A systematic review and critical appraisal of the scientific evidence on craniosacral therapy

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Authors' objectives
To gather and critically appraise the scientific basis of craniosacral therapy as a therapeutic intervention.

Searching
MEDLINE (1966 to 1998), EMBASE (1976 to 1998), HealthSTAR (1975 to 1997), MANTIS (1880 to 1998), AMED (1984 to 1998), SciSearch (1974 to 1998) and BIOSIS Previews (1969 to 1998) were searched. Keywords searched for included ‘craniosacral’, ‘cranial bones’ and ‘cranial sutures’ combined with ‘therapy’, ‘therapist’, ‘practitioner’, ‘massage’, ‘mobilisation’, ‘manipulation’, ‘motion’ and ‘movement’. Further searching was done on title keywords for ‘cerebrospinal pulse’ and ‘cerebrospinal fluid’. John E. Upledger, a major contributor in the field, was searched for as author and cited source. References of retrieved articles were searched by three authors for additional studies. The library catalogue of the University of British Columbia and Trace-it, a Canadian union catalogue, was also undertaken. Further studies and information were requested from a number of professional association. The Cochrane Library and various websites were also reviewed. Articles in languages other than English were excluded.

Study selection
Study designs of evaluations included in the review
Any primary research on any facet of the craniosacral system in humans. Systematic reviews of the literature and integrative analysis (e.g. cost-effectiveness analysis) were eligible for inclusion.

Specific interventions included in the review
Any manual therapy of the cranial sutures of the skull for the purpose of effective health benefits.

Participants included in the review
Any person with a physical or mental problem of any age group.

Outcomes assessed in the review
Any measurement pertaining to either assessment of cranial bone motion preliminary to craniosacral therapy or to the intervention itself.

How were decisions on the relevance of primary studies made?
Inclusion criteria were applied by two reviewers, disagreements were resolved by discussion.

Assessment of study quality
Studies were divided into the following three categories, and the validity of each study was assessed according to category specific criteria: 1. Pathophysiological mechanisms of craniosacral dysfunction: principles of research design (appropriate design, sampling techniques representative, outcome measures reliable and valid, and appropriate methods of analysis) were assessed. 2. Craniosacral assessment: studies were assessed on study characteristics and observer variability (purpose, input challenge, procedural components, observations, observers, scale of reporting output, scale of disagreement, index of accordance, procedural criteria, interpretation criteria, analysis, improvements and recommendations) according to the criteria of Feinstein (see Other Publications of Related Interest no.1). 3. Craniosacral treatment/interventions: study design was graded according to the Canadian Task Force on Preventive Health Care: grades of evidence (see Other Publications of Related Interest no.2) (grades evidence according to study design, ranges from I for evidence obtained from properly conducted RCTs, to III, opinions of respected authorities based on clinical experience, descriptive studies or reports of expert committees).

The critical appraisal criteria were applied by each reviewer independently, then compared, and any disagreements were resolved by discussion.
Data extraction
Not stated, but data is presented on the purpose of the study, study design, population/sampling technique, outcome measures and method of analysis.

Methods of synthesis
How were the studies combined?
A narrative synthesis was presented. Studies were divided into the following 3 categories: 1. Pathophysiological mechanisms of craniosacral dysfunction (evidence relating pathophysiology of dysfunction to poor health outcomes): the criteria of Hill (see Other Publications of Related Interest no.3) were applied to these studies, principles of research design were also considered. 2. Craniosacral assessment (evidence evaluating the validity of diagnosing craniosacral system dysfunction): the eight ‘guides’ of Sackett (see Other Publications of Related Interest no.4) were applied to these studies which were effectively examining a diagnostic tests. Evidence on the performance of craniosacral assessment methods were appraised, including sensitivity, specificity, predictive values, and the consequences of false positive and false negative results. 3. Craniosacral treatment/interventions (evidence relating to the effect of craniosacral therapeutic interventions on health outcomes): study results were reported narratively.

How were differences between studies investigated?
Differences between the studies were discussed in the narrative synthesis.

Results of the review
Thirty four studies were included. Twenty two looked at the pathophysiology of craniosacral dysfunction, of these three (n=1453, one study did not report on number of subjects) looked at the association between health and craniosacral mobility restrictions, nine (n=641, one study did not state number of subjects) looked at whether movement between cranial bones was possible, and ten (n not stated, but less than 30 for those studies that did report) looked at whether cerebrospinal fluid moves rhythmically. Five studies (n=115, one study did not state how many subjects were included) looked at craniosacral assessment (whether practitioners agree on craniosacral evaluation findings), and seven (n not reported) looked at whether craniosacral treatment is effective.

