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## Is Massage Beneficial for Pregnant Women and their Infants?

By Bridget S. Bongaard MD, FACP

*Fellow in Integrative Medicine; Director of the Integrative Medicine Service Line, CMC-Northeast Medical Center in Concord, NC; she reports no financial relationship relevant to this field of study.*

WHEN WE IDEALISTICALLY THINK OF BEING PREGNANT, DESPITE facing the hardships of labor and delivery of our new child, it is a vision of hopefulness, happiness, and expectations for a happy event. The path of the pregnant woman is, however, not so prosaic, and the reality of the stresses on her body and psyche are multifold. Her body undergoes a massive physical change, creating weight shifts to areas not normally used to support this physical load, as well as potentially disturbing changes in body image. The hormonal changes in women sometimes lead to low energy levels, and personal questions can arise regarding the woman's ability to be a good mother, or to be able to successfully complete the pregnancy with the delivery of a healthy infant.

Initial romantic thoughts are also tempered by the life settings of the mother. Whatever environmental stresses are currently ongoing with her immediate family, job, or responsibilities for other children may also create a significant psychological and physical burden for the woman. This can be alleviated by significant support from her partner, family, or friends; however, not all women have optimal support, leading to stress, which may precipitate the development of anxiety/depression in the expectant mother and affect the infant she is carrying the baby. Depressed pregnant women have altered neurotransmitters (elevated stress hormones consisting of cortisol and norepinephrine levels, and low levels of counteracting serotonin and dopamine).<sup>1</sup> These women are at higher risk for abortion, pre-eclampsia, preterm labor, intrapartum complications, and low birth weight, as well as post natal problems, such as depression, infant feeding problems, and perception of the infant as being fussy, hungry, or demanding.<sup>1</sup>

The infant is integrally a part of the mother and the stresses she encounters during pregnancy, as well as after birth. For instance, the

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development of the infant's circadian rhythm is established before birth, and by the third trimester of pregnancy, fetal diurnal rhythms are entrained to the maternal day-night rhythms.<sup>2</sup> If the mother is depressed, her newborn infant may exhibit depression-like symptoms and have the same levels of stress hormones as did the mother.<sup>1</sup> The infant's personal development is dependent upon optimal bonding between mother and baby. Post-partum disturbances of the maternal-infant relationship are quite common, and are present in 22% of peri-natal psychiatric referrals and in 29% of mothers diagnosed with postnatal depression.<sup>3</sup> These disorders run the gamut of a sad spectrum of bonding delay (ambivalence, or loss in maternal response), rejection (threatened or established), or pathological anger/impulse control (resulting in handling the baby roughly with contemplation to harm or even deliberate attempts to kill her infant).<sup>3</sup> The effects of this lack of normal bonding (lack of affection and stimulation) can last up until 18 months of age, and it has been shown that the children of women with postnatal depression later perform substandardly in terms of both behavior and intelligence.<sup>4</sup>

## Effects of Massage on Depressed Pregnant Women

Massage therapy significantly alters the biochemistry of the mother not only short term following the massage, but also over the course of serial massage therapy treatments, with marked reduction in cortisol, determined in salivary gland samples.<sup>5</sup> Dopamine, like serotonin, reduces depression and its stress effects.<sup>5</sup> In a study done

by Field and colleagues, 32 depressed adolescent mothers received two, 30-minute massage or relaxation therapy sessions per week, over a 5-week study period. In the randomized, controlled trial, both groups reported a reduction in anxiety following their first and last sessions; however, only the massage group showed behavioral and stress hormone improvements, including a decrease in anxious behavior, pulse, and salivary cortisol levels. Urinary cortisol levels remained diminished following the 5-week intervention period for the massage therapy group.<sup>6</sup>

Fujita and colleagues did a study to evaluate the effects of infant massage on their mothers' mood status. This randomized, controlled trial contained 39 post partum mothers who were evaluated at baseline and again after 3 months of baby massage using salivary cortisol levels and psychological measurements of depression and vigor (profile of mood states, or POMS). Baby massage positively affected the mood status of the mothers, but there were no significant differences in salivary cortisol levels at 3 months time.<sup>7</sup>

Another study by Field et al on 84 depressed pregnant women recruited during the second trimester and randomly assigned to progressive muscle relaxation, a control group, or massage therapy group consisting of two 20-minute weekly massages by their significant others. Results were interesting in that not only did the massage group report lower levels of both anxiety and depressed mood, they also experienced less back and leg pain by the end of the 16 week study.<sup>1</sup> Higher levels of maternal salutary neurotransmitters (dopamine and serotonin) were found, as well as conversely lowered stress hormones (cortisol and norepinephrine). This may have contributed to an additional benefit noted in the trial, that being the better neonatal outcome for the massage group in terms of lesser incidence of both prematurity and low birth weight.

In another trial, depressed mothers of preterm infants were studied and divided into two groups: ones who massaged their babies and the others, who watched their babies being massaged. Both groups of mothers had lower depressive scores; however, only the group who actually massaged their premature infants had lower anxiety scores.<sup>8</sup>

Oxytocin is another critical CNS neurotransmitter for maternal and child health. Across mammalian species, it is noted to promote maternal bonding behavior. A small controlled study done by Glover and colleagues looked at a cohort of post partum depressed women attending an infant massage class, and found that the study group had improved infant interaction, as well as less depressive symptoms, compared to the control group who

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

SENIOR VICE PRESIDENT/PUBLISHER: Brenda L. Mooney.  
ASSOCIATE PUBLISHER: Lee Landenberger.  
MANAGING EDITOR: Leslie Hamlin.  
GST Registration Number: R128870672.

Periodical postage paid at Atlanta, GA.

POSTMASTER: Send address changes to *Alternative Medicine Alert*, P.O. Box 740059, Atlanta, GA 30374.

