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CHAPTER 22

Prayer and Cardiovascular Disease

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Studies have shown that over 90% of people believe in God or a higher being.[1,2] Forty percent of Americans weekly attend mosques, synagogues, or churches.[3] When individuals become sick, many turn to prayer for comfort and solace. When caring for the sick, many include prayer.

Prayer has been a part of the human experience since early in history. Although people offer prayers for a myriad of reasons, one of the most consistent across the world's religions is the use of prayer and spiritually based healing practices during times of illness. Not surprisingly, early physicians found their base in religion, where the power of God or deities was considered the true source of healing effects. From Shamanic traditions to Chinese medicine, many healing traditions see tangible remedies such as herbal preparations not as a mechanistic tool for curing disease but as a tool through which the spirit or vital energy qi is released, enhanced, or otherwise made to flow. Even with the development of scientifically based allopathic medicine, prayer continues to be an integral part of the illness and healing experience for many individuals. Early hospitals were run by religious orders, the nursing profession was founded by nuns, and even today, most modern secular hospitals have chapels, chaplains, and services to attend to the spiritual needs of patients and families. Most religious congregations today conduct daily or weekly prayers on behalf of members who are ill, often naming them specifically, regardless of whether the subject is physically amongst the congregation during the prayer or away in a hospital.

Although the supportive nature of prayer is well understood, the direct therapeutic effects are not. Because the vast majority of concept and information about prayer is metaphoric rather than mechanistic, studying prayer as a therapy is a complex endeavor. Testing prayer as a therapy requires rigorous clinical trials. Although the literature in this area is growing, the field is still quite young. Trial designs are maturing; studies are being conducted on multiple diseases; and further investigations are being planned. To date, the quality of prayer trials varies considerably. Many of the earlier studies of prayer and healing have faulty methodology, which allows for justified criticism in interpreting their results, whereas others are quite provocative in their conclusions and challenge established healing paradigms. No prayer study in human subjects has shown a significant and reproducible treatment effect, although epidemiologic data are quite consistent in the indication that spirituality in an individual and in a community is associated with health-related benefits. Perhaps most importantly, no established mechanistic explanations for how prayer might heal exist to date. The very nature of prayer may even transcend modern scientific understanding, and because of this, explanatory models and scientific methodology such as testing the null hypothesis may not be appropriate in prayer trials.[4] However, as a practice that has been ubiquitous to civilization worldwide over the course of human history, the systematic exploration of prayer used for healing purposes and the relevance of these practices to modern health care cannot simply be overlooked.

This chapter introduces studies of prayer and cardiovascular disease. After defining terms and concepts which are paramount to the scientific investigation of prayer, the chapter will describe the major studies that have been conducted or are ongoing with regard to prayer and cardiac disease. We will also address larger systems-related issues with regard to studying prayer, including those related to informed consent and safety.

DEFINITION OF PRAYER

Certain terms and concepts must be defined to discuss studies of prayer. Prayer, in and of itself, can be many things. For some, it is the recitation of specific written passages, the performance of established rituals, or direct contact with another individual who has a connection to a higher power, energy, or intention. For others, it is a spontaneous expression of faith or spirituality without predetermined form. To study "prayer" as a standardized intervention for the purposes of health care, as many qualitative and quantitative aspects as possible must be rigorously defined.[4]

Furthermore, one must recognize that any clinical study cannot attempt or claim to study the effects of prayer *per se*. Families, friends, communities, and medical staff often pray for individuals who are ill, as might the individual by him or herself. Ultimately, given current knowledge, documenting or eliminating prayer for the sick from the hospital or healthcare environment is impossible. Ethically, any attempt to regulate or curtail these spontaneous prayers for recovery simply because an individual is participating in a study is equally problematic. Thus clinical investigations of the therapeutic benefits of prayer can, at

best, examine the effects of "supplementary" prayer as a systematic addition to the care environment as a feature of study design.

