were asked to pray at least once weekly, they may have prayed more frequently. Our study did not include intercessors of non-Christian religious backgrounds because of limited availability of non-Christian intercessors, rendering inadequate numbers for statistical significance in randomization. As a result, only self-professed Christians acted as intercessors in our study.

Potential Weaknesses of the Study

We acknowledge that this study had several potential weaknesses. First, the dose of prayer was variable, intercessors used nonstandardized prayers, the number of intercessors varied, and frequency and intensity of the prayers and beliefs by intercessors were not quantified. In addition, unknown intercessors may also have been praying for the patients, and the study lacked the ability to completely control or measure prayer for the patient rendered by intercessors who were not study participants.

Second, there were variations in the recipients of prayer. We did not track the spiritual beliefs or the receptivity to any possible healing effects of prayer in the patients studied. In addition, although all patients had a CV diagnosis, this was a medically heterogeneous group. Prayer may not be beneficial or have equal effect throughout this group.

Third, the outcomes measured may have been inappropriate. Because the mechanism of potential prayer effects is unknown, the primary end points selected may not have been affected by prayer, if indeed prayer has a benefit. Limited qualitative outcomes were assessed, and although no effect of prayer was seen, qualitative outcomes may be an area in which IP may alter event rates. For example, death—when it ends suffering in a high-risk patient—could be interpreted as an answer to prayer, while a sense of peace might be an indicator of prayer effect in an anxious low-risk patient. Also, we did not measure the effect of prayer on the intercessors themselves.

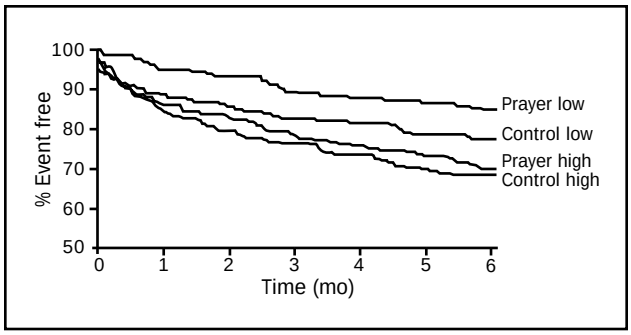

Figure 2. Event-free survival by high and low risk in intercessory prayer and control groups. Event-free survival was defined by absence of any primary end point. High risk was defined by the presence of any of the following: age 70 years or older; diabetes mellitus; prior myocardial infarction; or cerebrovascular or peripheral vascular disease. Low risk was defined by the absence of all defined risk factors.

Future Study of IP

Although we attempted to minimize the effects of some limitations, we recognize that many unanswered questions surround scientific studies of spiritual activity in general and IP in particular. Topics to be included in future research include, but are not limited to, assessment of patient beliefs and their role in the effect of IP, any effect of IP on the spiritual well-being of patients (especially when the prayer offered is a petition for spiritual well-being), and the use of a more standardized prayer and frequency with records of intercessor prayer activities and the possible derivation of a dose-response curve. In addition, assessment of intercessor belief in the power of prayer and an increased frequency of prayer offered may further standardize the treatment.

We are challenged in choosing clinical end points by which to measure prayer effect. The results of our study could be applied to a future study that independently assesses prayer effect in high-risk and low-risk subgroups based on different definitions of a "positive" or "desired" outcome. Such a study would present design and statistical challenges but might better assess the effect of prayer in a variety of patient populations. Patient logbooks or periodic surveys might place a stronger emphasis on patients' qualitative experience.

Increasing the power to detect an IP effect could strengthen future IP studies. Based on the CCU history, approximately 20% of our control group was expected to experience progression of CV disease within 26 weeks. A sample size of 800 patients provided a 90% power of detecting at least a 25% decrease in the incidence of CV disease progression, while we observed only a 13% decrease in CV disease progression. Using our observed event rates of 27.8% in the control group and 24.3% in the IP group, a future trial using similar end points would need to enroll more than 3000 patients to achieve 90% power.

Conclusions

In light of its widespread use in conjunction with illness, IP deserves further exploration. Various trials of IP have reported apparent positive medical effects in CCU patients,[11,12] rheumatic patients,[19] leukemic children,[20] and patients with the acquired immunodeficiency syndrome.[21] Our findings did not show a significant benefit of IP as administered in this study to CCU patients after hospital discharge. It should be noted that, in part due to the study's many limitations, this study did not measure the "power of God," nor should prayer offered for patients by loved ones, relatives, and friends be interpreted not to play a potentially important role in the healing process. This was a specific evaluation using specifically defined medical end points of IP rendered by intercessors unknown to or by the patients. These results do not suggest a contraindication to prayer, and further study is warranted to define the role of IP on quantitative and qualitative outcomes and to identify end points that best measure the efficacy of prayer in a variety of patient populations.

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