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Financial Disclosure

Russell H. Greenfield, MD (executive editor), David Kiefer, MD (peer reviewer), and Leslie Coplin (managing editor) have no financial relationships with companies having ties to the material presented in this continuing education program.

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Reiki for Psychological Outcomes and Pain Relief

By Dónal P. O'Mathúna, PhD

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THE TERM "REIKI" (PRONOUNCED "RAY-KEY") COMES FROM TWO JAPANESE words, *rei*, meaning universal spirit, and *ki*, meaning life energy.¹ Therapies based on this non-physical, vibrational life energy are known as biofield therapies, which include therapeutic touch and healing touch.² This concept of energy arises from Eastern ideology and philosophy where a continuous and unimpeded flow of life energy is required for sustained health and wellness.³

Interest in Reiki has been growing, both among the public and in conventional health care settings. Nurses, physicians, and rehabilitation therapists now practice Reiki in hospitals, nursing homes, and other settings.² Reiki is reported to be offered at 15% of U.S. hospitals.⁴ Health care professionals should be informed about Reiki to answer patients' questions about it and help them decide whether to incorporate it into their practices.

Procedure

When receiving Reiki, a person relaxes in any comfortable position. Practitioners gently rest their hands in specific ways on approximately 12 standard sites throughout the body. Reiki practitioners begin with the head and spend a few minutes at each site, with a complete session typically taking 45 to 90 minutes.

Practitioners are believed to act as passive channels for the life energy, which comes from a universal source. According to many practitioners, the energy cannot be directed by the human mind, but it guides itself to address patients' needs.¹ More advanced practitioners claim they do not need to be present with patients but can bring healing by visualizing their patients (called distance Reiki).

Practitioner Training

Reiki training involves opening trainees' life energy channels (or chakras) in special training sessions called initiations, empowerments, or attunements. Only Reiki Masters (or Level III practitio-

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ners) may perform attunements, also described as “sacred ceremonies.”^{1,5} During attunements, trainees’ hands become warm, signaling they are ready to channel life energy as Level I practitioners.

Reiki Level II is attained after another attunement when the practitioner “intuitively” receives special symbols, believed to be healing gifts from personal “spirit guides.”^{5,6} The symbols increase the practitioner’s healing powers. Practitioners draw the symbols on patients’ bodies, or visualize them, while silently chanting the symbol’s name. Level II must be attained before distance Reiki is possible.⁵ Becoming a Reiki Master requires another attunement during which additional symbols are received for use in initiating trainees.

Controversy

Reiki is an ancient healing practice, believed to have originated thousands of years ago in Tibet.¹ It was rediscovered in Japan by a Buddhist monk, Mikao Usui, during the mid-1800s. Usui trained others who were required to hold the initiation rites in secret. However, these practices were introduced into the Western world in the 1970s.⁵ Reiki is still practiced according to the “Usui System,” although many variations now exist.

Reiki is based on the belief that health requires a sustained and balanced flow of life energy throughout the body. Reiki is said to correct imbalances and blockages in this energy. During Reiki, people report a variety of experiences, most commonly that of being deeply relaxed and cared for, along with sensations of energy.³ Others

describe Reiki in terms of contact with “spirit guides, etheric bodies, chakras, and past lives.”⁶ This has caused controversy as these experiences “are frequently associated with profound religious experience and have been linked to ritual healing practices across cultures.”³ On the other hand, others are convinced that “Reiki is not a religion or cult.”¹

Clinical Studies

Some proponents claim Reiki treats many specific conditions, but research has focused primarily on promoting relaxation, healing, and wholeness. The beneficial effects claimed for Reiki are based primarily on anecdotal reports, descriptive studies, or controlled trials with small numbers of participants.⁷ Developing an authentic control therapy for Reiki is challenging. Most commonly, someone with no training in Reiki does the hand movements over a patient without understanding what true Reiki involves. This has been called “sham Reiki.” Most studies examine psychological outcomes and pain relief. Single studies addressing various other conditions have been reviewed elsewhere.²

Psychological Outcomes. One early study involved Reiki practitioners treating 15 healthy subjects recruited from relaxation courses offered by the researchers.⁶ Distance Reiki was used to either induce relaxation or arouse subjects’ autonomic activity at 30-second intervals in a randomly determined sequence (25 minutes altogether). A separate control group was not used nor was blinding. Relaxation responses did not differ significantly between relaxation and arousal periods.

In another single-group study, 23 healthy participants received 30 minutes of Reiki.⁸ Several outcomes were measured as indicators of levels of stress or relaxation. State anxiety mean scores were lower after Reiki than before ($P = 0.02$), as was systolic blood pressure ($P < 0.01$). Salivary IgA levels rose significantly ($P = 0.03$), but salivary cortisol, skin temperature, and electromyography did not change significantly.

In a controlled study, nursing students received either hands-on Reiki ($n = 22$) or mimic-Reiki ($n = 20$).⁹ Randomization and blinding were not mentioned. The mimic-Reiki was given by a research assistant who received 15 minutes of training in Reiki hand positions but no information about energy. No significant differences were found for perceptions of anxiety, personal power, or well-being.

One hundred undergraduate students were nonrandomly allocated to one of four groups.¹⁰ Each group experienced 20 minutes of either Reiki, mimic-Reiki, listening to a meditation tape, or listening to music. Relaxation was measured by a researcher-designed questionnaire, heart rate, and blood pressure. No significant differences were

Alternative Medicine Alert. ISSN 1096-942X, is published monthly by AHC Media, a division of Thompson Media Group, LLC, 3525 Piedmont Rd., NE, Bldg. 6, Suite 400, Atlanta, GA 30305.

