A systematic review of craniosacral therapy: biological plausibility, assessment reliability and clinical effectiveness

C. Green, C.W. Martin, K. Bassett, A. Kazanjian
University of British Columbia, Canada

SUMMARY. Objectives: The objective of this research was to review critically the scientific basis of craniosacral therapy as a therapeutic intervention. Design: A systematic search for and critical appraisal of research on craniosacral therapy was conducted. Medline, Embase, Healthstar, Mantis, Allied and Alternative Medicine, Scisearch and Biosis were searched from their start date to February 1999. Main outcome measures: A three-dimensional evaluative framework with related appraisal criteria: (A) craniosacral interventions and health outcomes; (B) validity of craniosacral assessment; and (C) pathophysiology of the craniosacral system. Results: The available research on craniosacral treatment effectiveness constitutes low-grade evidence conducted using inadequate research protocols. One study reported negative side effects in outpatients with traumatic brain injury. Low inter-rater reliability ratings were found. Conclusions: This systematic review and critical appraisal found insufficient evidence to support craniosacral therapy. Research methods that could conclusively evaluate effectiveness have not been applied to date.

INTRODUCTION

Craniosacral therapy is based on the theory that movement restrictions at the cranial sutures of the skull negatively affect rhythmic impulses conveyed through the cerebral spinal fluid from the cranium to the sacrum. All structures which are in contact with the cerebral spinal fluid, including the brain, the spinal cord, and their protective membranes, are seen as part of the cranio-sacral system and are potentially affected by it. All other structures in the body are potentially affected indirectly through innervations arising from, or returning to, the central nervous system, or directly through mobility of the musculo-skeletal system.

Craniosacral practitioners (who include physiotherapists, chiropractors, dentists, and osteopathic, medical or naturopathic physicians, as well as other regulated and unregulated health-care practitioners) claim that gentle pressure on external areas, such as the head and back, benefits patients with a variety of conditions, including musculoskeletal problems, learning difficulties, sinusitis, trigeminal neuralgia, colic and birth trauma.[1–3] The objective of this research was to review critically the scientific basis of craniosacral therapy as a therapeutic intervention.

Carolyn Green
BC Office of Health Technology Assessment, The University of British Columbia, 429–2194 Health Sciences Mall, Vancouver, British Columbia V6T 1Z3 Canada

Definition

Craniosacral therapy has been variously defined as:

> ...a systemic approach to evaluating and treating dysfunction occurring within the articulations of the skull...[4]

and

> ...a structured diagnostic process that evaluates the mobility of the osseous cranium, the related mobility of the skull and sacrum and the palpation of the CRI (craniosacral rhythm impulse) throughout the body. Craniosacral osteopathic

> manipulative techniques attempt to restore motion to restrictions within individual sutures of the skull, the skull as a total entity, and the skull in relation to the sacrum, and apply inherent force to the articulations of the vertebral axis, rib cage and extremity.[5]

Recognizing both the lack of consensus as to exactly what craniosacral therapy encompasses, and the limited number of studies on this subject, a broad definition was adopted for identifying relevant research.

METHOD

Search strategy and sources

Studies were included if they met pre-determined criteria. That is, if they reported: (1) primary data on any manual manipulation of the cranial sutures of the skull termed by the researchers as craniosacral therapy for the purpose of effecting health benefits; or (2) any primary research on any aspect of the craniosacral system put forward in the literature on craniosacral therapy as providing relevant evidence. The search was not limited to any specific craniosacral therapeutic technique, research design, health condition, patient population or health outcome. A search protocol was developed, and is detailed elsewhere.[6]

Medline, Embase, Healthstar, Mantis, Allied and Alternative Medicine, Scisearch and Biosis electronic bibliographic databases were searched from their start date to February 1999. Search terms included 'craniosacral', 'cranial bones,' 'cranial sutures,' 'cerebrospinal pulse' and 'cerebrospinal fluid'. A 'fugitive' literature search was conducted of relevant websites and professional organizations. Retrieved articles were also scanned for relevant citations.

Evaluative Framework

A three-dimensional evaluative framework was developed for assessing research evidence on craniosacral therapy, extending previous work in this area.[7–9] The two main reviewers placed each study in one of the following three categories: (A) craniosacral interventions and health outcomes; (B) validity of craniosacral assessment; and (C) pathophysiology of the craniosacral system.