1. Pathophysiological mechanisms of craniosacral dysfunction: a. Evidence on the effect of craniosacral dysfunction on health. Two studies were cross-sectional in design, the third study was observational but did not provide sufficient details on methodology. The quality of these studies was poor, and so the results should be interpreted with caution. A causal relationship between restrictions/misalignments of cranial bones and health was not demonstrated. Hill's criteria were not met for significant strength of association, experimental confirmation, specificity of relationship, and/or consistency of observed evidence. b. Existence of movement between cranial bones. The quality of the studies was variable. Five of the studies were performed on human cadaverous skulls, the other four studies were case reports ranging from 1 to 25 subjects. The evidence supports the theory that adult cranium may not always solidly fuse, and that minute movements between cranial bones are possible. However, one case report did not demonstrate that movement at cranial sutures can be achieved manually. c. Existence of cerebrospinal fluid movement. These studies were carried out to provide neurosurgeons with data on the pathophysiology mechanisms pertaining to CSF motion for diagnosis, treatment and monitoring of brain injury and other neurological disorders. The research quality was variable. Study designs were generally observational or case studies. The studies show that CSF movement and pulsation are phenomena measurable by encephalogram, myelogram, magnetic resonance imagining and intracranial and intraspinal pressure monitoring, thus meeting a number of Hill's criteria for establishing causation. The evidence supports the contention that there is a cranial 'pulse' or rhythm distinct from cardiac or respiratory activity. 2. Craniosacral assessment: The first two studies were undertaken in the late 1970s by an osteopath, the three more recent studies were undertaken by physical therapists. Four of the studies scored well in the validity assessment, meeting the following criteria: specified study purpose, blinded observations, competent observers, and procedural protocol. However, the studies were small and the subjects do not constitute a representative sample of patients who might be offered craniosacral therapy. One study reported, conducted in 1977, reported a high inter-rater reliability for some parameters comprising the assessment of craniosacral movement, however this study has a number of limitations, especially that all subjects had some degree of movement restrictions. The other studies did not confirm these findings. Intraclass correlation co-efficients ranged from -0.02 to 0.57. The trend of the more recent and better designed studies is that they
did not find assessment of craniosacral rhythm reliable. 3. Craniosacral treatment: All studies were of the lowest level of evidence (level III). One study used a retrospective case-control design, this study found no significant differences in obstetric interventions during labour and delivery in women who received craniosacral therapy in addition to standard care during pregnancy compared to those receiving standard care. One study used a before-after study design, this study used an inappropriate design considering the population studied and made invalid comparisons thus conclusions cannot be drawn from this study. Two studies used a retrospective case series design. One of these studies looked at patients with traumatic brain injury, three patients were found to have a very unfavourable response to therapy. The other study looked at patients with temporomandibular joint syndrome seen by the same osteopath during a nine year period. Health outcome measures were claimed to have improved but were not reported. Three studies presented case reports, all these studies found improvement with therapy.

Authors' conclusions
There is insufficient scientific evidence to recommend craniosacral therapy to patients, practitioners or third party payers for any clinical condition. The literature suggests that the adult cranium does not obliterate, fuse or ossify its sutures until well into late life. There is also some evidence that there is potential movement at these suture sites in earlier life. Questions remain as to whether such movement is detectable by human palpitation or whether mobility has any influence on health or disease. There is evidence for a craniosacral rhythm, impulse or primary respiration independent of other measurable body rhythms. However, these studies do not provide any valid evidence that such a craniosacral rhythm or pulse can be reliably perceived by an examiner. Craniosacral measurement has not been shown to be reliable.

CRD commentary
A good review of the area. A thorough literature search was conducted and it is unlikely that this search will have missed important studies. Inclusion criteria are clearly stated, an appropriate validity assessment was carried out and a narrative analysis was presented which, in view of the differences between studies, was appropriate. Individual study details are reported for most studies. However, for the treatment studies only case report details were tabulated, it would have been helpful to also tabulate the other studies. Although study details are reported for studies looking at cerebrospinal fluid motion and pathophysiological mechanisms of craniosacral dysfunction, only baseline details are presented, there were no individual study results which would have helped with the interpretation of the authors summaries of the results of these studies. The studies included in the review were all of very poor quality and thus it is difficult to draw any conclusions from the results of these studies. Although the review was good, its findings are limited by the quality of the included studies, and so the results of the review and the authors conclusions should be interpreted with extreme caution.

Implications of the review for practice and research
Rigorous and scientifically defensible studies are clearly possible on all aspects of craniosacral therapy. Such studies would be of great value in providing the necessary direction for administrators, practitioners and patients alike.

Bibliographic details

Original Paper URL
http://www.chspr.ubc.ca/node/373

Other publications of related interest

**Indexing Status**
Subject indexing assigned by CRD

**MeSH**
Cerebrospinal Fluid; Complementary Therapies; Cranial Sutures; Physical Therapy Modalities; Sacrum

**AccessionNumber**
11999009361

**Date bibliographic record published**
31/10/2000

**Date abstract record published**
31/10/2000

**Record Status**
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.