EXECUTIVE EDITOR: Leslie Coplin
MANAGING EDITOR: Neill Kimball
GST Registration Number: R128870672.

Periodicals Postage Paid at Atlanta, GA 30304 and at additional mailing offices.

POSTMASTER: SEND ADDRESS CHANGES TO *Alternative Medicine Alert*, P.O. Box 105109, ATLANTA, GA 30348.

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found between any of the groups.

A double-blind study randomized 30 inpatients at a stroke rehabilitation unit to one of three groups.¹¹ Each patient received up to 10 treatments over 2½ weeks from either a Reiki master, a first-degree Reiki practitioner, or a sham practitioner. A historic control group consisted of records randomly selected for 20 patients at the facility. No significant differences were found using validated tools of functional independence and depression. Post-hoc analyses suggested some effects on mood and energy levels, but the researchers concluded there were no clinically useful effects. Interestingly, the sham practitioners reported feeling heat in their hands more frequently than the Reiki practitioners ($P < 0.03$).

A double-blind study of Reiki randomly assigned 45 patients needing treatment for depression and stress to receive hands-on Reiki, distance Reiki, or mock distance Reiki.¹² Each treatment lasted 60-90 minutes, with weekly treatment for 6 weeks. Three standardized assessment tools measured depression, hopelessness, and stress at weeks 1, 6, and 52. Both treatment groups showed significant improvement on all three tests at weeks 6 and 52 compared to control ($P < 0.05$). The two treatment groups did not differ significantly between one another.

Reiki's effect on comfort and well-being was studied in cancer patients at an outpatient clinic.⁷ The 189 participants were assigned to one of three interventions: standard care, 20 minutes Reiki from a Reiki Master, or 20 minutes sham Reiki. The intervention offered on each day was randomly selected and all participants that day received that intervention. Nurses and patients were blinded and validated instruments were used. The standard care group showed no changes in comfort or well-being, while both Reiki and sham Reiki groups improved significantly on both outcomes ($P < 0.05$). However, the two intervention groups did not differ significantly. The researchers concluded that their study affirmed the importance of personal presence with cancer outpatients.

Thirty-five psychology undergraduates participated in a single-blind randomized study.¹³ Participants were randomly assigned to one of six groups, with three receiving Reiki and three receiving no-Reiki. Participants also were assigned randomly to one of three relaxation/hypnosis techniques. The practitioner remained behind the blinded participants administering either Reiki or no intervention. Each received ten 30-minute treatments over 2½ to 12 weeks. The two groups differed significantly on the Illness Symptoms Questionnaire ($P = 0.001$), but not in measures of depression, anxiety, sleep quality, and salivary cortisol. Illness symptoms did not change in the Reiki group, but they increased in the no-Reiki group. However, the two groups also differed significantly at baseline.

The same research team conducted a related study with

another 40 psychology students.¹⁴ The students were divided into two equal groups based on scoring high or low on a depression and anxiety scale. Members of each group were randomly assigned to Reiki or no-Reiki while they engaged in guided relaxation. Each participant received six 30-minute sessions over 2 to 8 weeks. For the whole group, depression, anxiety, and stress scores changed little with no significant differences between groups. Illness symptoms did not change as in the earlier study. The group that initially scored high on depression and anxiety showed a significant reduction in these scores after treatment ($P = 0.09$), whereas those with lower scores initially did not change significantly. The conclusion was that people with higher levels of depression and anxiety might stand to benefit more from Reiki than those with lower levels.

In another trial, 20 community-dwelling older adults were randomly assigned to Reiki or waiting list control.¹⁵ The intervention was 30 minutes of Reiki weekly for 8 weeks from a Reiki Master, accompanied by soft lighting and music. Before and after Reiki, a nurse measured pain, heart rate, and blood pressure and discussed either the past week's stressors or the upcoming week. The Reiki group compared to control had significantly improved pain, depression, and anxiety scores (all $P < 0.001$) on validated instruments. No significant differences in blood pressure or heart rate were noted.

A pilot study randomized 32 women undergoing breast biopsy to either Reiki plus standard care or standard care alone.¹⁶ The investigator, patients, and data collectors were blinded. Those in the Reiki group received one treatment session during the week before the biopsy and one in the week after. Treatment lasted 54 minutes on average. No significant differences were found in depression or anxiety scores between the two groups.

A randomized, crossover study involved 16 cancer patients who had recently completed chemotherapy.¹⁷ The intervention group received Reiki on 5 consecutive days, no Reiki for up to 7 days, 2 more days of Reiki, no Reiki for 7-14 days, and then the control protocol. During the control period, 45 minutes of rest at home replaced Reiki. Those undergoing Reiki had significantly improved scores for fatigue ($P = 0.05$), quality of life ($P < 0.05$), pain ($P < 0.005$), and anxiety ($P < 0.01$).

The level of evidence to support Reiki for psychological conditions is weak, although some beneficial results have been reported. Such conditions are challenging to control for, especially with a hands-on intervention like Reiki. Sham Reiki provides a way to blind patients, but those collecting outcomes also should be blinded. Researchers often provide Reiki, which confounds and potentially biases the results. Other confounding factors like music, lighting, and personal interactions should be the

same between groups, but often are not.