Studies of prayer as therapy generally have examined a form of prayer called *intercessory prayer*, which has been defined as prayer that calls specifically "for aid to others."[5] Intercessory prayer can have many forms. *Distant healing* prayer, in which the individual or congregation performing the prayers is physically separated from the patient, potentially by thousands of miles, has been studied. Other studies have used direct, hands-on prayer, in which the spiritual healer actually touches the intended beneficiary. A third format includes multiple tiers of prayer, in which one tier prays specifically for a patient while another tier prays for the prayers of the persons praying for the patient. To date, no available data suggest either mechanistic or outcomes insights into differences across these methods, thus again emphasizing the importance of methodologic definition to support the comparability or utility of pooling data across studies.

Other standards that characterize the investigation of all new treatment strategies may also be relevant to the concept of prayer as therapy. Not all individuals who pray may do so with the same conviction, intention, experience, or fervor; thus the efficacy of an individual intercessor may vary. In most traditions, characteristics of prayer offered by an individual may differ from the prayers offered by a congregation. Although doing so may seem odd, one must consider classical issues related to dose response. The frequency and duration of prayers, the actual content of sacred or mystical passages, and whether or not the prayer is said in proximity to the patient or with the patient's awareness, all must be accounted for.

When studies of prayer as therapy are conducted as experiments on human research subjects, many consider the ethical requirements of informed consent and safety absolutely imperative.[5] The equipoise of how or whether simple awareness of prayer studies affects the patients who participate and the ramifications of these considerations on trial design will be considered in greater detail later in this chapter. In fact, most prayer studies conducted to date appear to assume that prayer therapy is safe and carries no untoward side effects. Conceptually, however, in the absence of mechanistic knowledge, it must at least be considered that even a loving healing prayer in some patients, in some illnesses, may cause unintended harm. In fact in many traditions, prayer's highest level of healing achievement is the freeing of the spirit from the body, which in a clinical trial would be identified as death. In some settings, such as incurable cancer trials, this may be a positive endpoint and recognized as such. If such a process is inadvertently engaged in patients struggling to survive a heart attack, however, harm could result. At the current state of early investigation and fundamental mechanistic ignorance, obligations to protect human subjects with safety monitoring and informed consent in study designs bear strong consideration.

PRAYER AS AN INTERVENTION

The design and conduct of any clinical trial is challenging, but few are as challenging as a trial designed to evaluate the efficacy of prayer. Without an accepted

scientific basis for the potential effect of prayer on illness, identifying a "biologically plausible" endpoint to study in the trial is difficult. If the selected endpoint is not even relevant to the effects of prayer, study interpretation, especially of negative results, will be difficult. Second, the optimal timing, amount, and duration of prayer as well as optimal prayer methods are unknown, again in large part because of the lack of biologic knowledge on the basis of healing effects of prayer. Thus one might examine irrelevant clinical endpoints or administer an inadequate "dose" of prayer. This is particularly important because studies of prayer can at best look only at incremental benefit over and above whatever healing prayer and intention is ubiquitous in the environment, outside of the study design. Third, documentation of or specific instructions for how and when prayer is administered that supports a consistent study design produces changes in the prayer group's usual practice. This may affect the measurable therapeutic benefit and/or limit the generalizability of the trial results.

All of these considerations may be regarded essentially as key uncontrolled variables. An ideal study design would address each. The goal of the study—to elucidate mechanistic observations or to examine outcomes effects—must be clearly discerned. Although mechanistic knowledge may optimize outcomes studies, they do not depend on mechanistic knowledge *per se*. This notion is evidenced by the use of beta-blockers to reduce death rates after myocardial infarction, which is well proven in outcomes models even though to date the mechanism of this benefit remains elusive. Certain features, such as prayer in the culture at large, may be addressed by randomization. In other cases, relatively arbitrary decisions may need to be made largely from cultural practice or metaphoric beliefs. With due regard for all these issues, one must recognize that only through structured data collection and clinical studies can sufficient knowledge be gained to affect systematically health care practice and the curricula of health care training programs.

