

Painful Diabetic Neuropathy

Impact of an alternative approach

ELENA A. GILLESPIE, BS^{1,2}
 BRENDA W. GILLESPIE, PHD³
 MARTIN J. STEVENS, MD^{1,2}

Painful diabetic neuropathy (PDN) can be refractory to conventional pharmacologic therapy (1–3), which may have significant side effects. Reiki is a hands-on therapy based on the theoretical existence of a bioenergy field intrinsic to the human body (4). Reiki practitioners believe that this bioenergy field can be altered by a trained practitioner and that this can ameliorate disabling symptoms. However, its therapeutic efficacy remains unclear (5). This trial therefore assessed the efficacy of Reiki therapy to alleviate pain and improve mobility and quality of life in subjects with type 2 diabetes and PDN.

RESEARCH DESIGN AND METHODS

— A total of 207 subjects with type 2 diabetes and PDN were recruited. Analgesics including anticonvulsants, tricyclic antidepressants, and nonsteroidal antiinflammatory agents were permitted and equally distributed across groups, but no dosing adjustments were allowed. Subjects were stratified according to age, diabetes duration, diabetes control, and recruitment site. Written informed consent and ethical approval was obtained.

The study design was a randomized, semidouble-blind, placebo-controlled, 12-week trial. Subjects were randomized into one of three treatment groups (Reiki, mimic Reiki, or usual care) in a 1:1:1 fashion. Mimic practitioners were actors trained to mimic Reiki practitioners in style of practice. Reiki was applied as previously described (6). Practitioners were

75% female and of a similar age range to the patients. Patients randomized to Reiki or mimic Reiki underwent two treatments in the first week, followed by weekly treatments. Patients in the usual-care group were only assessed at the start and end of the 12-week period. Due to poor participant retention, this arm was discontinued after randomization of 26 subjects.

Therapy sessions of 25-min duration were conducted throughout the day with patients supine in a clinic room decorated to facilitate relaxation. The primary efficacy outcome was the McGill Pain Questionnaire (7). Secondary end points were the 6-min walk test (8), the Epidemiology of Diabetes Intervention and Complications quality-of-life questionnaire, the Well-Being Questionnaire, and the Diabetes Treatment Satisfaction Questionnaire (9–11).

Treatment group comparisons followed the intent-to-treat principle. Treatment groups were first compared using an overall (2 d.f.) test of difference. Pairwise comparisons were made using Tukey's test for multiple comparisons. Analyses were repeated after stratification in general linear regression models. Paired (pre/post) data were analyzed using Student's *t* test for the continuous variables. Participants without a final evaluation were dropped from the analysis. A significance level of 0.05 was used throughout the analyses.

RESULTS — Ninety-three subjects were randomized to Reiki group (mean \pm

SD age 66 ± 10 years, 63% male, A1C $8.7 \pm 1.5\%$, and diabetes duration 9.2 ± 7.6 years), 88 to the mimic-Reiki group (age 65 ± 10 years, 61% male, A1C $8.5 \pm 1.7\%$, and diabetes duration 9.8 ± 8.6 years), and 26 to the usual-care group (age 59 ± 10 years, 50% male, A1C $8.5 \pm 1.5\%$, and diabetes duration 9.6 ± 6.7 years). Overall, 82, 75, and 69% of subjects completed the final evaluation in the Reiki, mimic-Reiki, and usual-care groups, respectively.

Compared with baseline, the total score for pain descriptors improved significantly ($P < 0.05$) for both the Reiki and mimic-Reiki treatments but not for the usual-care group (Table 1). However, final pain scores were not significantly different between groups. The trends toward improvement in the visual analogue scale and present pain intensity were not statistically significant. Treatment differences at 12 weeks were not significantly different either adjusted or unadjusted for baseline values and stratification factors.

In the Reiki, mimic-Reiki, and usual-care groups, 7, 3, and 1 pain descriptors improved, respectively ($P < 0.05$). At the final visit, walking distance improved by 12% ($P = 0.005$), 12% ($P = 0.009$), and 6% ($P =$ not significant), respectively, in the Reiki, mimic-Reiki, and usual-care groups. There were no differences between treatments in the 12-week measures. Compared with baseline, at the final visit, no significant changes were detected in either the Well-Being Questionnaire or the Diabetes Treatment Satisfaction Questionnaire. The Epidemiology of Diabetes Intervention and Complications questionnaire detected borderline improvement within the Reiki group ($P = 0.05$).

