

A CRITICAL APPRAISAL OF EVIDENCE AND ARGUMENTS USED BY AUSTRALIAN CHIROPRACTORS TO PROMOTE THERAPEUTIC INTERVENTIONS

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ABSTRACT

The Australian Health Practitioner Regulation Agency is currently dealing with over 600 complaints about chiropractors. Common allegations in these complaints are that chiropractic adjustments are promoted for pregnant women, infants and children despite the lack of good evidence to justify many of these interventions. The majority of chiropractors complained about appear to be caring practitioners who genuinely believe that the interventions they promote are effective. However, belief based on disproven dogma, the selective use of poor-quality evidence, and personal experience subject to bias is no longer an appropriate basis on which to promote and practice therapeutic interventions. Nor should treatments be justified solely on the basis of possible placebo effect. This paper provides a critical analysis of some of the evidence and arguments used by chiropractors to justify treatments that have been the subject of complaints. This analysis amplifies the recent statement on advertising by the Chiropractic Board of Australia. It should assist practitioners to understand the difference between the high-level evidence required by the Board and the low-level evidence used by some practitioners to justify their promotion and practice. It supports efforts by the Chiropractors' Association of Australia to encourage more research. (Chiropr J Australia 2016;44:234-245)

Key Indexing Terms: Chiropractic, Paediatrics; Evidence-Based Practice

INTRODUCTION

The Australian Health Practitioner Regulation Agency (AHPRA) is currently examining more than 600 complaints about Australian chiropractors (1). Common allegations in these complaints are that chiropractic adjustments are promoted for pregnant women, infants and children despite the lack of good evidence to justify many of these interventions.

Over the last 5 years, the Chiropractic Board of Australia has produced numerous communiques about the need for practitioners to be aware of the provisions in the Health Practitioner National Law concerning advertising (2). These provisions include prohibiting advertising that is false, misleading or deceptive, that use testimonials, create an unreasonable expectation of beneficial treatment and encourage the indiscriminate or unnecessary use of health services.

In addition, the Board's *Code of Conduct* includes the need to provide treatment/care options based on the best available information, practising in an evidence-based context, making sure that any information published about services is factual and verifiable, and not being influenced by financial gain or incentives (3).

On March 7, 2016 the Board released a much more detailed statement on advertising, particularly concerning claims relating to infants and children (4). More recently, the Board has imposed conditions on the practice of 1 practitioner who produced a video showing chiropractic adjustment being used on the spine of a 4-day old baby, allegedly for the management of colic and reflux. This practitioner is now prohibited from undertaking spinal manipulative therapy on children up to the age of 6 years and requires supervision for any chiropractic treatment of patients between the ages of 2 to 18 years (5).

The majority of chiropractors cited appear to be caring practitioners who genuinely believe that the interventions they promote are effective. However, they appear to have difficulties in understanding the difference between various levels of evidence (6). Accordingly, this paper provides a critical analysis of some of the evidence and arguments used by chiropractors to justify treatments that have been the subject of complaints. I hope that this analysis will amplify the recent statement on advertising by the Chiropractic Board of Australia and assist practitioners to understand the difference between the high-level evidence required by the Board and the lower-level evidence used by some practitioners to justify their promotion and practice.

The Evidence Used by Chiropractors Who Have Been the Subject of Complaints

1. Practitioner experience

“As a chiropractor who has provided care to thousands of children over the last thirty plus years I can categorically say that children under my care have experienced amazing changes with conditions such as colic, reflux, recurrent ear infections, bed-wetting, headaches, migraines, constipation, plagiocephaly, vestibular system issues, learning difficulties, ADHD, to mention just a few. All chiropractors who see children in practice will experience this. Children respond amazingly to chiropractic care. Fact!”

There are a number of reasons why practitioners and patients report that a treatment is effective when it is not. These include the placebo effect (patient's expectation regarding an intervention), the natural history of disease (symptoms may wax and wane), regression to the mean, confirmation bias (seeing what you expect to see), cognitive dissonance (ignoring results not in accord with expectations) and endorsement by charismatic gurus who speak well at conferences, run seminars and promote their own unique technique.

In short, personal experience is easy, convincing and often wrong, while blinded, placebo-controlled clinical trials are laborious, complex and costly. However, the latter are crucial as they often show that initially promising results from observational studies are not replicated by well-conducted placebo-controlled trials. The plural of anecdote is not evidence!

2. Millions of people can't be wrong

“The only reason chiropractic has survived as a profession with all of the well-organised and well-funded attacks against us is due to one simple but very important fact; chiropractic works. Tens of thousands of babies and children

all over the world every week visit chiropractors because of this one simple fact”.