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received training in infant care. The mechanism of action was postulated to be increases in maternal plasma oxytocin concentrations occurring with massage, thereby potentially promoting the bonding relationship with the infant.<sup>4</sup>

### Other Areas of Potential Benefit Due to Massage Therapy

The sleep behavior of 50 normal and low birth weight (LBW) light preterm infants was studied by Kelmanson and Adulas in St. Petersburg, Russia.<sup>9</sup> Babies were enrolled at 2 months after birth and were matched with a control group. The study group received massage intervention consisting of gentle rubbing and stroking, as well as passive and kinesthetic movements of the limbs by professionals until the child was 8 months of age. Study group infants were found to have less likelihood of snoring during sleep, required less feeding on awakening at night, and appeared more alert during the day. There was no difference in sleep behavior between those born at full term and those at preterm in the massage group. It was, therefore, suggested that massage might be a valuable approach to reducing sleep-disordered breathing and improving sleep quality in LBW infants.

Others have commented on the potential benefits of using massage in preterm or LBW babies. Dr. Beachy noted that when infant massage therapy is properly applied to preterm infants in the neonatal intensive care unit (NICU), they respond with increased weight gains, improved developmental scores, and earlier discharge from the hospital.<sup>10</sup> This study also found that parents of preterm infants and their families benefited by performing the infant massage themselves, as it enhanced their bonding with the child and increased confidence in their parenting skills. In a Korean Nursing study of preterm infants using 10-minute massages twice daily for 10 days, it was discovered that the massage group had higher vagal tone after massage compared with the control group, and also significantly higher scores for awake state and motor activity. The authors concluded that massage therapy might enhance optimal physiological responses and behavioral organization of premature infants, and the nurses could use this to promote the infant's capacity to respond positively to their environment.<sup>11</sup>

### Using Massage in Perinatal Care

Adding essential oils is promoted as another way of providing a satisfying massage therapy experience. In a study by Imura and colleagues, healthy post partum mothers, having delivered normal full term infants, were given a 30-minute aromatherapy massage on the second post partum day. Compared with the non-massage con-

trol group, the post treatment scores significantly decreased for the Maternity Blues Scale, the State-Anxiety Inventory, and all except one of the Profile of Mood Subscales. Scores increased in the Profile of Mood-States-Vigor subscale and the Approach Feeling toward Baby subscale. Conflict Index of Avoidance/Approach Feeling towards Baby subscale scores significantly decreased, with the overall outcomes indicating less depression, better energy level, and better maternal-infant bonding interactions.<sup>12</sup>

Bastard and Tiran note that antenatal anxiety has been linked to changes in the maternal hypothalamic-pituitary-adrenal axis, which can affect fetal development and potentially have lasting effects on the child's development.<sup>13</sup> Their observation that psychotherapy and antidepressant treatment does not always effect long-term improvement led to their recommendation that midwives should incorporate aromatherapy and massage into their practices, but also encouraged further research to definitively establish efficacy and cost effectiveness.

As described in one study, labor pain can be impacted by massage therapy, in that massaged mothers reported a decrease in depressed mood, anxiety, as well as pain. They also showed less anxiety and agitated activity, as well as a more positive affect following the first massage during labor. Interestingly, the massaged mothers had significantly shorter labors, a shorter hospital stay, and less post partum depression.<sup>14</sup>

Nabb and colleagues established a massage program for women and their birth partners from 36 weeks gestation through labor and delivery. The intervention was developed on the basis of reports citing that repeated massage sessions over a 14-day period increase the pain threshold through an interaction between oxytocin and opioid receptors. Repeated massage-like stimulation induced long-term effects on nociception, an apparent contribution by oxytocinergic mechanisms.<sup>15</sup> Recordings were made at 90 minutes post partum and showed significant reduction in perceived pain in both nulliparous and multiparous women groups.<sup>16</sup> These data were compared to pain scales collected 2 days post partum, and were still lower than the control group. This finding could have the potential for significantly reducing the need for pharmacological analgesia in labor.<sup>15</sup>

Hur and colleagues investigated the effect of delivery nursing care using essential oils on labor stress response, labor anxiety, and post partum status anxiety for primiparous women. The study authors randomized 48 nulliparous women with full-term, uncomplicated pregnancies into experimental and control groups. Twenty-four hours after delivery, postpartum maternal anxiety level

was assessed and correlated to measurements of plasma epinephrine and norepinephrine from cord blood. The experimental group demonstrated significantly lower levels of the two neurotransmitters; however, no significant difference was found between the two groups with regard to anxiety during labor or postpartum.

## Conclusions

While many of the studies cited had positive outcomes both for the mother and the infant (either full term or preterm/LBW), it is noted that the majorities of the studies are small and flawed. No harm was reported, however, and massage therapy did have beneficial effects on hormones influencing stress, together with positive effects on sleep, crying, and mother-infant bonding. The findings provide tentative evidence to support recommending infant and perinatal massage, especially in high-risk groups, such as depressed mothers or LBW infants. Larger, methodologically sound trials are encouraged. ■

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## Hydrotherapy for Arthritis

By Marissa Blum, MD, and Sharon L. Kolasinski, MD

Dr. Blum is a rheumatology fellow in the Division of Rheumatology at the University of Pennsylvania School of Medicine; she reports no financial relationship relevant to this field of study. Dr. Kolasinski is Associate Professor of Clinical Medicine; Chief of the Clinical Service; and Program Director of the Rheumatology Fellowship Program in the Division of Rheumatology at the University of Pennsylvania School of Medicine; she reports no financial relationship relevant to this field of study.

**A**RTHRITIS IS A VERY COMMON AFFLICION, AFFECTING as many as 48% of Americans over the age of 65.<sup>1</sup> Chronic pain, decreased strength, and impaired mobility contribute to arthritis-related disability.<sup>2</sup> No curative therapies are known yet and, therefore, treatment focuses on management of symptoms and reduction of disability. Options for treatment of pain include supportive therapies, such as non-steroidal anti-inflammatory medications, topical agents, gym- and home-based exercises, and intra-articular corticosteroid and hyaluronic acid injections. Ultimately, patients may require total joint arthroplasty.

Exercise therapy in arthritis patients has been demonstrated to improve pain, physical function, and self-reported disability.<sup>3</sup> Hydrotherapy, or water-based exercise therapy, may provide another viable option for improving pain, mobility, and quality of life in patients with arthritis, and may be associated with high patient adherence to therapy. Several studies have attempted to examine the place of hydrotherapy in the management of patients with osteoarthritis or rheumatoid arthritis.