Eight patients withdrew from the study due to serious adverse events, and one patient died. No event was related to study treatment.

CONCLUSIONS — Complimentary and alternative modalities are increasingly used in the treatment of diabetes or its complications (12), but often their efficacy remains unvalidated. This study therefore explored the efficacy of Reiki to control PDN as a complication of type 2 diabetes.

From the ¹Division of Medical Sciences, University of Birmingham, Birmingham, U.K.; the ²Department of Internal Medicine, University of Birmingham, Birmingham, U.K.; and the ³University of Michigan Center for Statistical Consultation, University of Michigan, Ann Arbor, Michigan.

Address correspondence and reprint requests to Martin J. Stevens, MD, Division of Medical Sciences, The Medical School, University of Birmingham, Edgbaston, Birmingham, U.K. B15 2TT. E-mail: m.j.stevens@bham.ac.uk.

Received for publication 19 July 2006 and accepted for publication 28 December 2006.

Abbreviations: PDN, painful diabetic neuropathy.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

DOI: 10.2337/dc06-1475. Clinical trial reg. no. NCT00011075, clinicaltrials.gov.

© 2007 by the American Diabetes Association.

The costs of publication of this article were defrayed in part by the payment of page charges. This article must therefore be hereby marked "advertisement" in accordance with 18 U.S.C. Section 1734 solely to indicate this fact.

Table 1—Results of pain perception and 6-min walk tests

| | Reiki group | Mimic-Reiki group | P for two groups* | Usual-care group | P for three groups* |
|-------------------|---------------------------|---------------------------|-------------------|---------------------------|---------------------|
| <i>n</i> | | | | | |
| Baseline | 88† | 83† | | 26 | |
| 12 weeks | 76 | 66 | | 18 | |
| Total pain‡ | | | | | |
| Baseline | 16.5 ± 10.3 (15.7 ± 9.8) | 16.2 ± 10.5 (16 ± 10.9) | | 15.4 ± 10.1 (15.3 ± 4.6) | |
| 12 weeks | 12.9 ± 9.7 | 13.6 ± 9.7 | 0.601 | 13.6 ± 11.4 | 0.847 |
| Difference§ | 2.9 ± 7.9 | 2.3 ± 8.8 | | 1.8 ± 15.0 | |
| P | 0.002 | 0.039 | | 0.622 | |
| VAS¶ | | | | | |
| Baseline | 3.5 ± 2.8 (3.4 ± 2.7) | 3.4 ± 2.6 (3.3 ± 2.6) | | 3.5 ± 2.2 (3.5 ± 2.5) | |
| 12 weeks | 2.9 ± 2.6 | 3.0 ± 2.3 | 0.935 | 2.1 ± 2.5 | 0.497 |
| Difference§ | 0.5 ± 2.7 | 0.4 ± 2.4 | | 1.3 ± 2.9 | |
| P | 0.129 | 0.191 | | 0.129 | |
| PPI# | | | | | |
| Baseline | 1.5 ± 1.2 (1.4 ± 1.1) | 1.5 ± 1.1 (1.5 ± 1.1) | | 1.4 ± 0.9 (1.5 ± 0.9) | |
| 12 weeks | 1.1 ± 1.0 | 1.3 ± 1.2 | 0.558 | 1.0 ± 1.1 | 0.506 |
| Difference§ | 0.2 ± 1.1 | 0.2 ± 1.1 | | 0.5 ± 1.4 | |
| P | 0.085 | 0.150 | | 0.144 | |
| Baseline | 89 | 86 | | 25 | |
| 12 weeks | 68 | 62 | | 17 | |
| 6-min walk (feet) | | | | | |
| Baseline | 1,129 ± 320 (1,164 ± 322) | 1,108 ± 324 (1,151 ± 303) | | 1,110 ± 267 (1,148 ± 260) | |
| 12 weeks | 1,266 ± 371 | 1,244 ± 344 | 0.721 | 1,176 ± 280 | 0.564 |
| Difference§ | 137 ± 343 | 136 ± 334 | | 66 ± 271 | |
| P | 0.005 | 0.009 | | 0.699 | |