Unfortunately, popularity is not a reliable indicator for effectiveness. The history of medicine is littered with examples that demonstrate how misleading this fallacy can be. Bloodletting was believed to be effective, was widely practised for at least 3000 years and was highly popular, yet it certainly killed more patients than it ever helped. A recent book by Ian Harris, “Surgery, the ultimate placebo” provides many more examples (7). It reiterates the importance of submitting treatments thought to be effective to the discipline of randomised placebo-controlled clinical trials.

3. *We don’t treat, we simply remove blockages between the brain and the body*

“What I do as a chiropractor, what any chiropractor does, is really very simple. We don’t treat colic or reflux, we don’t treat breast-feeding dysfunction, we don’t treat constipation, we simply remove potential neural irritations or blockages between the brain and the body using gentle spinal adjustments so that the body can function the way it is designed to without interference.”

The clear implication is that removing “potential neural irritations or blockages between the brain and the body” produces the “amazing changes” cited for the numerous conditions mentioned above. The inevitable conclusion drawn by the public is that chiropractic adjustment cures or relieves these conditions. The AHPRA June 2016 newsletter is relevant (1),

“Our staff look at each advertising complaint on a case-by-case basis, and consider the overall impression of the advertisement as well as the likely impact the advertisement may have on a member of the public. They will consider what conclusions a member of the public can reasonably infer from material contained within an advertisement and whether the material is likely to mislead or deceive or breach other parts of the National Law.”

The suggestion that spinal adjustment removes potential neural irritations or blockages between the brain and the body, allows the body to function the way it is designed to, and thus cures or relieves various non-musculoskeletal conditions invokes the discredited chiropractic vitalistic dogma of subluxation. In 2005 in an article titled, “Subluxation: dogma or science?” Keating JC, et al, said (8),

“The dogma of subluxation is perhaps the greatest single barrier to professional development for chiropractors. It skews the practice of the art in directions that bring ridicule from the scientific community and uncertainty among the public. Failure to challenge subluxation dogma perpetuates a marketing tradition that inevitably prompts charges of quackery. Subluxation dogma leads to legal and political strategies that may amount to a house of cards and warp the profession's sense of self and of mission. Commitment to this dogma undermines the

motivation for scientific investigation of subluxation as hypothesis, and so perpetuates the cycle."

In May 2010 the General Chiropractic Council, the statutory regulatory body for chiropractors in the United Kingdom, issued guidance for chiropractors stating that the chiropractic vertebral subluxation complex "is an historical concept" and "is not supported by any clinical research evidence that would allow claims to be made that it is the cause of disease" (9). Chiropractic Australia (an alternative professional organisation to the Chiropractors' Association of Australia) have endorsed this statement by the General Chiropractic Council (10).

4. Selective use of low-level studies

a) Colic

"I experience a similar success rate in practice with my colicky patients to those results achieved in this research study carried out by a medical practitioner and two chiropractors published way back in 1989. Three hundred and sixteen cases of colic were adjusted over a period of two weeks with a 94% success rate. That's right; over nine out of every ten infants in this study had their colic resolved".

This study was by Klougart N, et al (11). It is an old, uncontrolled study. There was no placebo control group and no patient blinding. Of the infants who improved, there is no way of knowing whether this was due to the chiropractic intervention, or whether they improved because the infants grew out of it; the normal course for colic.

The authors of this study were aware of methodological problems with the study and regarded it as inconclusive. The conclusion section states:

"Because of the study design of this study a number of questions have not been sufficiently answered. Further studies must be designed in such a way that the number of sources of noise (bias) affecting the interpretation of the results is reduced so that the placebo effect can be more accurately estimated."

A 2010 review by Bronfort G *et al* titled, "Effectiveness of manual therapies: the UK evidence report" (authored by chiropractors) concluded that spinal manipulation is not effective for infantile colic (12).

Some chiropractors cite a 2011 review conducted by 3 chiropractors (13). The authors commented,

"Our findings reveal that chiropractic care is a viable alternative to the care of infantile colic and congruent with evidence-based practice, particularly when one considers that medical care options are no better than a placebo or have associated adverse events".

This conclusion appears to be based on the many uncontrolled case reports reviewed, not the systematic reviews. Of the latter mentioned, Hawk et al. concluded that there was insufficient evidence to make conclusions regarding

the evidence on the chiropractic care of infants with colic while Ernst concluded that the evidence for chiropractic for colic was not based on rigorous clinical trials and therefore failed to demonstrate effectiveness.

Subsequently, a 2012 Cochrane review by Dobson *et al* (14) concluded there was no evidence that manipulative therapies improved infant colic when they only included studies where the parents did not know if their child had received the treatment or not.