Pain Relief. Fewer studies have examined Reiki for pain relief. An uncontrolled pilot project used Reiki with 20 subjects experiencing different types of moderate pain.¹⁸ Subjects continued to use other analgesics and received Reiki in a dimly lit room accompanied by burning candles and soft music. Pain measured with a visual analogue scale (VAS) and Likert scale was significantly lower after treatment compared to beforehand ($P = 0.0001$).

The pilot study led to a controlled trial of patients with advanced cancer.¹⁹ Sample size calculations indicated 100 participants were needed. Recruitment stopped after 53 patients because participants insisted on being assigned to the Reiki group. Participants were randomly assigned to either standard opioid drugs plus 90 minutes Reiki (including physical touch) or opioids with 90 minutes rest (and no physical touch). Before and after the interventions, given on days 1 and 4, a research nurse measured pain scores, blood pressure, respiration rate, and heart rate. On days 1 and 7, quality of life and analgesic usage were measured. Results were based on 24 patients who completed the study (55% dropout). On day 1, the Reiki group compared to control had significant reductions in pain levels ($P = 0.035$), diastolic blood pressure ($P = 0.005$), and heart rate ($P = 0.0019$). On day 4, only the pain levels were significantly different between the groups ($P = 0.002$). Quality of life was measured on days 1 and 7, with significant improvements in the psychological components ($P = 0.002$), but not the social or physical components. Analgesic usage did not differ between the groups. The researchers urged caution in interpreting the results due to the small sample size, high dropout rate, and the confounding influence of the Reiki practitioner's presence and touch in the Reiki group.

In a controlled study, 21 patients were randomized to treatment or control (no intervention) after impacted third molars were extracted.²⁰ Three hours later the treatment group received distance Reiki and LeShan from "several" miles away, with practitioners alternating therapies every hour for 6 hours (LeShan healing is a meditative method that is believed to stimulate healing in another person). Two weeks later, the second lower third molar was removed and subjects crossed over to the other group. Pain intensity was evaluated hourly using a VAS. The treatment group had significantly lower pain intensity and significantly higher pain relief ($P < 0.05$).

Another study involved 120 volunteers with pain and stress for at least 1 year.²¹ They were randomly assigned to receive Reiki from a Reiki Master, progressive muscle relaxation, sham Reiki, or no treatment for 10 biweekly sessions. Participants completed 12 instruments at pretest, end of treatment, and 3 months follow-up. Significant improvements were noted with Reiki on 10 of the 12 scales,

with the largest effects found for depression ($P = 0.001$) and anxiety ($P = 0.0001$).

Adverse Effects

Practitioners claim Reiki cannot cause harm as the energy adjusts itself as needed. A recent study claimed, "Analysis of the literature found no adverse effects reported in any study."⁷ However, one study found that participants had varying experiences, including positive, neutral, and negative effects.⁶ The latter ranged from feelings of disappointment and boredom to agitation. Several participants experienced "panic" during the study, resulting in one participant trying to "block" the healer's influence. Many reported bodily experiences unlike anything they had ever felt before, including hot flushes and muscle spasms. One study reported depression triggered by Reiki, which led to adjustments in how the therapy was administered.¹⁵ An Australian nursing journal printed a letter claiming Reiki training caused a nurse much anxiety and discomfort.²² Controversy erupted, with some nurses reporting negative effects and others defending Reiki as completely harmless.²³ Unpleasant changes in states of consciousness and other negative experiences in people receiving other energy therapies are relatively uncommon occurrences, but further investigation is needed and effective communication required to ensure patients are appropriately informed.²⁴

Conclusion

A small but growing number of controlled studies have been published on Reiki. For psychological outcomes, most studies have not found significant improvements. Studies of pain are fewer, with more showing significant improvements with Reiki. However, general conclusions cannot be reached due to the wide variety of study designs and limitations like small sample sizes and varying treatment protocols. For example, one crossover trial included a washout period of 1-2 weeks, and there were variable durations of follow-up in other studies. Proponents generally claim sessions should last 45 to 90 minutes, yet in a number of studies Reiki was provided for only 20 minutes. Confounding factors like music, soft lighting, or conversations with nurses were often present and were not taken into account.

Recommendations

Uncontrolled studies show that outcomes like anxiety, depression, and pain may improve after patients receive Reiki. However, the source of these changes cannot be definitively attributed to Reiki itself in light of confounders such as the presence of healing practitioners or the relaxing atmosphere employed. The growing popularity of Reiki at least supports the importance of meaningful, personal in-

teractions between health care providers and patients. Improving upon and creating space for these interactions is a goal seemingly all can support, although this raises practical difficulties in today's health care settings.

Controversy regarding Reiki's spiritual roots and the range of psychological experiences triggered require further careful investigation. Such experiences may be particularly challenging for certain patients. Patients should be informed of the limited evidence supporting Reiki's effectiveness, the potential for rare adverse events, and the controversy surrounding its spiritual roots. This is essential to allow patients to make informed decisions about Reiki based on their therapeutic and spiritual goals. ■

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Dems Da Berries? Cranberries or Antibiotics to Prevent UTIs

ABSTRACT & COMMENTARY

By Russell H. Greenfield, MD

Synopsis: *In a lengthy intervention trial, antibiotic prophylaxis against recurrent urinary tract infections in premenopausal women was more effective than a cranberry extract; however, development of antibiotic resistance was significant.*

Source: Beerepoot MAJ, et al. Cranberries vs antibiotics to prevent urinary tract infections. A randomized double-blind noninferiority trial in premenopausal women. *Arch Intern Med* 2011;171:1270-1278.