CURRENT STATUS OF RANDOMIZED CONTROLLED TRIALS OF PRAYER

Scientific studies of prayer reported in the peer review literature have been conducted over the past 30 years. The vast majority of these trials suffer from a range of design deficiencies, including heterogeneous nomenclature, endpoints of unclear clinical significance, and small sample sizes with inadequate statistical power, thus resulting in mixed and contradictory findings. The heterogeneity of these studies results in an inability to perform useful pooling or to conduct an overall meta-analysis of the published literature. The consistent impression that a measurable treatment benefit associated with prayer may in fact exist may result from a reporting and/or publication bias. Nonetheless, independent reviews and recommendation papers have concluded on a consensus basis that better-designed scientific investigations of prayer were needed and were of scientific and clinical import.[6,7]

Knowing this background, we turn to the first major study of intercessory prayer in cardiac patients, which was conducted by Byrd in 1982 in the

Coronary Care Unit (CCU) at San Francisco General Hospital.[8] Four hundred fifty consecutive patients were approached to participate in this study of intercessory prayer; 393 agreed. The patients were randomized to receive standard CCU care or standard CCU care plus distant intercessory prayer. The prayer intervention consisted of daily prayer for the individual by three to seven born-again Christian intercessors, who only knew the patient's first name and diagnosis. Intercessors were given updates about the patient's general condition and progress, and the prayer intervention lasted for the entire duration of each patient's stay in the CCU. The primary outcome measured was a nonstandardized, nonvalidated global assessment of the CCU stay that considered major complications, procedures, medications, and other interventions. Outcomes were rated as "good," "bad," or "intermediate" and were assessed by an individual who was blinded to the treatment group of the individual. More patients in the prayer group had "good" outcomes than in the standard care group (85% in comparison to 73%), and fewer had a "bad" outcome (14% in comparison to 22%). These differences were statistically significant.

Although numerous critics of this study appropriately note significant limitations of this trial (e.g., the unvalidated composite clinical score makes the clinical importance of the "significant" findings impossible to interpret), Byrd broke through several barriers in conducting a clinical investigation of prayer as a therapeutic intervention. Byrd combined scientific methodology with a blinded, prospective randomized clinical trial design and acknowledged that because prayer from patients, families, and others was not controlled for, he was, in essence, measuring "supplemental" therapeutic prayer, or incremental benefit, not prayer *per se*. This study was an important step in defining the limitations of prayer studies and in properly framing the context for future investigations. Importantly, Byrd also studied prayer not as a replacement to the high technology of standard care, but as an adjunct in addition to standard care. Finally, by publishing these findings in a peer-reviewed journal, Byrd set the stage for serious Western clinicians and scientists in the study of spiritual intervention in patients with heart disease.

The second major trial of intercessory prayer in patients with heart disease was published over 10 years after Byrd's groundbreaking study. In 1999 Harris and colleagues[9] studied more than 1000 patients in the CCU and deliberately borrowed many features from the Byrd study. Patients were randomized to receive standard CCU care with or without an offsite intercessory prayer intervention, and intercessors were given the first name of the patient for whom to pray. In contrast with the earlier study, however, intercessors were not informed of the diagnosis or of the patient's condition, and the prayer intervention that was prescribed by the study was for "a speedy recovery with no complications" and "for anything else that seemed appropriate to them" for a total of 28 days. Two outcome measures were employed. One was the "good" and "bad" outcome scale developed by Byrd. The other was an illness-scoring system called the MAHI (Mid-America Heart Institute) scale, which, although it is more detailed than the Byrd score, was equally unvalidated for clinical relevance.

Study results showed no difference in the Byrd score (i.e., investigators were unable to reproduce the earlier findings). In comparing the unweighted MAHI CCU score, which totaled the number of medications prescribed, procedures performed, and clinical events, the intervention group had 10% fewer "elements" than the control group had. Similarly, in analyzing a weighted score, the prayer group had an 11% improvement in comparison to the standard therapy arm. Both of these values achieved statistical significance, although, as with the Byrd study, the clinical meaning of these results is unclear.