A 2014 update of the Bronfort report by Clar (also authored by chiropractors) changed the previous negative conclusion for spinal manipulation in treating infantile colic to “Inconclusive (favourable) evidence”. (15). This was based on a study by Miller (16). There were 2 treatment arms in this study: individualized chiropractic manual therapy of the spine where dysfunction was noted on palpation (with parents blinded or unblinded), and a control arm (where infants were not touched). Comparison of treatment with no treatment showed statistically significant differences in mean change in crying time from baseline at days 8 and 9 in favour of treatment (but not on days 3, 4, 5, 6, 7 or 10). When comparing the effects of parents blinded and not blinded to treatment, there were no significant differences in the reduction in crying, indicating that blinding the parent had no biasing effect on the report of infant crying behaviour. The authors noted “Although these results were statistically significant, the wide confidence intervals reflecting the variability in the data and small sample sizes indicate the need for caution and the difficulty in precisely estimating any treatment effect in the target population.”

Finally, the Chiropractic Board of Australia specifically included infantile colic as a claim that was not supported by satisfactory evidence in its March 7, 2016 “Statement on advertising” (4).

b) Traumatic birth syndrome

“Traumatic Birth Syndrome, whether it causes symptoms immediately or just diminishes human potential over the course of a lifetime, is a condition which should be addressed immediately after birth”.

“Although very well meaning, medical doctors get no training in the detection and correction of vertebral subluxation complex and will almost certainly miss the very subtle indications of potential spinal problems”.

“Dr. G. Gutmann, a German medical researcher discovered that over 80% of the infants he examined shortly after birth were suffering from injury to the cervical spine (the neck), causing all types of health problems. Of particular importance may be unresolved compression in the suboccipital region, (the base of the skull/top of the neck). Motion restrictions and asymmetries in this region are categorised as kinematic imbalances caused by suboccipital strain, otherwise known as KiSS syndrome. This is a well-documented condition throughout the medical literature. Medical researcher Dr Heiner Biedermann refers to this condition extensively in his book, ‘Manual Therapy in Children’. So it is a very real issue for newborn babies. Our recommendation, and this is

supported by best evidence, is that all children should be examined by a chiropractor immediately after birth”.

Similar claims state, *“Even a smooth [normal] birth can be very traumatic on the baby’s neck”* and *“chiropractic care can help with a wide range of infant health concerns, from colic to being tongue-tied and everything else in between”.*

Once again, these claims invoke the discredited chiropractic dogma of subluxation.¹⁰

A search of PubMed (17) for “Gutmann G [auth] birth injury” found no entries. The “KiSS Syndrome” is a creation of Dr Heiner Bierdermann (18) and its existence is contested, for example, Brand (19) and Happle C (20). I quote,

“In 1991, Biedermann coined the term "kinetic imbalance due to suboccipital strain" ("KiSS-syndrome"). He assumed a functional abnormality of the suboccipital-high cervical spine, resulting in positional preference of the infant’s head. A broad spectrum of symptoms and complaints have been attributed to "KiSS-Syndrome". Patients are advised to undergo manual therapy, with pressure applied locally in order to readjust the cervical spine. Life threatening side-effects have been published repeatedly. We present two infants with brain tumours who developed torticollis and further neurological findings such as ataxia and reflex differences. In both cases, symptoms caused by the tumour were interpreted as "KiSS-syndrome", and appropriate diagnostics and therapy were delayed for months. There is no scientific evidence for the actual existence of "KiSS-syndrome" as a clinical entity or for the positive effects of manual therapy. Approximately 12% of all infants <12 months show a positional preference of the head, about 8% present with body asymmetry. Whereas most cases are benign, there is a long list of serious differential diagnoses for torticollis in infants. We give an updated review of the literature regarding "KiSS-Syndrome" and discuss the differential diagnostics in infants with torticollis”.

In short, the totality of the literature casts doubts on the existence of a Traumatic Birth or KiSS syndrome and fails to provide good evidence to substantiate the claims that all children should be examined by a chiropractor immediately after birth.

c) Pregnancy

“Should I have chiropractic care in pregnancy? The answer is unequivocally ... absolutely! An article “Chiropractic and Pregnancy” published in 1990 by Dr Joan Fallon commented that chiropractic care in pregnancy has been shown to significantly reduce the time a woman labours. First time mums averaged a 24% shorter labour time, while mothers who have already given birth experienced a 39% reduction in the average length of their labour”.

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Other claims made for the benefits of chiropractic adjustments in pregnancy include, *“Preventing a potential caesarean delivery”* and a *“50% decrease in the need for painkillers during delivery”*.

The claim that chiropractic care reduces the duration of labour is repeated on a number of chiropractic web sites, some of whom cite 2 references to Fallon (21,22).