CRANBERRY (*VACCINIUM MACROCARPON*) JUICE AND EXTRACTS have long been promoted as effective interventions

against recurrent urinary tract infections (rUTIs). The researchers behind this study sought to compare the use of a standardized cranberry extract in capsule form and antibiotic therapy as prophylaxis against rUTIs over the course of 1 year in a double-blind, double-dummy, randomized noninferiority trial in premenopausal women.

Community women aged 18 years or older with a history of at least three symptomatic UTIs (self-report) during the prior year were recruited via advertisements and physician and hospital referrals from throughout the Netherlands. Exclusion criteria included active UTI symptoms, pregnancy, and recent use of antibiotics or cranberries in the previous 2 weeks. Subjects were randomized to take over the ensuing year either (1) 1 tablet with 480 mg trimethoprim-sulfamethoxazole (TMP-SMX) at night and 1 placebo capsule twice daily, or (2) 1 capsule with 500 mg cranberry extract (Cran-Max; Proprietary Nutritionals, Inc, Kearny, New Jersey) twice daily and 1 placebo tablet at night. Patients were asked to avoid prophylactic antibiotics or cranberries during the intervention period and for 3 months following discontinuation of the intervention.

Immediately before initiation of the study medication and monthly thereafter until 3 months after discontinuation, subjects completed a questionnaire addressing UTI symptoms, adverse events, infections other than UTI, and antibiotic consumption. At these same specified time points, participants also were asked to collect urine (a dipslide and a sample to measure antibacterial activity) and feces. Adherence to antibiotic prophylaxis was assessed by measuring antibacterial activity in urine. Urine and fecal samples obtained at study entry, after 1 and 12 months of prophylaxis use, and 1 and 3 months after discontinuation of study medication were analyzed for antibiotic resistance of *Escherichia coli* isolates, and susceptibility to antibiotics most commonly prescribed for the treatment of UTI was determined. When symptoms compatible with rUTI developed, subjects were asked to collect urine using a dipslide and send it to the laboratory for culture.

Primary clinical outcomes of interest were mean number of self-reported rUTI (termed clinical recurrences, or CRs, and defined on the basis of symptoms including dysuria, frequency, and urgency) over 12 months; proportion of subjects with at least one symptomatic UTI during prophylaxis; and median time to first symptomatic UTI. Additional analysis of the primary outcomes was performed for the 3 months after discontinuation of the study medication. Secondary outcomes included mean number of microbiologically confirmed symptomatic rUTI (termed microbiologic recurrences, or MRs, and defined as a UTI on the basis of a combination of clinical symptoms and bacteriuria); percentage of participants with at least 1 MR; median time to first MR during prophylaxis and in the 3 months thereafter. Prevalence of asymptomatic bacteriuria at 1 and

12 months of prophylaxis, and proportion of patients experiencing serious adverse events, also were monitored.

Following 12 months' prophylaxis, the mean number of CRs was 1.8 (0.8-2.7) in the TMP-SMX and 4.0 (2.3-5.6) in the cranberry group. The between-group difference of 2.2 CRs (95% confidence interval, 0.3-4.2; $P = 0.02$) was outside the noninferiority margin of 1.3 CRs. Proportion of patients with at least 1 symptomatic UTI was also higher in the cranberry than in the TMP-SMX group (78.2% vs 71.1%). Median time to first recurrence was 8 months for the TMP-SMX and 4 months for the cranberry group ($P = 0.03$). After 1 month of TMP-SMX prophylaxis, resistance to TMP-SMX, TMP, and amoxicillin increased from 21.1%-27.8% to 72.5%-90.5% in both feces and urine, with a return to baseline resistance levels 3 months after antibiotic therapy was stopped.

E. coli was the most prevalent causative microorganism (78.9% TMP-SMX, 75.9% in the cranberry group). Resistance percentages of the *E. coli* isolates causing UTIs in the TMP-SMX group were similar to, and in the cranberry group somewhat lower than, corresponding resistance percentages of *E. coli* from feces or urine of asymptomatic women. Resistance rates for ciprofloxacin and norfloxacin in urinary *E. coli* isolates increased, from 8.3% at baseline to 23.1% after 12 months of TMP-SMX. After 1 month, 22 of the 83 women in the TMP-SMX group (26.5%) and 32 of the 89 women in the cranberry group (36.0%) had asymptomatic bacteriuria. At 12 months, these percentages were 30.2% (16 of 53) and 37.0% (17 of 46), respectively. Antibacterial activity was present in 632 of 722 urine samples (87.5%) obtained from women during TMP-SMX prophylaxis use. There were no statistically significant differences between the two groups with respect to adverse effects; however, one subject in the TMP-SMX group developed Stevens-Johnson syndrome.

The study authors concluded that once daily antibiotic therapy with TMP-SMX is more effective in premenopausal women against rUTI than cranberry capsules, but at the price of increased bacterial resistance to antibiotics.