## Background

Hydrotherapy is based on an ancient modality called balneotherapy or bath therapy.<sup>4</sup> Balneotherapy has classically been used to reference bathing in thermal or mineral waters, and today has been equated with spa therapy. Therapeutic baths were used in Roman times to treat various disorders, including painful musculoskeletal complaints, as well as to provide a forum for social interaction. Following the decline of the Roman Empire, spa therapy fell out of vogue, being considered “unmanly and devigorating” by some authors.<sup>5</sup> However, by the 16th century, spa therapy was rediscovered and has been used continuously since then to treat a host of conditions.<sup>5</sup> Hydrotherapy is a modern derivation of balneotherapy that involves exercise in warm water under the supervision of a physiotherapist.

## Mechanism of action

Hydrotherapy has multiple potential mechanisms of action stemming from the effects of water and warmth on joints and soft tissues. On a biochemical level, little is known about the effects of “taking the waters.” An almost two decade-old reference suggests that water immersion may alter circulating serum opioid peptide levels.<sup>6</sup> On a more macroscopic level, benefits include pain relief and promotion of muscle relaxation that may be mediated by a number of factors. Joint swelling may be improved, since it has been shown that the size of edematous joints can be reduced following water immersion.<sup>7</sup> Further, by decreasing the gravitational forces on joints, hydrotherapy reduces loading on damaged arthritic joints. On the other hand, hydrostatic pressure may shift blood volume from the lower extremities toward the core of the body, resulting in diuresis, natriuresis, and inhibition of the sympathetic nervous system.<sup>8,9,10</sup> Water therapy may help to increase oxygen delivery to the tissues by improving venous and lymphatic return and, thus, increase perfusion of muscle and periarticular struc-

tures.<sup>11,12</sup> The warmth that accompanies hydrotherapy may further add to its ability to relax muscles and increase circulation to symptomatic areas. Finally, the pleasure of the experience of water immersion may also have a significant effect on improving feelings of health and well-being.

## Clinical Studies

Although a number of studies have evaluated hydrotherapy in arthritis patients, few are designed well enough to make definitive statements about the place of hydrotherapy in the management of arthritis. The Cochrane Collaboration has published a protocol for review of this topic to be completed soon.<sup>13</sup> However, several recent reports provide support for some role for hydrotherapy.

Hall and colleagues used a randomized, controlled design to study the effects of hydrotherapy compared to land exercise, progressive relaxation, or water immersion.<sup>14</sup> This study is of note because of the extensive evaluation methods employed and the relatively large sample size. Hall et al evaluated a group of patients with chronic, active rheumatoid arthritis (RA) on stable, though varied, drug regimens. One hundred forty-eight participants entered the trial, and 139 completed it 4 weeks later. All interventions took place at the Royal National Hospital for Rheumatic Diseases in Bath, UK. Patients were randomized to attend two 30-minute sessions twice a week in all four intervention groups. Hydrotherapy consisted of warm water immersion and exercise designed to increase range of motion and strength in upper and lower extremities. Land exercise consisted of similar exercises performed on land. The progressive relaxation group performed mental imagery tasks as directed by a physiotherapist reading from a standard script in a quiet, darkened room while seated on comfortable mats. The water immersion group relaxed in the pool on weighted chairs with legs dependent immersed in warm water to the suprasternal notch with legs dependent. Assessments of physical functioning included the Ritchie articular index of tender joints, minutes of morning stiffness, grip strength measured by digital hand held monitor, range of motion measured by goniometer, and C-reactive protein (CRP) levels. Pain was assessed by the McGill Pain Questionnaire (MPQ) and The Beliefs in Pain Control Questionnaire (BPCQ). Health status was assessed by the Arthritis Impact Measurement Scales 2 (AIMS2). All assessments were performed at study start and finish, as well as at a 3-month follow-up.

Hall et al found that, regardless of the intervention group, all patients showed significant improvement in joint tenderness by the Ritchie articular index between the start ( $21.2 \pm 9.7$ ) and the end of the study ( $17.3 \pm 9.4$ ,  $P = 0.002$ ). However, the hydrotherapy group had the greatest improvement ( $21.3 \pm 10.6$  to  $15.5 \pm 9.4$ ,  $P = 0.03$ ), with a mean decrease of 27% in joint tenderness. On the other hand, only those in the land exercise group maintained their improvement in joint tenderness at follow-up 3 months later. Only women participating in hydrotherapy showed improvement (6.6° increase) in knee, but not other joint, range of motion. Among the pain outcomes, all patients had significant ( $P = 0.005$ ) reductions in evaluative/affective pain scores measured by the MPQ from the start compared to the end of the intervention, although not maintained at the 3-month follow-up. Similarly, all subjects reported a significant ( $P = 0.049$ ) reduction in the belief that pain was controlled by chance at the end of the intervention, but the change was not sustained at 3-month follow-up. In fact, this belief was strengthened in the immersion group at follow-up. Changes in health status seemed a bit more durable. All patients had a significant improvement (4.8%) in their physical capacity after treatment, as measured by the AIMS2, and this was maintained at follow-up. Overall, all subjects had significant improvements in mood and tension, which was also sustained at follow-up. Furthermore, those receiving hydrotherapy demonstrated the greatest improvement in affect ( $P = 0.03$ ). Those in the progressive relaxation group had an increase in pain by about 12%, measured by the AIMS2, which persisted at follow-up. No changes were noted in grip strength, wrist range of motion, duration of morning stiffness, or CRP. One participant withdrew from the trial after having a myocardial infarction, but only 9 drop-outs occurred before the completion of the intervention (due to transportation difficulties, time constraints, and lack of interest).