Data are means ± 1SD. Numbers in parentheses represent data from subjects who completed the study. †In each of the Reiki and Reike-mimic groups, five subjects did not complete pain questionnaires or the 6-min walk test and withdrew from the study after being randomized. §Pre/posttreatment differences are based on subjects with both pre- and posttreatment values. The sample sizes for the difference (and Student's paired *t* test) are equal to the number of subjects with posttreatment evaluations, given at the top of each section. ‡Total score of all 17 descriptors of pain on the McGill Pain Questionnaire; 0 = no pain, 3 = severe pain. ¶VAS, visual analogue scale (0 = no pain, 10 = maximum pain tolerated); #PPI, present pain indicator (0 = no pain, 1 = mild pain, 2 = discomforting pain, 3 = distressing pain, 4 = horrible pain, 5 = excruciating pain). ||P value based on Student's paired *t* test of baseline versus 12-week values; *P value based on linear regression comparing 12-week means across treatment groups adjusted for baseline values.

Global pain scores and walking distance improved from baseline in both the Reiki and mimic-Reiki groups. However, there were no significant differences between groups at the final visit. These results indicate that in this population, the application of Reiki was not effective for the treatment of PDN, and the responses observed in both Reiki and mimic-Reiki subjects are consistent with those expected for a clinical trial (13,14). However, limitations of this study that may have reduced the power to detect a difference between groups were the relatively low pain scores at baseline in all groups and the inability to retain usual-care subjects.

In conclusion, Reiki is no more effective than mimic-Reiki in decreasing pain perception and improving walking distance in subjects with PDN. However, the reduction of pain symptoms observed in both treatment groups is consistent with the concept that the formation of a “sus-

tained partnership” between the health care provider and the patient can have direct therapeutic benefits (15).

Acknowledgments— This work was supported by National Institutes of Health Grants R01-F000727 and P50-AT-00011, the General Clinical Research Centers Grant M0-1RR-00042, the Juvenile Diabetes Research Foundation, Eli Lilly, and the American Diabetes Association.

We thank the Reiki practitioners, as well as Renu Mahajan and Robert Adwere-Boamah.

References

1. Boulton AJM, Vinik AI, Arezzo JC, Bril V, Feldman EL, Freeman R, Malik RA, Maser RE, Sosenko JM, Ziegler D: Diabetic neuropathies: a statement by the American Diabetes Association (Position Statement). *Diabetes Care* 28:956–962, 2005
2. Calissi PT, Jaber LA: Peripheral diabetic neuropathy: current concepts in treat-

- ment. *Ann Pharmacother* 29:769–777, 1995
3. Galer BS: Neuropathic pain of peripheral origin: advances in pharmacologic treatment. *Neurology* 45 (Suppl. 9):S17–S25, 1995
4. Post-White J, Kinney ME, Savik K, Gau JB, Wilcox C, Lerner I: Therapeutic massage and healing touch Improve symptoms in cancer. *Integr Canc Ther* 2:332–344, 2003
5. Olson K, Hanson J, Michaud M: A phase II trial of Reiki for the management of pain in advanced cancer patients. *J Pain Symp Man* 26:990–997, 2003
6. Miles P, True G: Reiki: review of a biofield therapy history, theory, practice, and research. *Altern Ther Health Med* 9:62–72, 2003
7. Melzack R: The McGill Pain Questionnaire: major properties and scoring methods. *Pain* 1:277–299, 1975
8. American Thoracic Society: Guidelines for the six-minute walk test. *Am J Resp Crit Care Med* 166:111–117, 2002

9. Bradley C: *Handbook of Psychology and Diabetes*. Reading, U.K., Hardwood, 1994
10. The Diabetes Control and Complication Trial Research Group: Influence of intensive diabetes treatment on quality-of-life outcomes in the Diabetes Control and Complications Trial. *Diabetes Care* 19: 195–203, 1996
11. Jacobson A, Barofsky I, Cleary P, Rand L, the DCCT Research Group: Reliability and validity of a diabetes quality-of-life measure for the Diabetes Control and Complications Trial (DCCT). *Diabetes Care* 11:725–32, 1988
12. Garrow D, Egede LE: Association between complementary and alternative medicine use, preventive care practices, and use of conventional medical services among adults with diabetes. *Diabetes Care* 29: 15–19, 2006
13. Brody H: The placebo response: recent research and implications for family medicine. *J Fam Pract* 49:649–654, 2000
14. Benedetti F, Amanzio M: The neurobiology of placebo analgesia: from endogenous opioids to cholecystokinin. *Prog Neurobiol* 52:109–125, 1997
15. Leopold N, Cooper J, Clancy C: Sustained partnership in primary care. *J Fam Pract* 42:129–137, 1996