■ COMMENTARY

Recurrent urinary tract infection is a significant problem associated with significant morbidity and negative impacts on quality of life. Prevalence is high, and although prolonged antibiotic prophylaxis may be effective, many women fear the potential complication of infection with a resistant organism. The use of cranberry or blueberry juice or extracts have become very popular in this setting, and have been reported to also be effective, likely due to their ability to inhibit bacterial adhesion to the bladder wall. This study shows, however, that antibiotic therapy is the more effective of the two interventions. The price of added effectiveness, however, is high.

The study results may be called into question if for no other reasons than some of those put forth by the authors themselves — the adequate dose of cranberry extract has yet to be determined, and the concentrations of type A proanthocyanidins (deemed responsible for anti-adherence activity) necessary may be significantly higher than those employed here — there were 9.1 mg/g of type A proanthocyanidins present in the cranberry extract, but recent *in vitro* data cited by the authors suggest 72 mg/d may be required for a protective effect.¹ In addition, subject adherence with the cranberry extract dosing could not be confirmed in an absolute sense, nor could the incidence of CRs, and there was a significant dropout rate. All this stated, the study was extremely well-done. Which leaves the clinician to ponder, “What intervention might be best?”

Use of cranberry or blueberry extracts, or juice (the low-sugar varieties might be best), remain reasonable options for many women with rUTI, especially if the incidence is relatively low. For those with more frequent rUTI antibiotic therapy may be necessary, perhaps with the addition of a probiotic. ■

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Once Yearly Vitamin D for Falls and Fractures: Not A Good Idea

ABSTRACT & COMMENTARY

By David Kiefer, MD

Dr. Kiefer is Clinical Instructor, Family Medicine, University of Washington, Seattle; Clinical Assistant Professor of Medicine, University of Arizona, Tucson; and Adjunct Faculty, Bastyr University, Seattle; he reports no financial relationships relevant to this field of study.

Synopsis: *The oral administration of 500,000 IU cholecalciferol in fall or winter resulted in a slightly higher risk of falls and fractures vs placebo in 2,256 community-dwelling women aged 70 and above.*

Source: Sanders KM, et al. Annual high-dose oral vitamin D and falls and fractures in older women: A randomized controlled trial. *JAMA* 2010;303:1815-1822.

THE AIM OF THIS STUDY WAS TO CLARIFY SOME OF THE CONFLICTING results in the literature about whether or not vitamin D supplementation can help to prevent falls or fractures. A variety of demographics and dosing regimens previously have been examined; the researchers behind this study chose a dose of vitamin D known to prevent winter drops in serum 25-hydroxyvitamin D (25(OH)D), and a regimen (once yearly) that would address concerns about adherence that may have affected past studies' results.

In the area of southern Victoria, Australia, recruitment letters were sent to community-dwelling women 70 years old or older who were on a list of registered voters. Women were included in the trial if they were considered “high risk” for fracture, that is, if they had maternal hip fracture, past fracture, or had fallen by self-report. Women were excluded if they were in a high-level care facility, could not provide falls or fracture data, had elevated serum calcium or creatinine levels, were taking vitamin D in a dosage greater than 400 International Units (IU) daily, or were on anti-fracture pharmaceutical treatment. Out of this effort, 2317 women consented to participate, but then 59 withdrew prior to the randomization, leaving 2258 women to be randomized to receive 500,000 IU cholecalciferol (vitamin D3) orally (50,000 IU daily for 10 days) or identical placebo each fall or winter for 3-5 years. These women were contacted regularly by postcard or e-mail about whether or not they had a fall or fracture event; if such an event occurred, follow-up by telephone took place, and all reported fractures had to be corroborated by a radiograph prior to inclusion in the analysis. There were a total of 226 withdrawals (a variety of reasons, similar between treatment and placebo groups) during the study period, but all of these were accounted for in the final analysis by intention-to-treat, increasing the statistical validity of the results.

There were a total of 5404 falls, including 2892 falls in the vitamin D group vs 2512 in the placebo group; the relative risk (RR) was 1.15 (confidence interval [CI], 1.02-1.30; $P = 0.03$), just barely significant. A statistically significant (RR = 1.31, CI = 1.12-1.54) increased incidence in falls occurred within 3 months of dosing. With respect to total fractures, there were 171 in the vitamin D group, and 135 in the placebo group, with an RR = 1.26 (CI = 1.00-1.59, $P = 0.047$), again just barely statistically significant. The RR for nonvertebral fractures was not significant between the treatment and placebo groups. There was not a statistically significant temporal effect of dosing on fractures.

A questionnaire about calcium intake found no difference between the treatment and placebo groups; the average intake was 976 mg daily. One hundred thirty-seven people (75 from vitamin D group, 58 from placebo group) consented to blood tests; the median baseline 25(OH)D was 49 nmol/L (no difference between the two groups),

and 12 months after dosing the vitamin D group showed marked increases in 25(OH)D (median 55-74 nmol/L, range 25-120 nmol/L), which were significantly higher than the placebo group each year ($P < 0.05$).

Adverse events, including serious ones, were similar between the treatment and placebo groups, barring injury (which included fracture) that, as mentioned above, occurred more in the vitamin D group (15.2% vs 12.1%, $P = 0.03$).

■ COMMENTARY

Investigations into the use of vitamin D cover many medical conditions, but the primary focus of research has been on bone health and the prevention of falls and fractures. In addition, numerous dosing regimens (dose, frequency, form) have been studied, as reviewed in a past issue of *Alternative Medicine Alert*.¹ When interpreting new vitamin D research results, it is important to keep all of these details in mind, as well as the specific demographic involved, baseline characteristics (diet, serum 25(OH)D, etc.), and any confounding supplement or nutritional variables.