A very recent study has revisited the question of hydrotherapy for rheumatoid arthritis. Eversden and colleagues evaluated hydrotherapy compared to land exercises in patients with stable rheumatoid arthritis.<sup>15</sup> Subjects were on stable doses of disease-modifying anti-rheumatic drugs (DMARD) for 6 weeks prior to entering the trial. One hundred fifteen participants were randomized to receive 30-minute sessions of either hydrotherapy or land-based exercise for 6 weeks. Only 86 completed the trial (46 in the hydrotherapy group; 40 in the land exercise group). Primary outcome was the self-rated overall effect of

treatment measured on the day of treatment completion, recorded on a 7-point scale, with 1 being “very much worse” to 7 being “very much better.” Secondary outcomes were collected at study start, study completion, and 3 months post treatment. These included pain scores assessed with a 100 mm visual analog scale (VAS); physical function assessed with the health assessment questionnaire (HAQ); performance assessed by 10 meter walk time; and quality of life assessed through the EuroQol-5D valuation questionnaire (EQ-5D).

Eversden et al demonstrated a robust response in the primary outcome favoring hydrotherapy in RA. Significantly more patients in the hydrotherapy group (87%) felt “much better” or “very much better” (scoring 6 or 7 on the self rated overall effect of treatment scale) than patients in the land exercise group (47.5%,  $P < 0.001$ ). This conclusion was supported even if all non-completers were considered non-responders, an analysis performed because of the greater drop-out rate in the land exercise group. However, there were no significant differences between the two intervention groups with regard to the secondary outcome measures. Ten meter walk times did improve after treatment and were maintained at follow-up in both groups. However, there was no significant change in pain by VAS, physical function by HAQ, or quality-of-life EQ-5D scores between the groups at the end of the intervention. Interestingly, there was a significant increase in pain and decrease in health status in both groups at the 3-month follow-up. In addition to the 26% drop-out rate, a weakness of this trial is that medication changes occurred commonly during the trial. By the time the 3-month follow-up occurred, 17.5% of the hydrotherapy subjects and 15.5% of the land exercise group had made changes in their DMARDs, and 7% in both groups had received corticosteroid joint injections.

Two additional studies from the osteoarthritis (OA) literature are worthy of mention. Pharmacologic treatment options for osteoarthritis, the most common form of arthritis, are more limited than that for rheumatoid arthritis. Thus, physical therapy and exercise interventions assume substantial importance as first line therapy in the osteoarthritis treatment armamentarium.

In 2003, Foley and colleagues from South Australia evaluated hydrotherapy against a gym-based resistance exercise program in 105 community dwelling individuals with radiographic evidence of hip and/or knee OA.<sup>16</sup> Subjects were recruited from physiothera-

py, orthopedic, and rheumatology practices, and were excluded if they had undergone physiotherapy or hydrotherapy within the last 6 weeks or were enrolled in community-based exercise classes. Participants were randomly assigned to one of three intervention groups: 3 water-based therapy sessions per week for 6 weeks; 3 gym-based therapy sessions per week for 6 weeks; or a control group who received telephone calls regarding their status every 2 weeks and were offered free exercise treatment at the end of the trial. Clinical response was assessed at study start and at study conclusion 6 weeks later. Outcome measures included quadriceps strength testing with a hydraulic leg extension machine, a 6-minute walk test and 4 self-reported outcome questionnaires: Western Ontario and McMaster Universities Osteoarthritis index (WOMAC) measuring pain stiffness and physical function; the Adelaide Activities Profile assessing domestic chores, household maintenance, social activities, and service to others; the Short Form-12 Health Survey (SF-12) measuring physical and mental components of quality of life; and the Arthritis Self Efficacy Questionnaire measuring pain, function, symptoms, and satisfaction.

Quadriceps strength improved on the left side only in the hydrotherapy group ( $P = 0.01$ ) while improving in both the left and right quadriceps in the gym group ( $P < 0.001$ ), but not at all in the control group. Walking speed and distance improved significantly ( $P < 0.001$ ) in the hydrotherapy and gym groups, but neither improved in the controls. WOMAC pain score significantly improved from baseline in the hydrotherapy group, although the change in pain was not significantly different between groups. No significant differences occurred for WOMAC function or stiffness, the Adelaide Activities Profile or the Arthritis Self Efficacy Questionnaire. At 6-week follow-up, the hydrotherapy group showed a significant improvement from baseline in the SF-12 physical component score (31.4 at baseline vs 37.1 at follow-up,  $P = 0.002$ ), and this was significantly different from the controls. The gym group showed a significant improvement from baseline in the SF-12 mental component score, but this change did not differ significantly between groups. Only one subject in the hydrotherapy group changed their medication, while 9 gym and 11 control group subjects made changes. This study concluded that both forms of exercise were beneficial compared with no exercise intervention, and that hydrotherapy could result in improved walking speed and distance, but that neither are likely to result in

improved strength. Foley et al suggested that improved ability to walk enhanced participants' sense of functional independence. They noted, however, that their results might not be generalizable since their recruits were highly motivated to participate in an exercise program.

A more recent Australian OA trial assessed hydrotherapy in comparison to tai chi, an intervention previously investigated and found to be of value in some patients with OA.<sup>17,18</sup> Fransen and colleagues evaluated the effects of a hydrotherapy program in a randomized, controlled trial involving 152 participants with symptomatic osteoarthritis of the knees or hips.<sup>19</sup> Participants were randomized to one of three groups: a hydrotherapy group where specific pool-based exercises were performed twice weekly for 1 hour; a Tai Chi group where specific exercises were performed twice weekly for 1 hour; or a waiting list control group. The primary outcome measures were pain and physical function scores using the (WOMAC), with higher scores indicating greater pain or physical disability. Secondary outcome measures included SF-12, the Depression, Anxiety, and Stress Scale (DASS21), patient global assessments, and physical performance tests (the Up and Go test, 50-foot walk time, and stair climb). Assessments were made at the study start, study end at 12 weeks, and at follow-up at 24 weeks.

Both exercise groups improved in at least some of the outcome parameters. At 12 weeks, moderate but significant improvements in WOMAC physical function were seen in both groups compared to controls. Only the hydrotherapy group experienced significant improvement in pain level, but treatment effects were small. Among the secondary outcomes, the hydrotherapy group made significant improvements in the SF-12, the DASS21, and all three physical performance tests. In terms of global assessment, 67% of the hydrotherapy group, 46% of the Tai Chi group, and 15% of controls reported that their signal hip or knee joint was "better" or "much better" compared with 3 months earlier. At the 6-month follow-up, 66% of the hydrotherapy 12-week responders and 58% of the tai chi 12-week responders were still treatment responders. A surprisingly high 11 participants were hospitalized for unrelated problems during the trial, and one in each exercise group withdrew due to exacerbation of low back pain.