It proved feasible to include craniosacral pathophysiology as the third dimension in the evaluation, since deficiencies in the understanding or even acceptance of any physiological or biochemical mechanism have led to debate regarding this type of evidence,[10] thereby stimulating research.

Under dimension A, evidence on the effectiveness of craniosacral therapy in altering health outcomes was graded according to the Canadian Task Force on Preventive Health Care, formerly The Canadian Task Force on the Periodic Health Examination[11] guidelines:

1. At least one properly randomized controlled trial.
2. a. Well-designed controlled trials without randomization.
   b. Well-designed cohort or case control analytic studies.
   c. Comparisons between times or places with or without the intervention.
3. Opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees.

In addition, studies were appraised using a standard BC Office of Health Technology Assessment Intervention Study Appraisal Form.[6]

Under dimension B, evidence on the reliability of assessment of craniosacral dysfunction, criteria were developed from two sources. The first was Feinstein's[12] criteria for ensuring the replicability of observations by multiple independent observers along 13 dimensions, namely: purpose; input challenge; procedural components; observations; observers; scale of reporting output; scale of disagreement; index of concordance; procedural criteria; interpretation criteria; analysis; improvements; and recommendations. Second, because the clinical assessment tools of craniosacral practitioners are diagnostic processes, eight 'guides' by Sackett et al.,[13] aimed at evaluating the literature on diagnostic tests, were applied.

Finally, for dimension C, pathophysiology of the craniosacral system, three aspects were considered (Table 1). With regard to whether a causal relationship exists between health and movement of cranial bones, evaluation criteria were developed using Hill's criteria,[14] namely: strength of association; consistency of the observed evidence; specificity of the relationship; temporality of the relationship; biological gradient of the dose-response; biological plausibility; coherence of the evidence; experimental confirmation; and reasoning by analogy. Given the heterogeneous nature of the study designs employed, other research pertaining to the pathophysiological basis of craniosacral therapy was evaluated using relatively non-specific criteria of research quality as defined in the literature, namely by asking whether: (i) the research design was appropriate; (ii) sampling techniques were representative; (iii) the outcome measures were reliable and valid; and (iv) the methods of analysis were appropriate.

Critical-appraisal criteria appropriate for the class of research were applied by each reviewer independently, compared, and disagreements resolved by discussion.

RESULTS

Thirty-three studies were identified providing primary data on craniosacral therapy.

Table 1 The overall results of the systematic review for primary data on craniosacral therapy

A. Craniosacral treatment	B. Craniosacral assessment	C. Pathophysiology of craniosacral dysfunction		
Is craniosacral treatment effective?	**Can practitioners agree on craniosacral evaluation findings?**	**Is there an association between health and restrictions?**	**Is movement between cranial bones possible?**	**Does cerebrospinal fluid move rhythmically?**
Baker 1971[15]	Upledger 1977[19]	Frymann 1966[24]	Todd and Lyon 1924[26]	O'Connell 1943[34]
Blood 1986[19]	Upledger and Karni 1979[20]	Upledger 1978[2]	Baker 1971[15]	Du Boulay et al. 1972[35]
Frymann et al. 1992[3]	Wirth-Pattullo and Hayes 1994[21]	White et al. 1985[25]	Greenman 1970[27]	Cardoso et al. 1983[36]
Hollenbery and Dennis 1994[1]	Hanten et al. 1998[22]		Frymann 1971[28]	Takizawa et al. 1983[37]
Greenman and McPartland 1995[5]	Rogers et al. 1998[23]		Hubbard et al. 1971[29]	Avezaat and van Eijndhoven 1986[38]
Phillips and Meyer 1995[17]			Kokich 1976[30]	
Joyce and Clark 1996[18]			Heifetz and Weiss 1981[31]	Enzmann et al. 1986[39]
			Pitlyk et al. 1985[32]	Feinberg & Mark 1987[40]
			Kostopoulos and Keramidas 1992[33]	Ursino 1988[41] (parts 1 & 2)
				Zabolotny et al. 1995[42]
				Li et al. 1996[43]

Craniosacral treatment effectiveness

Seven studies were identified and critically appraised which reported on the effectiveness of craniosacral therapy in altering health outcomes. Study designs used were retrospective case control,[17] retrospective case series,[5,16] before-after[3] and case reports.[1,15,18]

The available studies are of the lowest (Level III) grade evidence as rated by the Canadian Task Force on Preventive Health Care[7] ranking system, and are of poor quality when judged using standard critical appraisal criteria.[6] Of concern is the report by Greenman and McPartland[5] of adverse effects in some patients with traumatic brain injury.