What could explain the surprise results of this approach to vitamin D repletion, which led not to an improvement in bone health, but rather, an increased risk of falls and fractures? Some nuances in the study design may help to answer this question. For example, unique aspects of this study are the use of annual vitamin D dosing, and the fact that the study subjects were community-dwelling women, not those in long-term care facilities as in many past research efforts. In addition, the researchers also did not provide supplemental calcium; most past vitamin D supplementation studies that had a positive effect on fall or fracture risk also included supplemental calcium. The baseline calcium intake for women in both arms of this study was reasonably close to most recommendations, so it is unclear whether or not the lack of calcium supplementation would have made any difference in the results noted.

The authors mention another study with increased fracture risk in women, but not men, receiving 300,000 IU intramuscular ergocalciferol (vitamin D₂) once annually.² Interestingly, fall risk was not increased, though, again, the treatment group did not receive supplemental calcium. There might, indeed, be a risk with high, single-dose treatments without added calcium. The authors note that serum 25(OH)D peaked 1 month after the oral dosing, gradually decreasing (half-life of vitamin D is 60-90 days) to levels 41% higher than the placebo group after 1 year, and they also documented a temporal effect on increased fracture risk at 3 months. Were some patients exceeding a safe level of serum 25(OH)D within the 3 months after dosing? That is possible, although the au-

thors point out that the highest serum 25(OH)D in the subgroup that underwent blood testing reached 208 nmol/L at 1 month, while “toxic” levels are thought to be in the range of 375-500 nmol/L. Nonetheless, the authors postulate a possible connection between temporal high serum 25(OH)D, vitamin D metabolites, or the resulting decrease in levels that “might be causal.”

With respect to repletion, the dose in this study was probably sufficient. The 500,000 IU once annually, as referenced by the authors to past research, has been shown to increase serum 25(OH)D sufficiently, and correspond to the thresholds of approximately 700-1000 IU daily oral supplementation that seems to be more effective at fracture reduction than lower-dosed studies using 400 IU daily.

In summary, as much as clinicians might be attracted to once annual vitamin D dosing because of increased patient adherence, the results of this study point out that this may lead to an increased risk of falls and fractures if used in community-dwelling women who are not taking supplemental calcium. Similar improvements in 25(OH)D as would occur with 500,000 IU once annually can be achieved with lower, more frequent dosing, and, as per the medical literature, this appears to not lead to increased falls nor fracture risk. Our recommendations to patients need to be tailored individually based on their demographic, medical history, and baseline nutrition and supplement intake, and, in this respect, the results of this research trial are but one piece of the vitamin D puzzle, highlighting what NOT to do. ■

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Mindfulness for Physician Burnout

By Luke Fortney, MD

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DEATH BY SUICIDE IS A SIGNIFICANT OCCUPATIONAL HAZARD for physicians.¹ This is strongly associated with pro-

professional burnout, which is characterized by a loss of emotional, mental, and physical energy due to continued job-related stress. Studies have identified three factors that are independently associated with burnout for both surgeons and internal medicine physicians — hours worked per week, experiencing a work/home conflict within the last three weeks, and how the most recent work/home conflict was resolved.² In general, up to 60% of physicians report having experienced burnout³ at some point in their career, with up to 30-40% experiencing burnout currently.⁴ This is particularly concerning given the fact that many aspects of patient care — such as physician self-reported medical errors, lower empathy, early retirement, higher job dissatisfaction, and lower patient satisfaction and treatment adherence — are affected by burnout.⁵

As the Patient Protection and Affordable Care Act gears up for implementation within the United States, absent from this legislation is consideration about how health care reform will affect physicians, particularly in primary care. Providing insurance to 30 million previously uninsured citizens will increase demand for primary care where an increasing elderly population, decreased supply of primary care physicians, low primary care interest among medical students, poor reimbursement, and increased workload demands from health system employers already add further strain.

Research suggests that physician burnout begins in medical school prior to the clinical years of medical education. A cross-sectional survey administered to third-year medical students in New York found that 71% of medical students met criteria for burnout.⁶ This is particularly concerning given that suicidal ideation among medical students is nearly double compared to the general population.¹ In addition, it is troubling that there is a paucity of intervention research in physician and medical student burnout, noting that very few health employers, medical schools, and residency programs offer any skills or support that adequately address burnout prevention and facilitate well-being.

It is interesting to note that the strongest burnout factor reported by medical residents is a mental attitude of pessimism. Contrary to this, mindfulness meditation teaches practices that cultivate the mental attitudes of acceptance, letting go, non-striving, non-judging, patience, trust, beginner's mind, and forgiveness, among others. Further, the practice of meditation is correlated with lower burnout scores and increased well-being.⁷ Mindfulness is a fundamental aspect of the meditation experience that reflects the basic and fundamental human capacity to attend to relevant aspects of experience in a nonjudgmental and non-reactive way, which in turn cultivates clear thinking, equanimity, compassion, and open-heartedness.⁸ Stated as simply as possible, mindfulness means being present with what is happening moment by moment, whether it is

pleasant, unpleasant, or neutral. The goal of mindfulness is to maintain fluid awareness in a moment by moment experiential process that helps one disengage from strong attachment to beliefs, thoughts, or emotions in a way that generates a greater sense of emotional balance and well-being. Of all the meditation styles and practices, mindfulness is particularly useful for physician burnout because it has a large and growing corpus of research in the medical literature. It is also non-religious, which allows for wider secular and academic appeal. However, mindfulness has been used in many different religious settings and is not discriminating in this way.