## Conclusion

Hydrotherapy has the potential to positively affect

the pain level and functional status of patients with arthritis. Well-designed, relatively large trials of patients with RA and OA suggest that hydrotherapy can meaningfully and reproducibly contribute to pain management and improvement in function, as well as contribute to psychological well being. In comparison with other exercise techniques, hydrotherapy may offer benefits that are particular to arthritis patients due to the buoyant environment and reduced stress to joints or other factors. However, hydrotherapy is not likely to offer the same benefits as land-based exercise in terms of increases in strength. Other observations have suggested that hydrotherapy may be associated with higher compliance rates than other forms of exercise, an important consideration in arthritis patients with life-long disease.<sup>20,21</sup>

## Recommendation

Hydrotherapy should be strongly considered when developing a treatment plan for people with arthritis. Hydrotherapy can improve pain and quality of life in patients with rheumatoid arthritis and osteoarthritis. It also provides a social environment for patients to come together while exercising and working to improve joint pain and mobility. Hydrotherapy is an important component of the comprehensive management of arthritis, and provides an evidence-based option for symptom control. ■

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## CME Questions

**CME Instructions:** Physicians participate in this continuing medical education program by reading the articles, using the provided references for further research, and studying the CME questions. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material.

After completing this activity, participants must complete the evaluation form provided at the end of each semester (June and December) and return it in the reply envelope provided to receive a credit letter. When an evaluation form is received, a credit letter will be mailed to the participant.

After completing the program, physicians will be able to:

- present evidence-based clinical analyses of commonly used alternative therapies;
- make informed, evidence-based recommendations to clinicians about whether to consider using such therapies in practice; and
- 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.

**46. Depressed pregnant women are at higher risk for which of the following?**

- abortion
- pre-eclampsia
- preterm labor
- low birth weight
- All of the above

**47. Massage therapy for pregnant women has been shown to have positive beneficial effects on which of the following?**

- sleep
- crying
- mother-infant bonding
- All of the above

**48. For rheumatoid arthritis and osteoarthritis, it is suggested that hydrotherapy can meaningfully contribute to which of the following?**

- pain management
- improvement in function
- psychological well being
- All of the above

**Answers:** 46. (e); 47. (d); 48. (d)

## Clinical Briefs

*With Comments from Russell H. Greenfield, MD*

*Dr. Greenfield is Clinical Assistant Professor, School of Medicine, University of North Carolina, Chapel Hill, NC; and Visiting Assistant Professor, University of Arizona, College of Medicine, Tucson, AZ.*

### CoQ10, ecSOD, hike! CoQ10 and CAD

**Source:** Tiano L, et al: Effect of coenzyme Q10 administration on endothelial function and extracellular superoxide dismutase in patients with ischaemic heart disease: a double-blind, randomized controlled study. *Eur Heart J.* 2007;28:2249-2255.

**Goal:** To determine whether or not supplementation with oral coenzyme Q10 (CoQ10) improves extracellular superoxide dismutase (ecSOD) activity and endothelium-dependent (ED) vasodilation in subjects with coronary artery disease (CAD).

**Study Design:** Double-blind, randomized, controlled trial.

**Subjects:** People with CAD whose

events (CABG, PTCA/myocardial infarction) occurred at least 3 months prior to enrollment ( $n = 38$  with 33 men, mean age, 55 years); data available for analysis on 33 subjects (including all those in the active intervention group).

**Methods:** Subjects were randomized to 2 groups; one received CoQ10 100 mg orally 3 times daily, while the other received placebo in the same dosing schedule, each for one month. At baseline and at the end of one month, subjects underwent brachial artery ED assessment (fasting state), cardiopulmonary exercise testing, and measurement of endothelium-bound ecSOD activity. With regard to the latter, baseline venous samples were obtained and then a 5,000 U heparin bolus was administered IV. Blood samples for ecSOD were obtained at 1, 3, 5, 7, and 10 minutes after infusion.

**Results:** Supplementation resulted in a 4-fold increase in plasma CoQ10 levels. EcSOD activity increased from 17.3 to 22.4 in the CoQ10 group, compared with a change from 16.6 to 17.3 in the placebo group. Increases in ecSOD activity were most notable for those subjects with the lowest baseline levels of endothelium-bound ecSOD.

Baseline flow-mediated dilation was strongly correlated with endothelium-bound ecSOD activity, and ED relaxation improved in the CoQ10 group, but not the placebo group. Enhanced ED relaxation was linked to increases in plasma CoQ10. Improvements in other cardiopulmonary parameters were also statistically greater in the group receiving CoQ10.

**Conclusion:** Oral supplementation with CoQ10 300 mg daily for one month results in improved endothelial function

and endothelium-bound ecSOD activity in subjects with known CAD.

**Study strengths:** Employ of multiple measures of cardiovascular function; unique focus on ecSOD.

**Study weaknesses:** Small sample size; short study duration.

**Of note:** CoQ10 has been shown to improve ED in people with diabetes mellitus; subjects in this trial had normal left ventricular ejection fractions (EF) with a mean EF = 58% (normal typically considered 55-70%); recent data suggest that CoQ10 improves cardiac contractility in people with ischemic heart disease; people engaged in cardiac rehabilitation were not eligible for participation in this study; medications were not changed throughout the study, including beta blockers; ecSOD is specifically released from the endothelium into the plasma by heparin bolus injection.

**We knew that:** CoQ10 has been suggested to have antioxidant and mitochondrial bioenergetic actions; some studies have shown beneficial effects on cardiac performance in people with heart failure or CAD; ecSOD is a major antioxidant enzyme system of blood vessel walls, and ecSOD activity is reduced in people with CAD; low levels of ecSOD would suggest increased susceptibility to oxidative stress; ED vasodilation is strongly correlated with endothelium-bound ecSOD levels; the highest tissue concentrations of ecSOD are found in blood vessels, the lung, kidney and uterus; endothelial dysfunction of peripheral vasculature correlates well with coronary arterial endothelial dysfunction.