In addition to studying a larger cohort of patients and the attempt to build upon the findings of an earlier study, the landmark feature of the Harris study was that informed consent was not obtained from patients and the CCU staff were not informed that a study was in progress. As explicitly discussed in the report of this trial, the investigators were concerned that knowledge about the study would affect the "spiritual terrain" of the CCU, and/or that patients might feel extra anxiety by worrying that they might *not* be receiving intercessory prayer. The study was reviewed and approved by the institutional review board at the MAHI, which allowed these theoretical concerns to override the use of the traditional informed consent process in the context of the assumption that patients who were either receiving or not receiving the prayer therapy could not have been harmed. This issue remains highly controversial. Furthermore, data from this study provide no insight into the concern that mere awareness of a prayer study might change the outcome of the study.

The third published CCU study involved 800 patients from the Mayo Clinic but tested a somewhat different research hypothesis, specifically asking if 26 weeks of remote prayer therapy initiated at the time of hospital discharge might affect long-term outcome.[10] In this trial, traditional clinical endpoints of death, coronary revascularization, rehospitalization, or an emergency department visit for a cardiac problem were analyzed. Follow-up extended for 6 months after discharge. Patients all gave informed consent to participate in the trial. In comparison to the earlier CCU studies, the specifics of the prayer intervention were not as strictly prescribed. Intercessors were not specifically directed how to pray but were asked to do so at least once per week. The content of the prayer was not predetermined, and in fact the authors acknowledge that a possible limitation in this study was that the "dose" of prayer was not standardized. Although it was conducted as a prospective, randomized study, the Mayo design uniquely stratified randomized treatment relative to risk categories.

Although several trends favored the prayer-treated group, no significant difference was seen between the prayer group and the control group with regard to the predefined clinical endpoints or in a quality of life score. Importantly, however, the trial studied hard endpoints of clear clinical relevance in a thoughtful study design. Two features of the data are notable as potential confounding variables. First, the event rate in the control population was lower than predicted for sample size calculation, meaning that the trends seen could represent a treatment effect underpowered for the cohort enrolled. In addition, patients were enrolled while still in the CCU, while the prayer therapy was not initiated until discharge from the CCU. With the assumption that time is linear in the effect of

prayer on healing, this particular intervention may simply have been too late to reduce events in the CCU nor did it minimize post-CCU events.

The fourth published study of prayer in cardiovascular patients was the Monitoring and Actualization of Noetic Trainings (MANTRA) pilot study.[11] In this study offsite prayer was studied in parallel with other intangible ("noetic") modalities, including healing touch, stress relaxation, and imagery. This was conducted at the Veterans Affairs Medical Center in Durham, North Carolina and enrolled 150 male patients with acute coronary syndromes who were scheduled for urgent percutaneous coronary intervention (PCI) for clinical indications. The MANTRA pilot was a prospective, five-way randomized trial comparing the four noetic therapies with a standard care group. In three arms (healing touch, stress relaxation, and imagery) a trained practitioner administered therapy at the bedside before the PCI procedure. The other two-fifths of the patients remained double-blinded, with half receiving offsite prayer intervention and half receiving standard care. Although the MANTRA pilot was designed as a feasibility and safety study, the primary endpoints, like the Mayo Clinic protocol, consisted of standard clinical outcomes during the index hospitalization and mortality out to 6 months. No statistical differences between the groups were found; however, the study was not powered to show efficacy. A 27% absolute reduction of in-hospital complications was observed in the noetic groups overall compared to the standard care group, with the lowest absolute complication rate in-hospital observed in the off-site prayer group. At 6 months, mortality was lowest in the standard care and prayer groups, with a trend toward higher mortality in the three other noetic therapies.

Several features of the MANTRA pilot design were unique in comparison to previous published investigations of distant prayer in patients with heart disease. The male patient cohort was a pure coronary disease population who were being treated in the acute setting and enrolled just before an invasive procedure rather than CCU patients of mixed gender with mixed cardiac pathologies (arrhythmias, heart failure, valvular disease) as in previous trials. Unique descriptors in the study included documentation of patient awareness of nonstudy related prayer on his or her behalf as well as documentation of the pre-PCI presence of family, community members, or hospital chaplains. In the MANTRA pilot nearly 40% of all enrolled patients were aware of someone praying for their recovery outside of the study protocol, and more than two-thirds of patients were visited by family, community, or chaplains before the PCI, thus reinforcing the awareness that clinical trials in this area can examine only incremental benefit over and above what is already a part of the fabric of cultural healing systems in the United States. Finally, the MANTRA pilot prayer intervention arm was unique in its structure compared to previous trials. A total of nine prayer congregations covering a variety of ethnic belief systems (Catholic, Baptist, Fundamentalist, Moravian, Unitarian Christian; Jewish; Buddhist) dwelling across an array of time zones (Nepal, Jerusalem, France, east coast United States, midwest United States) were all provided with the patient's name, age, and illness for each patient assigned to prayer therapy. All prayer groups conducted their prayers