In addition to the many health benefits of meditation — which have been widely documented in the medical literature⁹ — the teaching and practice of mindfulness for physicians in regard to burnout is adeptly poised to address this problem. Many studies have demonstrated that training in mindfulness reduces anxiety and increases positive affect^{10,11} while others show benefit in preventing recurrence of depression.¹² Research suggests that practicing mindfulness cultivates present-moment awareness that helps reduce medical error and improve patient care. For example, faulty thinking, such as snap judgments, distracted attention, inadvertent stereotyping, and other cognitive traps, leads to critical mistakes in patient care.¹³ Preliminary research also shows that practitioners who themselves exhibit healthy habits are more effective in motivating patients to make significant positive change in their own life.¹⁴ This is also true of health practitioners who themselves practice meditation. In a randomized controlled trial, patients of interns who received mindfulness training did significantly better than those patients treated by interns who did not receive mindfulness training.¹⁵ Another study involving primary care physicians assessed the impact of an 8-week mindfulness continuing education course. The 15-month study reported improvements in mindful awareness, burnout, depersonalization, personal accomplishment, empathy, and emotional stability among physician participants.¹⁶

To further address burnout among physicians, a study is being conducted using mindfulness education for primary care physicians to help address burnout, compassion, resiliency, and work satisfaction.¹⁷ A collaborative online education and resource module (<http://www.fammed.wisc.edu/mindfulness>) was created and is freely available to provide ongoing support for mindfulness practice and to help clinicians bring mindfulness into the clinical encounter. Given the time demands on medical learners and practicing physicians, it is important that further research and novel curricula explore methods that can teach skills such as mindfulness in ways that are easily and widely accessible, honor time limitations, and are effective. There is a growing interest in research that supports web-based interventions such as this one, with promising results showing

significant long-term improvements for mindful awareness, distress, and negative affect following the web-based training.¹⁸ Programs and institutional-based approaches that address burnout among physicians are few and far between, and further effort that supports well-being and stress reduction among physicians is needed. ■

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From Observation to Measurement: How Research Gets Started

By *Howell Sasser, PhD*

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Editor's Note: This is the first in a three-part series about the design and conduct of clinical research. It is not meant to make an expert of anyone, but it is intended to demystify the research process and perhaps make the reader a more astute consumer of the clinical literature. An understanding of the process by which it is created is a very useful tool in judging the quality of the results that it produces.

IT WOULD BE FAIR TO SAY THAT NEARLY ALL FORMAL CLINICAL research begins before it is even recognized as such. Observant clinicians note patterns, or what appear to be patterns, in those they treat. These may be broad (“there appear to be more women than men with lupus”) or specific (“it appears that those taking a statin and niacin for cholesterol control do better than those taking a statin alone”). Many such observations are fleeting, or turn out to be spurious. Those that survive to be acted on must be recast as questions that can be tested.

These questions are sometimes called falsifiable propositions because they are couched in terms that allow them to be either proven or disproven. So, rather than ask simply whether patients do better on Drug A than on Drug B, we might ask whether patients taking 50 mg of Drug A twice a day for 3 weeks have a lower rate of relapse (to be defined as a specific percent difference) than those taking 100 mg of Drug B once daily for the same period. This gives the designer of the study clear guidance as to what the study procedures should be, and gives the study statistician the information necessary to determine how to assess the study results and also to calculate the number of participants needed to ensure that the study results are statistically sound.

As this example may suggest, the production of ques-

tions is an especially important part of the research process, since the way the question is phrased plays a role in how a subsequent study is designed to evaluate it. This, in turn, affects the quality of inference that can be drawn from the study's results. A study that answers the wrong question, or that produces inconclusive results, can be worse than no study at all.

Although the questions that are the nucleus of clinical research cover every imaginable disease process and therapeutic strategy, they can be grouped into a small number of generic categories. As described here, the categories are most applicable to experimental studies (i.e., those in which the investigator manipulates the exposure of interest, usually by determining who receives it and in what manner). However, they can easily be adapted to observational studies (i.e., those in which the investigator observes and records the characteristics and outcomes of a population, but does not intervene to alter the distribution or intensity of potentially protective or harmful exposures). At the risk of reductionism, the categories might be described as better than nothing, as good as what we have, and better than what we have.

Better than nothing: At times, there is no effective, or at least generally accepted, treatment available for a condition. In such situations, there is not necessarily any scientific or ethical objection to comparing an experimental therapy to existing supportive or palliative treatments, to a placebo, or to nothing. The common thread is that there must be a comparison. Simply trying a therapy in a series of patients and reporting the results leaves unanswered the question of what those patients' outcomes would have been had they been treated in any other way. If those outcomes would not have been meaningfully different, what claim can we make about the effectiveness of the new therapy? The value of using a placebo in a group of "control" patients, or at least of trying to be systematic about what non-curative treatments they receive, is that it makes the later statistical comparison cleaner. The fewer the unknown and uncontrolled factors, the clearer the inference about what effect the experimental treatment had.