**Comments:** The findings of this study are certainly intriguing, but as my radiologist friends often advise, “this requires further clinical correlation.”

CoQ10 has been under intense research scrutiny for over 4 decades because of its potential for increasing cellular ener-

gy levels, and potent antioxidant activity. Like the current study, however, many CoQ10 trials utilize creative diagnostics, but are plagued by methodologies rife with small numbers of participants and short durations of intervention. There is promise of benefit in the use of CoQ10 for people with established cardiovascular disease, but the topic cries out for definitive study. Aside from CoQ10’s expense and the potential for its interacting with warfarin, there is little reason to recommend against its use in the setting of CAD and heart failure. It would be so much better, however, if in these settings there were definitive reason to actively promote its use. That time has still not arrived. If CoQ10 is to assume an important role in the management of cardiovascular disorders, researchers must better bridge the gap between clinical potential and clinical performance.

**What to do with this article:** Keep a copy on your computer.

## MDs and DS: Are Regulations Understood?

**Source:** Ashar BH, et al: Physicians’ understanding of the regulation of dietary supplements. *Arch Intern Med.* 2007;167:966-969.

**Goal:** To assess the level of physician understanding of US dietary supplement (DS) regulation and the process of adverse event reporting (AER). In addition, to determine whether or not an interactive online curriculum could be a useful physician tool in this regard.

**Subjects:** Internal medicine residents and attendings from 15 different residency training programs.

**Methods:** A didactic module on DS regulation was developed with a focus on 5 content objectives as follows: 1) DS do not require approval before being sold; 2) Efficacy data are not needed before DS are sold; 3) Safety data are not needed before DS are sold; 4) No current regulations exist to ensure prod-

uct quality of DS; 5) Adverse events due to DS should be reported through the FDA MedWatch system. Pre- and post-training multiple choice tests were developed based on clinical cases (5 questions each, with one question per content objective) by a varied group of experts in their fields. Post-test answers could not be accessed until the training module was completed. The training module was made available to 1,541 residents. Pretest performance assessed baseline understanding of DS regulation, and together with results of the post-test were used to evaluate the effectiveness of the online teaching tool.

**Results:** A total of 335 physicians completed the entire training module, including pre- and post-tests, with 90% being residents (21% were interns, 34% were PGY-2s, 35% were PGY-3s, and 10% were attendings). At baseline, understanding of the fundamentals of DS regulation was demonstrably low, with an average pretest score of but 59%. Over 1/3 of participants were unaware that DS do not require FDA approval before being marketed and sold. Few (approximately 40%) were aware that AER related to use of DS should go through the FDA MedWatch system. Upon completion of the online module, however, average post-test scores rose to 91%. Test scores did not improve with increasing level of residency training, although attending physicians did score significantly higher on two of the 5 content objectives.

**Conclusion:** In this sample of physicians in training and attendings, knowledge of DS regulation and AER was poor, but an online DS educational module significantly improved awareness and understanding of key concepts.

**Study strengths:** Random pilot testing before actual study began; analysis based on years of training / experience; tested for participation bias.

**Study weaknesses:** Poor participation rate (22%); a sample of 5 test questions may not adequately assess knowledge

of key concepts of regulation.

**Of note:** The FDA MedWatch program is used to monitor the safety of drugs, devices, biologicals, and DS; while reportedly uncommon, instances of adulteration or contamination of DS have been documented, and there exist concerns that such problems are under-reported; until recently, the source of most inquiries into the safety of specific DS was consumers; studies have shown that healthcare practitioners desire more education on Complementary and Alternative Medical (CAM) therapies; a growing number of medical schools have incorporated select aspects of CAM therapies into the curriculum, most often as electives, but some as part of the standard course of study; some educators have proposed that understanding of governmental regulation of DS be considered a core competency for medical school curricula in integrative medicine.

**We knew that:** The Dietary Supplement Health and Education Act (DSHEA) of 1994 established regulation of vitamins, supplements and herbs as DS, permitting such products to be marketed and sold without prior FDA approval, and without requiring completion of safety and efficacy studies; DSHEA also enabled the FDA to establish Good Manufacturing Practices (GMPs) for DS, similar to those in place for pharmaceuticals, although such regulations have yet to be fully enacted.

**Comments:** The attitudes of conventional Western medical practitioners towards DS run the gamut from benign neglect to support to antagonism, but the fact that our patients are using DS is now undeniable. Patients can turn to the teenaged health food store clerk, the Internet, or popular books and periodicals for advice on how they should use DS, or they can turn to their doctors. Indeed, when surveyed, users of DS would prefer to get credible, non-judgmental information on DS from their doctors. In order to serve patients well, healthcare practitioners must possess

fundamental knowledge regarding DS use, of which regulation and standardization would seem paramount so that appropriate recommendations can be made and AER undertaken appropriately. This information is still not readily taught to medical students and residents, so the development of a curriculum to address this shortcoming is very important. This study has flaws, but the authors are to be commended.

**What to do with this article:** Keep a hard copy in your file cabinet.

## Fish with Sugar? O-3s and Childhood Type 1 Diabetes

**Source:** Norris JM, et al. Omega-3 polyunsaturated fatty acid intake and islet cell autoimmunity in children at increased risk for type 1 diabetes. *JAMA*. 2007;298: 1420-1428.

**Goal:** To determine whether development of islet cell autoimmunity (IA) is associated with dietary omega-3 (O-3) and omega-6 (O-6) fatty acid intake in children.

**Study Design:** Prospective, longitudinal observation study (the Diabetes Autoimmunity Study in the Young, or DAISY) conducted between 1994-2000, as well as a related case-cohort study examining risk of IA according to polyunsaturated fatty acid (PUFA) content of red blood cell membranes.

**Subjects:** Children at risk for type 1 diabetes (DM) defined as either possessing a high DM risk HLA genotype, or having a parent or sibling with DM ( $n = 1,770$ ). The case-cohort part of the trial involved 244 subjects.

