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Study Raises Important Issues About the Potential Benefit of Osteopathy in the Cranial Field to Patients With Parkinson’s Disease

To the Editor:

In their article, “A Retrospective Study of Cranial Strain Patterns in Patients With Idiopathic Parkinson’s Disease” (J Am Osteopath Assoc. 2002;102:417-422), Sonia Rivera-Martinez, DO, et al hypothesize that osteopathy in the cranial field (OCF) “may contribute significantly to the management of patients with neurologic disorders.”

We commend the authors for identifying an important clinical problem that may be amenable to OCF and for discussing a possible relationship between osteopathic lesions and the clinical presentation of patients with Parkinson’s disease.

Evidence-based medicine ensures that we provide patients with optimal treatment based on rigorous study. Accordingly, it is important that trials contain study designs that evaluate the diagnostic and treatment regimens we offer, especially when treating patients with complex chronic illnesses such as Parkinson’s disease.

The study by Rivera-Martinez et al—though inconclusive as a basis for clinical recommendations—raises important issues and should serve to promote further research into OCF techniques. However, concerns that include the study design used make this trial too preliminary to establish the effectiveness of OCF in treating patients with Parkinson’s disease.

Patient encounters described in the article were extrapolated from clinical records, with inclusion criteria based on a diagnosis of Parkinson’s disease and documented findings of somatic dysfunction by osteopathic physicians competent in manipulative medicine. The range of such dysfunction makes studying discrete groups, necessary for scientific comparison and establishment of treatment protocols, a challenge. Further complicating the study of OCF is the fact that diagnostic findings regarding cranial dysfunction continue to be debated within the osteopathic medical profession. Although current studies lend credence to the concept of cranial bone mobility, the physiologic significance and clinical implications of such mobility remain to be established.

A review of current medical literature reveals insufficient statistically significant correlations between cranial interventions and positive patient outcomes.3 A recent attempt to substantiate interexaminer reliability revealed a disappointing correlation between trained physicians placed at a patient’s head and feet, further compounding the dilemma of evaluating the potential effectiveness of OCF.2 Such inconsistency among osteopathic physicians proficient in the diagnosis of cranial dysfunction further distances the possibility of finding an association between Parkinson’s disease and cranial abnormalities.

Parkinson’s disease is certainly a neurologic disorder; however, the spectrum of its clinical presentation suggests that which applies to this disease is not applicable to all neurologic disorders. Although OCF may enable the identification of patterns in neurologic disorders in general, this study emphasized Parkinson’s disease; therefore, the study title and conclusions should reflect this.

An additional concern regarding the study is the number of patients in the research group with diagnosed cranial dysfunction. Of those patients with documented parietal or temporal rotation—both internal and external—only 10% (n=3) met the inclusion criteria to be considered part of the research group. Forty percent (n=8) of patients with parieto-occipital rotatory dysfunction met inclusion criteria to be classified as controls. And while 15% (n=3) of control patients had frontosphenoidal dysfunction, only 33% (n=1) of patients with Parkinson’s disease had similar pathology.

Although the occurrence of occipital lesions in participants with Parkinson’s disease is considered statistically significant in this study, such small study populations do not have the power to support the study’s conclusions; therefore, findings cannot be applied to the population of Parkinson’s patients. (What validity does an n of 1 have?) It is premature to use this study to suggest that “treatment of cranial findings may improve the outcome of disease progression.”

Osteopathic medicine was born out of the need to protect patients from untested or
potentially unsafe practices. The profession began and remains patient-centered and encourages scientific scrutiny as it relates to clinical outcomes.

If OCF is to flourish, current research must support clinical application. Yet a Medline search reveals the lack of longitudinal, random-controlled prospective studies that examine OCF. The shift toward evidence-based medicine necessitates such a critical perspective.

A comprehensive review of the literature conducted by the British Columbia Office of Health Technology Assessment concluded that insufficient evidence exists to support the continued practice of third-party reimbursement for craniosacral manipulation.1

As osteopathic physicians, we hope to provide therapeutic benefit to our patients, especially those suffering from such a debilitating illness as Parkinson’s disease. Osteopathy in the cranial field may be found to benefit patients with this disease, but clearly defined diagnostic and treatment criteria as well as rigorous, prospective studies with appropriate sample sizes are necessary to support such a claim.

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References

Response

We appreciate the interest in our study1 shown by Boehm et al. However, many of their concerns seem to arise from examining excerpts of our article out of context. Therefore, we will address these concerns by presenting excerpts in their original context.