Agreement by practitioners on craniosacral assessment findings

Five studies were identified and critically appraised that provided primary data on the assessment of craniosacral dysfunction by CST practitioners.[19–23] The 1977 study by Upledger[19] reported high interrater reliability for some parameters that make up the assessment of craniosacral movement. This study has a number of limitations, however. None of the subjects were distinguished as normal; that is, all subjects studied (25 children between the ages of 3 and 5) were judged to have cranial movement restrictions on multiple parameters. In order to demonstrate the ability of a test to distinguish adequately between affected subjects, however, a study of this type should also include a sufficient number of subjects classified as normal.

Furthermore, the study itself has not been replicated in the intervening 20 years. More recent research refutes Upledger's findings. Intraclass correlation coefficients were minus 0.02 in the Wirth-Pattullo and Hayes' study,[21] 0.20 in the Hanten et al.'s study,[22] 0.08 and 0.19 in the Rogers et al.'s study[23] and 0.57 in the Upledger's 1977 study[19] (recalculation). The more recent and better designed studies were consistent in not finding assessment of craniosacral rhythm reliable.

Pathophysiology and craniosacral dysfunction

The potential association between health and craniosacral mobility restrictions

Direct evidence–Three studies[2,24,25] directly examined the potential association between health and craniosacral mobility restrictions. Two of the three studies were cross-sectional studies, that is, the craniosacral system and health outcomes were measured at the same point in time. The third study was clearly also observational (i.e. not a prospective trial). However, insufficient description of the methodology in this latter study precluded further classification.

A cross-sectional study design may provide evidence, albeit weak, regarding associations between craniosacral dysfunction and disease. The above-mentioned studies, however, ranked low according to standard principles for judging the quality of this type of study design. For example, key features, such as study enrolement and population characteristics, were not described.

The validity and reliability of subjective methods for classifying craniosacral movement restrictions is especially problematic. No validation studies have been conducted to demonstrate that craniosacral assessment 'measurements' do, in fact, measure what they are intended to. Available research on interrater reliability has not been able to demonstrate reliability (see previous results). In the studies by Frymann[24] and Upledger,[2] health states were subjectively determined; no explicit classification criteria were used to establish content validity, and categories were arbitrary, lacking face validity. The Upledger study was particularly questionable since classification was undertaken by parents, educators and a variety of health-care providers, but no assessment of agreement amongst them was carried out.

Indirect evidence – Indirect evidence was examined from studies that investigated: (1) the existence of movement between cranial bones; and (2) the existence of rhythmic flow patterns in cerebrospinal fluid. This evidence has been used in debates in the literature between sceptics who deny the existence of these components, and proponents who use this literature as supportive of two of the potential links in a causal chain between craniosacral mobility restrictions and health.

Motion/fusion between cranial bones

Nine studies were identified and retrieved that reported on mobility or fusion at cranial sutures in adults.[15,26–32] The quality of the available evidence was variable, as were the study designs used. Most of the study designs were appropriate only for hypothesis generation and were not aimed at evaluating any causal association. Although incomplete, the research evidence supported the theory that the adult cranium is not always solidly fused, and that minute movements between cranial bones are possible. However, none of the identified research demonstrated that movement at cranial sutures can be achieved manually.

Cerebrospinal fluid rhythmic flow patterns

Eleven studies reported primary data on the motion of cerebrospinal fluid.[34–43] None of these studies was undertaken to contribute to knowledge of craniosacral therapy. Rather, this set of studies represents research carried out primarily to provide neurosurgeons with data on pathophysiology pertaining to cerebrospinal fluid motion for diagnosis, treatment and monitoring of brain injury and other neurological disorders.