**Methods:** Two groups of children were followed, the first being unaffected first-degree relatives of patients with type 1 DM who were identified and recruited between birth and 8 years of age, and the second group being babies screened

at birth for the presence of diabetes-susceptibility alleles in the HLA region. Dietary intake of PUFAs was assessed starting at age one year using a validated 111-item semiquantitative food frequency questionnaire (FFQ). Starting at age 2 years, or at enrollment if older than age 2, the FFQ was administered annually, during which parents were asked to recall the children's diets over the prior year (dietary advice was not provided). Intakes of PUFAs were calculated based on established food composition values. Children recruited at birth were tested for autoantibodies to pancreatic islet antigens at 9, 15 and 24 months, and annually thereafter. Those recruited at a later age had blood drawn at the time of study enrollment and then annually. Children who tested positive for any of the autoantibodies were then placed on an accelerated schedule of blood draws. Random blood glucose and glycolated hemoglobin were also obtained at each clinic visit. Timing of introduction of cereal into the infant diet was evaluated as well. The primary study outcome of interest was risk of IA defined as being positive on 2 consecutive visits at least 3 months apart, and at trial's end, for antibodies against insulin, glutamic acid decarboxylase (produced by pancreatic islet cells), or insulinoma-associated antigen-2, or by having DM at the last clinic visit.

**Results:** Mean age at follow-up was 6.2 years. A total of 58 children developed IA, and after adjustment for potential confounding factors, total O-3 intake (but not marine PUFA intake) was inversely related to risk of IA (Hazard Ratio, or HR,  $=0.45$ ), an association strengthened when outcome was limited to those positive for 2 or more autoantibodies ( $HR=0.23$ ). Total O-6 intake was not associated with increased risk for IA. Vitamin D intake was found to be neither a covariate nor a confounder. Results of the case-cohort trial showed that O-3 content of erythrocyte membranes was inversely correlated with risk of IA ( $HR=0.63$ ). No association between timing of introduction of cereal and risk of IA was identified.

**Conclusion:** Higher dietary intake of O-3 fatty acids as reported on repeated FFQs is associated with a reduced risk of IA in children who are otherwise at increased genetic risk for type 1 DM. In addition, a higher proportion of O-3s in red blood cell membranes is also associated with decreased risk for IA.

**Study strengths:** Dietary intake data were dynamically updated with each IA event; in a subset of subjects aged 1-3 years (n = 68), results of FFQs were compared to four 24-hour food recalls collected from parents throughout the year; assessment of vitamin D intake as potential confounder; consideration of supplements and vitamins, as well as sociodemographic factors.

**Study weaknesses:** Challenges inherent in the use of annual FFQs (recall bias, etc.); staggered enrollment meant differing amounts of data available for each child.

**Of note:** In a prior, retrospective study, infant supplementation with cod liver oil was associated with a decreased risk of type 1 DM; cod liver oil is often quite high in vitamin A, as well as vitamin D; experts believe that both genetic and environmental factors play a role in initiation of the autoimmune process at work in the development of type 1 DM; in addition, dietary factors have been implicated, with some studies suggesting that vitamin D intake may play a protective role; no attempt was made to assess dietary intake of subjects during the first year of life; a prior study suggested that early introduction of cereal into the infant diet was associated with an increased risk of IA; erythrocyte samples were not available until 2000, so the number of IA cases in the case-cohort analysis was lower.

**We knew that:** Type 1 DM is an autoimmune disease characterized by destruction of the insulin-producing beta cells of the pancreatic islets; the clinical phase of type 1 DM is preceded by an asymptomatic period of variable duration during which autoantibodies to beta cells and their antigens are detectable in the blood; a number of studies suggest that O-3s dampen local and systemic inflammatory responses, leading some to believe that the Western diet traditionally low in O-3s may predispose to development of type 1 DM; alpha-linolenic acid (ALA) is the principal O-3 in Western diets, and serves in a limited capacity as a precursor for EPA and DHA (most commonly found in cold water fish); linoleic acid is the most abundant O-6 in the Western diet, and competes with ALA for key enzymes involved in fatty acid metabolism and subsequent conversion to either pro- or anti-inflammatory prostaglandins and related molecules; O-3s reduce levels of oxidative stress in the body.

**Comments:** The burdens for individuals with DM, both acute and chronic, are relatively well known, but

what may not be is the increasing burden on society. Expenses associated with the care of people with diabetes are skyrocketing, with the annual cost associated with treating complications of DM now averaging \$10,000 per person. For the individual as well as the healthcare system as a whole, such a circumstance seems unsustainable. As with most chronic maladies, the focus needs to be on prevention as well as treatment, which is what makes the published report at hand so important.

Compelling data have long been accumulating on potential neurodevelopmental and anti-inflammatory benefits with increasing dietary intake of omega-3 fatty acids in childhood, but the results of this article call for nothing less than our rapt attention. To be sure, the authors of this important paper are quick to state that further research is warranted, but their excitement is palpable - "...omega-3 supplementation could become a mainstay for early intervention to safely prevent development of type 1 diabetes." May it be so.

**What to do with this article:** Make copies to hand out to your peers. ■

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## In Future Issues:

## Hawthorn and Hypertension

# ALTERNATIVE MEDICINE ALERT™

*A Clinician's Evidence-Based Guide to Alternative Therapies*

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Clinical Assistant Professor  
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Chapel Hill, NC  
Visiting Assistant Professor  
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## Patient Handout: Massage Therapy as CAM

**M**assage therapy is a practice that dates back thousands of years. There are many types of massage therapy; all involve manipulating the muscles and other soft tissues of the body. In the United States, massage therapy is sometimes part of conventional medicine, as practiced by holders of MD (medical doctor) or DO (doctor of osteopathy) degrees and by their allied health professionals, such as physical therapists, psychologists, and registered nurses.<sup>1</sup> In other instances, it is part of complementary and alternative medicine (CAM). Complementary medicine is used together with conventional medicine, and alternative medicine is used in place of conventional medicine.<sup>2</sup> This Backgrounder provides a general overview of massage therapy used as CAM and suggests some resources you can use to learn more.

