



## EDITORIAL

# The enigmatic case of cranial osteopathy: Evidence versus clinical practice



A recent report<sup>1</sup> on cranial osteopathy from the *Collectif de recherche transdisciplinaire esprit critique et sciences* (CORTECS), requested by the French Physiotherapy Council highlighted the current lack of scientific evidence to support the clinical use of cranial techniques and recommended that French physiotherapists avoid them. Professional bodies often request reviews, either systematic or narrative, to formulate guidelines or recommendations that orient clinical practice in an evidence-based environment. Further, health-care professionals should incorporate these recommendations into the clinical decision-making process to improve the outcomes of the care provided. Despite the role of these documents and the ethical attitudes of clinicians, care is required when reading, interpreting, and applying guidelines or recommendations. According to international scientific and public health authorities, third parties, such as national health bodies (e.g., National Institute of Health in Italy), who have no conflicts of interest and have excellent competencies, should provide guidelines and recommendations that respect the equity, validity, and specificity of the procedures applied. Following this model will increase the likelihood of producing documents that adhere to high scientific standards to improve healthcare systems in a person-centred environment. The CORTECS Report on cranial osteopathy was produced so recommendations could be applied by physiotherapists. However, all the studies included in the report involved osteopathic research that enrolled any physiotherapist operator and used any physiotherapy approach; therefore, the recommendations may cause

confusion about the clinical impact of the report for manual practitioners.

The results of the CORTECS Report are not new to the osteopathic scientific community. Rather, they seem to confirm findings proposed 10 years ago, which suggested removing materials related to osteopathy in the cranial field (OCF) from educational institutions and from clinical practice.<sup>2</sup> More recently, systematic reviews have evaluated the clinical benefits of OCF and found a paucity of clinical trials and a lack of sound methodology, making it difficult to draw definitive conclusions.<sup>3,4</sup> Despite this known lack of scientific evidence, OCF remains a popular technique for some practitioners for the treatment of specific groups of patients. In a recent survey of UK osteopaths,<sup>5</sup> patients seeking treatment from practitioners using OCF presented most frequently with problems relating to musculoskeletal pain or stiffness in the lumbar spine, head/facial, and cervical spine areas. Babies or infants and patients aged over 70 years were the 2 main groups of patients receiving OCF.<sup>5</sup> As such, these results seem to highlight the dichotomy between the scientific paucity of evidence and clinical use of OCF, and practitioners should be critical when considering OCF as clinically meaningful.

Single- and multi-centred randomised clinical trials (RCTs) have suggested that the use of OCF, alone or in combination with other techniques, may be safe and may eventually produce clinical results in different age groups. Recent studies<sup>6–11</sup> in neonatology have demonstrated the use of OCF and the safety of the approaches used for evaluation and treatment of newborn and preterm

infants. However, a recent study<sup>12</sup> on the effects of craniosacral therapy (CST) on the general movements of newborns (spontaneous movement patterns of babies at rest) showed no statistically significant effects. Two recent RCTs evaluated the effectiveness of CST on adults with chronic spinal pain.<sup>13,14</sup> Sixty-four patients with chronic low back pain received 10 sessions of CST and had greater pain reduction compared with a control group which received 10 sessions of classic massage ( $p < 0.008$ ), but there was no difference in disability between groups as measured with the Roland Morris Questionnaire.<sup>13</sup> In another study,<sup>14</sup> 54 patients with chronic neck pain received 8 sessions of CST and had significant and clinically relevant pain reduction at the end of treatment ( $p = 0.001$ ) and 3 months later ( $p = 0.003$ ) compared with a light-touch sham treatment group. As in previous reports, no serious adverse events were reported in these 2 RCTs.<sup>13,14</sup>

Despite the results from systematic reviews, should the little evidence available in favour of CST and OCF be considered when making clinical decisions? Evidence, by itself, cannot solely influence clinical decisions, but it can support the patient care process and enhance practice so optimal clinical outcomes and quality of life are achieved. However, in osteopathic practice, a strict adherence to evidence-based medicine (EBM) may be difficult due to lack of high-quality evidence. A better approach would be *evidence-informed practice*<sup>15</sup> or *evidence-informed osteopathy*.<sup>16,17</sup> Guiding principles behind evidence-informed practice are the use of research evidence when available and personal recommendations that are based on clinical experience, but practitioners retain transparency about the process used to reach their clinical decisions.<sup>15</sup> While this decision-making process is used and promoted by all professionals to improve the care of patients, this approach should also include some form of critical appraisal that may not always be available for clinicians. A challenge of this approach is the type of methodology used to build the evidence, especially when treatment deals with complex interventions, such as osteopathy, that were evaluated within a pharmacological paradigm in the past.<sup>18</sup> This limitation also applies to RCTs where, historically, crucial aspects of the methodology to evaluate the effectiveness of a pharmacological intervention cannot be applied to manual interventions. New tools such as the template for intervention description and replication (TIDieR)<sup>19</sup> have been recently introduced to specifically improve the design and reporting of clinical trials that evaluate manual therapy

interventions. Such tools may contribute to the establishment of research gold standards in this field. Further, this changing paradigm for evaluating manual treatments may not be reflected in current systematic reviews that professional bodies have used to formulate guidelines based on a biomedical model.

To improve the clinical decision-making process, Leboeuf-Yde et al.<sup>20</sup> proposed the "Traffic Light System" (green = go, yellow = go with care, red = stop), which is a simple approach to deal with the triad of evidence, plausibility, and clinical experience. The traffic light system consists of 3 questions to help clinicians deal with the complexities of clinical practice, particularly what to do when clear clinical evidence is lacking. Clinicians follow a simple algorithm based on the 3 following questions: (1) Are there objectively tested facts to support the concept? (2) Are the concepts that form the basis for this clinical act or decision based on scientifically acceptable concepts? and (3) Is the concept based on long-term and widely accepted experience? According to a yes or no answer for each question, the algorithm produces a result in terms of the green, yellow, or red recommendation. Using this model, a practitioner aware of the scientific literature for OCF would most likely associate its potential use with a red traffic light system. Only the last question may have a partially positive response in this scenario, but evidence-informed osteopathy, by definition, challenges all accepted experience to improve patient care. The first 2 questions would likely have negative responses and, thus, highlight the challenges related to OCF, which are lack of scientifically acceptable concepts and objectively tested facts to support them. This outcome also seems to be the case for the model proposed by Sutherland<sup>21</sup> in 1944: the proposed tenets for OCF and CST are untenable based on current knowledge of physiology.<sup>22</sup> Other critical appraisals of Sutherland's model have been proposed that are supported by current scientific evidence, such as the mechanical properties of cranial bones and sutures with muscle contraction are the main cause of skull deflection and may be amenable to palpation.<sup>23</sup>

In conclusion, because we value and encourage reports such as the one published by CORTECS and because we give credit to its conclusions regarding OCF, we would like to encourage authors to give readers, especially those clinicians who are unfamiliar with recent methodologies used to evaluate the effectiveness of manual treatments, access to tools that can evaluate the process that led to such conclusions. Since clinicians are now trained to use

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