wholly in accordance with their ethnic traditions—there were no prescribed instructions from the protocol.

In addition to prayer trials involving cardiac disease, other illnesses have also been studied in prospective randomized trials. Although many of these trials are significantly flawed, we will examine two of the better studies in detail, one trial that studied patients with infertility[12] and one that studied patients with the human immunodeficiency virus (HIV).[13] Both of these highlighted studies are provocative in their approach to trial design, and both provide clinically interpretable results.

The infertility study was conducted under the auspices of Columbia University. Study subjects included 219 women participating in an in-vitro fertilization (IVF) and embryo transfer program in Korea. Women were randomized to receive standard IVF therapy or standard IVF therapy plus a prayer intervention. The intervention method used a two-tiered or "prayer amplification" structure, with one group of intercessors praying directly for the women to have a successful pregnancy, while a second group of intercessors prayed specifically that the prayers of the first group would be answered. The intercessors who prayed directly for the patients received digital photos of the patients for whom they were praying. The primary study endpoint was the presence of a healthy term baby.

Like the staff of the MAHI study mentioned previously, the clinic staff caring for the patients were unaware of the study, and patients did not give informed consent to participate in a clinical trial. As mentioned previously, failure to obtain informed consent remains highly controversial and perhaps borderline unethical.

Interestingly, the results of this study constitute the most striking report of effects of prayer on somatic health. Twice as many women in the prayer group had successful pregnancies (50% as opposed to 26% in the control, which was also the typical success rate for that clinic), which was both highly statistically significant as well as obviously clinically relevant. This study is remarkable for the unique population studied; the unique structure of the prayer intervention; and the dramatic, clinically and statistically significant outcome findings, although to date these findings have not been confirmed.

A second study worthy of mention investigated the role of distant healing for patients with HIV disease. As opposed to most clinical prayer trials in which patients are "assigned" a certain intercessor or groups of intercessors, this trial allowed for a rotation between the patients and those praying for them. The authors designed this specifically to account for any differences in efficacy between intercessors. They chose not to view prayer as a necessarily binary intervention (that a patient would either receive or not receive prayer) but possibly one with varying degrees of intensity. Also, prayers in this trial came from intercessors of multiple different ethnic backgrounds (Christian, Jewish, Buddhist, Shamanic traditions, Native American) as well as other trainings that might or might not be characterized as prayer, such as graduates of bioenergetic and meditative healing schools.

In this trial, informed consent was obtained, but patients and physicians were blinded as to whether the individual was receiving prayer therapy. Intercessors

were directed to pray for 1 hour per day for 6 consecutive days, specifically with "an intention for health and well-being." The intervention group spent fewer days in the hospital, had fewer total hospitalizations, had a less severe illness score, and had better mood. They also had fewer AIDS-defining illnesses and fewer outpatient doctor visits. There was no difference in CD4 lymphocyte counts between the two groups. However, concern that the investigators' decision to not correct for multiple comparisons likely improved the chances of finding a positive result remains. As was the case with the infertility trial described previously, these findings have not been replicated.

What makes this trial different from the others is the attention paid to rotating intercessors as well as the intermixture of "prayer" with "energy" or "intentionality" healing modalities in the treatment cohort. Although other trials may have used multiple intercessors or groups of intercessors for any given patient, this was the first to openly acknowledge that not all prayer may have the same "strength." Essentially, through the rotation this model provides a degree of quality control.