Boehm et al excerpted the following from our article: “OCF [osteopathy in the cranial field] may contribute significantly to the management of patients with neurologic disorders.” Based on this excerpt, the authors questioned our use of a retrospective study design to determine the effectiveness of OCF in the treatment of patients with Parkinson’s disease. The sentence as it originally appeared read “these reports suggest that OCF may contribute significantly to the management of patients with neurologic disorders.” A review of our article will reveal that we did not presume to establish the effectiveness of OCF in patients with Parkinson’s disease. Rather, we suggest that there may be a basis for examining this possibility.

The authors comment on the elusiveness of the association between Parkinson’s disease and cranial abnormalities in light of inconsistencies on this subject among physicians proficient in the diagnosis of cranial dysfunction. We recognize the problem of conducting studies on interexaminer reliability in cranial findings and in physical diagnosis in general, as both are interpretations based on training and clinical experience. It is interesting to note that the examiners in the study quoted by Boehm et al were physical therapists (there was no mention of their credentialing) with only 11 months’ experience in palpating cranial rhythm.2 Furthermore, the examiners palpated the cranial rhythmic impulse (CRI) rate on each subject in separate sessions, not concomitantly.2 In contrast, our study only included data on physicians who were board-certified in osteopathic manipulative medicine and held a certificate of competency in cranial osteopathy.1 The CRI, as with any rate that occurs in the body, is variable from one minute to the next. In light of this fact, how could it be expected that the examiners would be in agreement on the CRI rate as the measurements were taken at different times? In that setting, it is highly unlikely that interexaminer agreement would be achieved.

The purpose of our study was to determine if there were any common cranial findings in patients with Parkinson’s disease as compared to normal controls. This is a population-based experimental approach that uses the hypothesis that diagnoses could emerge at a significantly higher frequency in patients with Parkinson’s disease if these diagnoses are nonrandom relative to a matched population of subjects without Parkinson’s disease. The study established—within the limits of our sample populations—that this is true. This implies that there may be a basis for the diagnosis of particular types of cranial abnormalities and Parkinson’s disease, elusive or not.

Another concern raised by Boehm et al is that although Parkinson’s disease is a neurologic disorder, the “spectrum of its presentation” is not applicable to all neurologic disorders and that the study’s title and Conclusion section should reflect that the study emphasized Parkinson’s disease. Our original statement in this regard read “it may follow that from a therapeutic standpoint, OCF may be able to reduce the progression of neurologic disorders. Frymann et al3 observed that children with diagnosed neurologic problems had marked improvement of their neurologic performance after OCF. Arbuckle4 reported similar findings in patients with cerebral palsy. These reports suggest that OCF may contribute significantly to the management of patients with neurologic disorders.” We believe that the literature we discussed3,4 makes this a reasonable statement for discussion. As for the need to make the emphasis of the study clear in the title and Conclusion section, we suggest that Boehm et al actually read both the title and Conclusion of our article, at which time they will discover that we did emphasize that researchers were attempting to find patterns between OCF and Parkinson’s disease, not between OCF and all neurologic disorders. That we suggest that cranial findings and manipulation may be applicable to other neurologic disorders is well within the bounds of a discussion of the subject, which is why this conjecture was placed in the Discussion section and does not form part of our conclusions. The purpose is to generate questions that will lead to further research on this subject.

The authors also express concern about the number of patients in the research group diagnosed with cranial dysfunction. We recognize the limitation of the number of subjects in our study and repeat several times in our article the need for further study. We are uncertain as to the point Boehm et al are trying to make by noting that some diagnoses did not occur with sufficient frequency to be significant. Clearly if several hundred subjects could have been monitored, differences in less frequent diagnoses could have been identified. We wished to examine the possibility that any of the possible diagnoses considered might appear with a frequency significantly above control. In regard to concern about the validity of “n=1,” we ana-
lyzed our data on the basis of frequencies of occurrence, compared with expected frequencies of occurrence from a control population. This is statistically valid for the sample sizes used in our study. An n of 1 can have validity if the expected frequency predicts that this number should be significantly higher. In addition, the inclusion and exclusion criteria used in our study—clearly stated in the Methods section—did not include type of cranial dysfunction. Moreover, we excluded from statistical analysis the types of dysfunctions that occurred in frequencies of less than 10%.

Boehm et al state that cranial findings in this study are premature to suggest that treatment based on these findings may improve the outcome of disease progression. In our article, we address that issue by stating “we propose that more research is needed, not only regarding the strain patterns relative to certain disease processes, but more important, regarding the possibility that treatment of cranial findings may improve the outcome of disease progression.”1 We believe that presenting the excerpted phrase in its context is sufficient to reveal its original intent. In summary, we hope that readers who review our article will readily understand the limited scope of our study, its points of discussion, and the intent of our conclusions. We wish that our findings will stimulate further study of an area of osteopathic medicine clearly in need of further examination.◆

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