The research quality was variable. The methodological strength of a number of the studies is that they used measurement tools capable of producing valid and reproducible observations, for example: intracranial pressure monitoring;[34,36,37,43] magnetic resonance imaging;[39,40] and encephalograms/myelography.[35] The consistency of the observed phenomena, and the fact that these studies were performed in a discipline not linked to the practice of craniosacral therapy, tend to strengthen the confidence that can be placed on the observations. The limitations of the research apply to the distinct nature of the research questions addressed more than to questions about the existence of cerebrospinal fluid movement. For example, most of the studies examined patients with neurological disorders. The flow patterns observed, therefore, may not be representative of individuals undergoing craniosacral therapy.

DISCUSSION

This systematic review found insufficient evidence to support craniosacral therapy. Research methods that could conclusively evaluate effectiveness or lack of effectiveness of craniosacral therapy as an intervention have not been applied to date.

The available research on craniosacral treatment effectiveness represents a low grade of evidence conducted using inadequate research protocols. The report by Greenman and McPartland[5] of adverse effects in outpatients with traumatic brain injury contradicts claims that it is without negative side effects.

J. E. Upledger, osteopath and founder of the Institute of Craniosacral Integration, argues that:

> [P]ositive patient outcomes as a result of CranioSacral Therapy should weigh greater than data from designed research protocols involving human subjects, as it is not possible to control all of the variables of such studies.44

This point of view has successfully been countered by groups such as the Quantitative Methods Working Group of the U.S. National Institutes' of Health Office of Alternative Medicine,[45] as well as the Cochrane Complementary Medicine Field.[46] Many validated measures of a variety of health outcomes exist to measure 'positive patient outcomes'. Complex complementary medical systems can be studied as 'gestalts' (integrated wholes) for the purpose of evaluation from within an intervention/trials framework. Claims that the scientific methods currently available are not suitable for evaluating the therapies variously categorized as 'non-traditional', 'alternative', or 'complementary' are not valid.

The reliability of observation amongst multiple observers is a basic requirement of a scientific measurement tool. A high correlation indicating agreement between craniosacral therapy practitioners would, accordingly, have validated craniosacral rhythm as an observable phenomenon. Inter-observer agreement studies have found, however, that assessment of craniosacral dysfunction by practitioners of craniosacral therapy is unreliable, i.e. two or more assessors do not agree on craniosacral findings to the extent required of scientific measures.

The available research was not able to demonstrate, conclusively, a causal relationship between restrictions/misalignments in the movement of cranial bones and health. A key appraisal issue for this literature is the validity of the tools used to measure craniosacral dysfunction.

Two sets of research were identified and critically appraised providing indirect evidence on the question of whether or not there is an association between health and craniosacral dysfunction. This research provides some support for the claims that: minute movement between cranial bones is possible and that cerebrospinal fluid flows in a pulse-like rhythmic manner. However, the support for these two claims does not adequately support the theory that craniosacral dysfunction is associated with health outcomes, because the relationship between these discrete phenomena has not been studied. There is no evidence to show they are linked in a way that would connect cranial bone positions to health.

Missing from the causal chain are evidential links to show that different cranial bones positions produce different cerebrospinal fluid flow patterns and that such different cerebrospinal fluid flow patterns produce different health outcomes.

These significantly large gaps in the scientific chain of evidence, coupled with a noticeable lack of discussion of the leaps or assumptions made, undermine the validity of any conclusions drawn on the basis of current evidence. At the same time, they offer considerable opportunities for evidence-based practitioners and researchers to enter this field.

ACKNOWLEDGEMENT

Support was provided from British Columbia Ministry of Health grant through the Office of the Coordinator of Health Sciences, The University of British Columbia. Workers' Compensation Board of British Columbia. British Columbia Health Research Foundation.

REFERENCES

1. Hollenbery S, Dennis M. An introduction to craniosacral therapy. Physiotherapy 1994; 80(8): 528–532.
2. Upledger JE. The relationship of craniosacral examination findings in grade school children with developmental problems. J Am Osteopath Assoc 1978; 77(10): 760–776.
3. Frymann VM, Carney RE, Springall P. Effect of osteopathic medical management on neurologic development in children. J Am Osteopath Assoc 1992; 92(6): 729–744.