### Key Points

- People use massage therapy as CAM for a variety of health-related purposes, from treating specific diseases and conditions to general wellness.
- Scientists do not fully know what changes occur in the body during massage, whether they influence health, and, if so, how. The National Center for Complementary and Alternative Medicine (NCCAM) is sponsoring studies to answer these questions and identify the purposes for which massage may be most helpful.
- There appear to be few risks to massage therapy if it is used appropriately and provided by a trained massage professional.
- Tell your health care providers about any CAM therapy you are considering or using, including massage therapy. This helps to ensure safe and coordinated care.

### What Massage Therapy Is

The term massage therapy (also called massage, for short; massage also refers to an individual treatment session) covers a group of practices and techniques. There are over 80 types of massage therapy. In all of them, therapists press, rub, and otherwise manipulate the muscles and other soft tissues of the body, often varying pressure and movement. They most often use their hands and fingers, but may use their forearms, elbows, or feet. Typically, the intent is to relax the soft tissues, increase delivery of blood and oxygen to the massaged areas, warm them, and decrease pain. A few popular examples of this therapy are as follows:

- In Swedish massage, the therapist uses long strokes, kneading, and friction on the muscles and moves the joints to aid flexibility.
- A therapist giving a deep tissue massage uses patterns of strokes and deep finger pressure on parts of the body where muscles are tight or knotted, focusing on layers of muscle deep under the skin.
- In trigger point massage (also called pressure point massage), the therapist uses a variety of strokes but applies deeper, more focused pressure on myofascial trigger points--"knots" that can form in the muscles, are painful when pressed, and cause symptoms elsewhere in the body as well.
- In shiatsu massage, the therapist applies varying, rhythmic pressure from the fingers on parts of the body that are believed to be important for the flow of a vital energy called *qi*. In traditional Chinese medicine, the vital energy or life force proposed to regulate a person's

spiritual, emotional, mental, and physical health and to be influenced by the opposing forces of yin and yang..

Massage therapy (and, in general, the laying on of hands for health purposes) dates back thousands of years. References to massage have been found in ancient writings from many cultures, including those of Ancient Greece, Ancient Rome, Japan, China, Egypt, and the Indian subcontinent.

In the United States, massage therapy first became popular and was promoted for a variety of health purposes starting in the mid-1800s. In the 1930s and 1940s, however, massage fell out of favor, mostly because of scientific and technological advances in medical treatments. Interest in massage revived in the 1970s, especially among athletes.

More recently, a 2002 national survey on Americans' use of CAM (published in 2004) found that 5 percent of the 31,000 participants had used massage therapy in the preceding 12 months, and 9.3 percent had ever used it. According to recent reviews, people use massage for a wide variety of health-related intents: for example, to relieve pain (often from musculoskeletal conditions, but from other conditions as well); rehabilitate sports injuries; reduce stress; increase relaxation; address feelings of anxiety and depression; and aid general wellness.

## Who Provides Massage Therapy

A person who professionally provides massage therapy is most often called a massage therapist, although there are some other health care providers (such as chiropractors) who also have massage training. This Backgrounder mainly uses the term massage therapist. Most massage therapists learn and practice more than one type of massage.

To learn massage, most therapists attend a school or training program, with a much smaller number training instead with an experienced practitioner. Many students are already licensed as another type of health care provider, such as a nurse.

There are about 1,300 massage therapy schools, college programs, and training programs in the United States. The course of study typically covers subjects such as anatomy and physiology (structure and function of the body); kinesiology (motion and body mechanics); therapeutic evaluation; massage techniques; first aid; business, ethical, and legal issues; and hands-on practice of techniques. These educational programs vary in many respects, such as length, quality, and whether they are accredited. Many require 500 hours of training, which is the same number of hours that many states require for certification. Some therapists also pursue specialty or advanced training.

Licensing and Certifications		
Licenses or certifications for massage therapists include:		
•	LMT	Licensed Massage Therapist
•	LMP	Licensed Massage Practitioner
•	CMT	Certified Massage Therapist
•	NCTMB	Has met the credentialing requirements (including passing an exam) of the National Certification Board for Therapeutic Massage and Bodywork, for practicing therapeutic massage and bodywork
•	NCTM	Has met the credentialing requirements (including passing an exam) of the National Certification Board for Therapeutic Massage and Bodywork, for practicing therapeutic massage

At the end of 2004, 33 states and the District of Columbia had passed laws regulating massage therapy--for example, requiring that massage therapists graduate from an approved school or training program and pass the national certification exam in their field in order to practice. Cities and counties may have laws that apply as well. Professional organizations of massage therapists have not agreed upon the standards for recognizing that a massage therapist is properly and adequately trained. ■

## References

- 1 Conventional medicine is medicine as practiced by holders of M.D. (medical doctor) and D.O. (doctor of osteopathy) degrees and by their allied health professionals, such as physical therapists, psychologists, and registered nurses. An example of massage therapy as conventional medicine is using it to reduce a type of swelling called lymphedema.
- 2 CAM is a group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine. While some scientific evidence exists regarding some CAM therapies, for most there are key questions that are yet to be answered through well-designed scientific studies. An example of massage therapy as CAM is using it with the intent to enhance immune system functioning.

Source: <http://nccam.nih.gov/health/massage/>  
Accessed on November 20, 2007.

# ALTERNATIVE MEDICINE ALERT™

*The Clinician's Evidence-Based Guide to Complementary Therapies*

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Please take a moment to answer the following questions to let us know your thoughts on the CME program. Fill in the appropriate space and return this page in the envelope provided. **You must return this evaluation to receive your certificate.** Thank you.

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1. If you are claiming physician credits, please indicate the appropriate credential:  MD  DO  Other \_\_\_\_\_

	<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Slightly Disagree</b>	<b>Slightly Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
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2. Present evidence-based clinical analyses of commonly used alternative therapies.
3. Describe controversies, advantages, and disadvantages of those advances.
4. Make informed, evidence-based recommendations to clinicians about whether to consider using such therapies in practice.
5. 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.
6. The test questions were clear and appropriate.
7. I am satisfied with customer service for the CME program.
8. I detected no commercial bias in this activity.
9. This activity reaffirmed my clinical practice.
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If so, how? \_\_\_\_\_

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12. Do you have any general comments about the effectiveness of this CME program?
- \_\_\_\_\_

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