For example, Barrett and colleagues compared echinacea with a placebo for the treatment of recent-onset cases of the common cold.¹ They recruited 719 people between the ages of 12 and 80 and assigned them randomly to receive a pill containing echinacea and labeled as such, a pill containing echinacea but not identified (a "blinded" group), an identical-appearing pill containing only inert ingredients (a placebo, also blinded), or no pills at all. The study's effects were assessed by measuring the time to resolution of symptoms in each group. There was a trend toward shorter duration of symptoms with echinacea, but this effect was not pronounced enough to be statistically significant.

As good as what we have: Whenever an existing treatment is available that is judged to be efficacious — even imperfectly so — the use of a placebo-controlled design becomes ethically suspect. Withholding a treatment with known benefit for the purpose of scientific observation is almost always impermissible. When an effective treatment is already in use, the experimental focus turns to how a new treatment performs in comparison with it. In some cases, the goal may be to show that the new therapy is as effective as the existing one. If the new treatment has fewer side effects, or is easier to administer, or is less expensive, comparable efficacy may be all that is required. Studies with this goal are sometimes called bioequivalence trials. Because showing precisely the same effect with two or more agents is unlikely, a range is defined within which observed effects are understood to be functionally equivalent, even if not identical. This is a statistical process, but it is driven by clinical considerations.

Studies of this type are still uncommon in the complementary and alternative medicine (CAM) literature, in part because they typically require very large study populations and, as a consequence, are often very cumbersome and expensive to conduct. An example from elsewhere in the literature is a study by Baruch and colleagues assessing the relative accuracy of calculated and directly measured low-density lipoprotein cholesterol (LDL-C).² The calculated method is less expensive and may have greater validity as a measure because much of the published literature on LDL-C is based on it. A group of 81 participants had LDL-C measured simultaneously by both methods, and some had follow-up measurements made as well. All pairs of measurements were included in the analysis. The results showed that while the two methods were highly correlated, there was a difference of adequate magnitude between them in enough cases to question whether they are equivalent, and whether the direct method can fairly stand in for the calculated method in cases where the latter is not feasible.

Better than what we have: This is perhaps the most familiar situation in current clinical research practice. Because many conditions have therapies or clinical management strategies, many new agents and approaches are tested against the existing standard of care. The usual goal is to show that the new therapy is "better," though how much better it must be, and indeed how better is defined, is case-specific and may even change over the course of a single study. The key issue with this sort of question is clarity and precision in what is being compared.

An example of this is a 2002 study by Targ and Levine comparing standard group support and a CAM-based intervention for women undergoing treatment for breast cancer.³ A group of 181 women were assigned randomly to the two interventions and assessed on a number of measures of psychological well-being after 12 weeks. Those

in both therapeutic arms showed meaningful before–after improvements, and those in the CAM arm showed greater improvement on some measures. The investigators concluded that the interventions were similar in their effect, although this was not a formal bioequivalence trial.

As is implied in the descriptions above, the main question spawns a series of subsidiary questions: How much “better” is enough? As compared to what? Under what set of clinical or demographic or social conditions? The answers to these questions help to flesh out the design of a study that may produce results bearing on the main question. The importance of asking — and answering appropriately — the questions that guide the design of a study cannot be overemphasized. Careful planning at the beginning of a research project improves the probability of producing clinical and statistically relevant results later.

The next article in the series will deal with how the study question connects with one of the available study designs. ■

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CME Instructions

To earn credit for this activity, please follow these instructions.

1. Read and study the activity, using the provided references for further research.
2. Log on to www.cmecity.com to take a post-test; tests can be taken after each issue or collectively at the end of the semester. First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice or renewal notice.
3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.
4. After successfully completing the last test of the semester, your browser will be automatically directed to the activity evaluation form, which you will submit online.
5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly.

CME Objectives

After completing the program, physicians will be able to:

- a. present evidence-based clinical analyses of commonly used alternative therapies;
- b. make informed, evidence-based recommendations to clinicians about whether to consider using such therapies in practice; and
- c. describe and critique the objectives, methods, results and conclusions of useful, current, peer-reviewed clinical studies in alternative medicine as published in the scientific literature.

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CME Questions

34. The life energy upon which Reiki is based is a:

- a. magnetic field energy.
- b. mechanical energy.
- c. non-physical life energy.
- d. All of the above

35. According to Reiki practitioners, the energy is directed toward patients:

- a. by the energy’s own ability to know where it is needed.
- b. by the practitioners’ mind.
- c. by the motion of the practitioners’ hands.
- d. All of the above

36. Controversy exists about Reiki because of:

- a. its spiritual and religious roots.
- b. the small number of controlled clinical trials conducted on it.
- c. inconsistent findings from clinical trials.
- d. All of the above

37. Mindfulness is an aspect of meditation that emphasizes:

- a. thinking.
- b. forcing the mind to stop thinking.
- c. non-judgmental present-moment awareness.
- d. relaxation.

38. Physician burnout is a significant occupational hazard that is largely unaddressed by training programs and institutions.

- a. True
- b. False

39. Physician burnout is associated with:

- a. medical errors.
- b. attitude of pessimism.
- c. suicide.
- d. All of the above

40. Mindfulness is potentially useful in health care because:

- a. mind-body intervention with strong research base.
- b. it has wide appeal for both secular and religious communities.
- c. it has been proven to be superior to other forms of meditation.
- d. Both A and B
- e. All of the above

In Future Issues:

**Dietary Supplements for Migraine
Teas and Supplements for Infants**