4. Rogers JS, Witt PL. The controversy of cranial bone motion. J Orthop Sports Phys Ther 1997; 26(2): 95–103.
5. Greenman PE, McPartland JM. Cranial findings and iatrogenesis from craniosacral manipulation in patients with traumatic brain syndrome. J Am Osteopath Assoc 1995; 95(3): 182–188.
6. Green CJ, Martin CW, Bassett K, Kazanjian A. A systematic review and critical appraisal of the scientific evidence on craniosacral therapy. Vancouver, BC: University of BC, 1999. British Columbia Office of Health Technology Assessment Report 99: 1J
7. Kazanjian A, Cardiff K, Pagliccia N. Design and development of a conceptual and quantitative framework for health technology decisions: a multi-project compendium of research underway. Vancouver, BC: University of BC, 1995. BC Office of Health Technology Assessment Report 95: 2D.
8. Kazanjian A. Doing the right thing, not just doing things right. In: Gender Working Group, United Nations Commission on Science and Technology for Development. Missing links: gender equity in science and technology for development. New York: International Development Research Centre in association with Intermediate Technology Publications and UNIFEM, 1995, 159–180.
9. Green CJ, Bassett K, Foerster V, Kazanjian A. Bone mineral density testing: does the evidence support its selective use in well women? BC Office of Health Technology Assessment Report Vancouver: University of BC, 1997
10. Complementary medical research: tactics strategies, and problems. In: Lewith G, Kenyon J, Lewis P (eds) Complementary Medicine: An integrated approach. Oxford: Oxford University Press, 1996, 14–20.
11. Dingle JL. Methodology. In: The Canadian Task Force on the Periodic Health Examination. The Canadian guide to clinical preventive health care. Ottawa: Minister of Supply and Services; 1994
12. Feinstein AR. Clinical epidemiology: the structure of clinical research. Philadelphia: WB Saunders, 1985; 648.
13. Sackett DL, Haynes RB, Tugwell P. Clinical Epidemiology: a basic science for clinical medicine, 2nd ed. Boston: Little, Brown, 1991; 366–367.
14. Hill AB. Principles of medical statistics. New York: Oxford University Press, 1971.
15. Baker EG. Alteration in width of maxillary arch and its relation to sutural movement of cranial bones. J Am Osteopath Assoc 1971; 70: 559–564.
16. Blood SD. The craniosacral mechanism and the temporomandibular joint. J Am Osteopath Assoc 1986; 86(8): 512–519.
17. Phillips CJ, Meyer JJ. Chiropractic care, including craniosacral therapy, during pregnancy: a static-group comparison of obstetric interventions during labor and delivery. J Manipulative Physiol Ther 1995; 18(8): 525–529.
18. Joyce P, Clark C. The use of craniosacral therapy to treat gastroesophageal reflux in infants. Inf Young Children 1996; 9(2): 51–58.
19. Upledger JE. The reproducibility of craniosacral examination findings: a statistical analysis. J Am Osteopath Assoc 1977; 76(12): 890–899.
20. Upledger JE, Karni Z. Mechano-electric patterns during craniosacral osteopathic diagnosis and treatment. J Am Osteopath Assoc 1979; 78(11): 782–791.
21. Wirth-Pattullo V, Hayes KW. Interrater reliability of craniosacral rate measurements and their relationship with subjects' and examiners' heart and respiratory rate measurements. Phys Ther 1994; 74(10): 908–920.
22. Hanten WP, Dawson DD, Iwata M, Seiden M, Whitten FG, Zink T. Craniosacral rhythm: reliability and relationships with cardiac and respiratory rates. J Orthop Sports Phys Ther 1998; 27(3): 213–218.
23. Rogers JS, Witt PL, Gross MT, Hacke JD, Genova PA. Simultaneous palpation of the craniosacral rate at the head and feet: intrarater and interrater reliability and rate comparisons. Phys Ther 1998; 78(11): 1175–1185.