The previously mentioned studies illustrate a wide array of approaches as well as a central core of common design elements. All studies used prospectively defined therapies and outcomes, and all used randomized treatment assignments. On the other hand, the patient cohorts selected, the choice of endpoints, the characteristics of prayer intervention, and the overall study quality varied greatly across trials.

The studies also illustrate the important difference between statistical significance and clinical relevance. In spite of the negative results, the Mayo study[10] and MANTRA Pilot[11] used hard, easily reproducible endpoints of death, myocardial infarction, hospitalization, and revascularization. The infertility study[12] followed successful embryo implantations producing healthy term pregnancies, and the HIV study[13] documented healthcare use such as hospitalization and outpatient visits as well as the number of AIDS-defining illnesses and mood scales. Therefore interpreting the clinical relevance of the results is somewhat easier, although all the mechanistic questions remain unanswered by these data. The other CCU studies, on the other hand, report statistically significant differences in composite clinical scores, but because these scores have not been validated, what clinical conclusions can be drawn from the results remains unclear.

FUTURE TRIAL DESIGN AND INFORMED CONSENT

A recently published consensus paper describes recommendations for designing high quality studies of prayer.[5] The authors explore the different components and controversies of prayer research and base their suggestions on the standards of the Consolidated Standards of Reporting Trials (CONSORT) group.[14] It essentially recommends that high-quality prayer research endeavor to systematically define methodology and terminology with endpoints and statistical analyses defined *a priori*. As with other clinical trials, patient selection,

randomization, data collection, and blinding are suggested as clinical trial tools that may help cope with an area full of uncontrolled variables and assumptions in the complete absence of mechanistic knowledge.

For both ethics and safety, the consensus group challenges the notion that prayer trials can occur without the informed consent process. In the modern research age of the Health Insurance Portability and Accountability Act (HIPAA), protected health information may not be collected without patient consent or justified waivers. One of the major arguments used in the trials that did waive informed consent is the assumption that receiving prayer therapy can do no harm. Because this idea has not yet been scientifically established, however, that argument may not carry sufficient justification for waiving informed consent. Additionally, some patients may not wish to participate in a study of prayer, may have concerns about being assigned to a group not receiving prayer, or may not wish to be prayed for by individuals of religious backgrounds other than their own. Ethically, respect for such individual preferences in addition to the potential safety issues is seen as far outweighing the theoretical concern that awareness of the study might change the spiritual landscape.

Equally important to discussing those aspects that make for a high quality clinical trial of intercessory prayer, it is imperative to consider aspects of healing prayer that may not be suitable for clinical study. Questions such as whether a deity exists or which religious modality has the best prayer or other flashpoint issues could be considered outside of the healthcare agenda. Similarly, studies that seek to replace advanced modern technological care are less likely to be considered relevant in comparison to studies that incorporate prayer as an adjunct, especially in cardiac patients. Finally, there is simply no way to test whether prayer works because of the widespread presence of healing prayer across most cultural traditions around the world.

Although healing prayer is an ancient tradition widely practiced throughout the world, the scientific literature in this area is still very young at best.[15,16] No understanding of the mechanism in how or whether prayer actually affects somatic healing has been reached. With the development and use of standardized nomenclature and definitions and clinically meaningful endpoints, study models might ultimately support the imputation of mechanistic insights and advance the field overall.

CONCLUSION

As the current literature stands today, considering concrete clinical recommendations for the use of prayer as therapy for cardiovascular disease—or any changes in practice along these lines at this time—is still premature. The trials presented above provide some intriguing "food for thought." Preliminary, suggestive findings and the intuitive appeal of a healthcare system that combines the finest of modern technology with systematic attention to the rest of the human being certainly supports the notion that further study in this area appears warranted. In addition to attention to the scientific basis of robust study

designs, the purpose and intention of study in this area must be carefully scrutinized. The mission of such science cannot be to advance philosophies or defend metaphorical claims or preferences. Study designs in this area should be focused on the advance of health care, with data that yield the basis for mechanistic insights, educational curricula, practitioner certification standards and practice guidelines, or redefinition of healthcare roles commensurate with a modern—if somewhat enlightened—vision of evidence-based medical practice in cardiovascular care.

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