24. Frymann V. Relation of disturbances of craniosacral mechanisms to symptomatology of the newborn: study of 1,250 infants. J Am Osteopath Assoc 1966; 65(10): 1059–1075.
25. White WK, White JE, Baldt G. The relation of the craniofacial bones to specific somatic dysfunctions: a clinical study of the effects of manipulation. J Am Osteopath Assoc 1985; 85: 603–604.
26. Todd TW, Lyon DW Jr. Endocranial suture closure: its progress and age relationship. Part I: adult males of white stock. Am J Phys Anthrop 1924; VII(3): 325–384.
27. Greenman PE. Roentgen findings in the craniosacral mechanism. J Am Osteopath Assoc 1970; 70(1): 60–71.
28. Frymann VM. A study of the rhythmic motions of the living cranium. J Am Osteopath Assoc 1971; 70(9): 928–945.
29. Hubbard RP, Melvin JW, Barodawala IT. Flexure of cranial sutures. J Biomech 1971; 4(6): 491–496.
30. Kokich VG. Age changes in the human frontozygomatic suture from 20 to 95 years. Am J Orthod 1976; 69(4): 411–430.
31. Heifetz MD, Weiss M. Detection of skull expansion with increased intracranial pressure. J Neurosurg 1981; 55(5): 811–812.
32. Pitlyk PJ, Piantanida TP, Ploeger DW. Noninvasive intracranial pressure monitoring. Neurosurgery 1985; 17(4): 581–584.
33. Kostopoulos DC, Keramidas G. Changes in elongation of falx cerebri during craniosacral therapy techniques applied on the skull of an embalmed cadaver. Cranio 1992; 10(1): 9–12.
34. O'Connell JE. The vascular factor in intracranial pressure and the maintenance of the cerebrospinal fluid circulation. Brain 1943; 66: 204–228.
35. Du Boulay G, O'Connell J, Currie J, Bostick T, Verity P. Further investigations on pulsatile movements in the cerebrospinal fluid pathways. Acta Radiol [diagn] (Stockh) 1972; 13: 496–523.
36. Cardoso ER, Rowan JO, Galbraith S. Analysis of the cerebrospinal fluid pulse wave in intracranial pressure. J Neurosurg 1983; 59(5): 817–821.
37. Takizawa H, Sugiura K, Baba M, Tachizawa T, Kamatsuka E, Hayama N. Spectral analysis of cerebrospinal fluid pulse wave [Engl abstract]. No To Khinkwi 1983; 35(12): 1227.
38. Avezaat CJ, van Eijndhoven JH. Clinical observations on the relationship between cerebrospinal fluid pulse pressure and intracranial pressure. Acta Neurochir (Wien) 1986; 79(1): 13–29.
39. Enzmann DR, Rubin JB, DeLaPaz R, Wright A. Cerebrospinal fluid pulsation: benefits and pitfalls in MR imaging. Radiology 1986; 161(3): 773–778.
40. Feinberg DA, Mark AS. Human brain motion and cerebrospinal fluid circulation demonstrated with MR velocity imaging. Radiology 1987; 163(3): 793–799.
41. Ursino M. A mathematical study of human intracranial hydrodynamics, part 1: the cerebrospinal fluid pulse pressure. Ann Biomed Eng 1988; 16(4): 379–401.
42. Zabolotny W, Czosnyka M, Walencik A. Cerebrospinal fluid pulse pressure waveform analysis in hydrocephalic children. Childs Nerv Syst 1995; 11(7): 397–399.
43. Li J, He W, Yao J, Wen H. Possibility of observing the changes of cerebrospinal fluid pulse waves as a substitute for volume pressure test. Clin Med J (Engl) 1996; 109(5): 411–413.
44. Upledger JE. Research and observations that support the existence of a craniosacral system. 1995 [cited 1998 Apr 15]. Available from: URL: http://www.cranio.org/JEU_Article_en.htm.

45. Levin JS, Glass TA, Kushi LH, Schuck JR, Steele L, Jonas WB. Quantitative methods in research on complementary and alternative medicine. A methodological manifesto. NIH Office of Alternative Medicine. Med Care 1997; 35(11): 1079–1094.
46. Cochrane Collaboration. Cochrane complementary medicine field. In: The Cochrane Library [database on CDROM]. Oxford: Update Software; 1998. Issue 3.