Neither of these references could be found on-line but the first was obtained from an inter-library loan from RMIT. I quote,

“Statistics from the author's case files were tabulated and a comparison of average labor time made. Twenty-seven primagravida and 31 multiparous women were compared as to their mean duration of labor. We can see by these statistics what with all else being equal, the mean labor times were reduced by 25 percent in the primagravida women, and by 31 percent in the multiparous women”. This in no way represents a controlled study...”

The second reference was obtained from Macquarie University. I quote:

“Sixty-five (65) women were used as subjects, all of whom received chiropractic care from at least the 10th week of pregnancy through labor and delivery. Their mean labor times were recorded and compared to the mean labor times as statistically averaged by at least 4 sources, as well as compared to those of a local midwife/obstetrician practice. The national averages for labor time are primigravidae 16 hours, multiparous 10 hours, with the midwife/obstetrician group primigravidae 9 hours and multiparous 8.5 hours. With chiropractic care primigravidae 9 hours and multiparous 5.5 hours. These statistics represent a decrease of approximately 24% in the primigravidae and 39% in the multiparous over the national average for labor time”.

Both these references are old, poorly controlled and unreplicated case series reported by the same chiropractic author. They do not justify their widespread citation by chiropractors as to the benefits of chiropractic in reducing the time of labour

The common claim that chiropractic adjustments during the pregnancy produced a 50% decrease in the need for painkillers during delivery was attributed (on some other chiropractic web sites) to Frietag P (23).

This old reference could also not be found by my University librarian. It can only be assumed that this statement is the personal opinion of author; if it was based on legitimate studies the latter should have been published in the public domain. No other reference substantiating this claim could be found.

5. Testimonials

“Something we frequently hear in our office often involves a patient or perhaps the parent of a patient relating the seemingly amazing changes to their health

since beginning care. This may be a change in sleep patterns, digestive processes, immune system or emotional balance.”

“When I first came to the clinic many years ago I was a sceptic. But the crew at X chiro clinic changed my life for ever...”

“Dr Y is awesome and is fantastic with my two-year-old. He is highly knowledgeable in his profession. My boys always come out happy. I’d highly recommend going to see Y”.

Numerous testimonials have been complained about on chiropractic web sites and Facebook pages because s.133 of the National Law prohibits their use. Anecdotes are unacceptable low-level evidence, published testimonials are not necessarily representative of all patient’s experience and occasionally they are fabricated.

In summary, the scientific literature used to justify these chiropractic claims are often low-level testimonials, case reports, “expert” opinion, uncontrolled observational studies, or cherry-picked studies that do not reflect the totality of the literature. The Chiropractic Board of Australia has been very clear that high-level evidence is required substantiate advertising claims. These includes meta-analyses, systematic reviews and high-quality, replicated randomised controlled trials.

“But What’s Wrong with Using the Placebo Effect”?

It has been argued that, even if the benefit of an intervention is only due to a placebo effect, who cares, the patient still feels better. A study by Wechsler (24) is relevant. These authors compared asthma patients receiving “placebo acupuncture” with those receiving a real salbutamol inhaler. They found that the placebo effect from the sham acupuncture could make patients feel they were less short of breath, even though pulmonary function tests revealed that their lung function had not improved. This finding shows how dangerous it could be to rely on placebo effects to treat asthma as it could lull the patient into a false sense of security of not feeling short of breath when, from a physiologic standpoint, they could be at serious respiratory risk. In addition, suggesting a treatment solely on the basis of possible placebo effects (and charging a patient for it) raises an important issue of informed consent.

CONCLUSION

I reiterate that the majority of chiropractors who have been cited appear to be caring practitioners who genuinely believe that the interventions they promote and practice are effective. However, belief based on disproven dogma, the selective use of poor-quality evidence, and personal experience subject to bias, is no longer an appropriate basis on which to promote and practice therapeutic interventions. Nor should treatments be justified solely on the basis of their placebo effect. These problems are not unique to chiropractors. These are also found in complaints submitted to AHPRA about other health professions, including medical practitioners (25) and in numerous complaints submitted to the Therapeutic Goods Advertising Complaint Resolution Panel. The latter body publishes the determinations it makes about individual complaints which provides a valuable education resource (26). Regrettably, AHPRA and the National Boards do not. I hope that this analysis of

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some of the common problems in the use of evidence will amplify the Chiropractic Board's "Statement on Advertising", assist all health practitioners to critically review their promotion and practice, and encourage more research.

DISCLOSURE OF INTERESTS

Dr Ken Harvey was a member of the expert group that drafted the World Health Organization's "Ethical Criteria for Medicinal Drug Promotion". His interest in ethical promotion led to involvement in a number of Australian government reviews on the regulation of therapeutic goods promotion and complementary medicines. He currently represents consumer interests (as a nominee of the Australian Consumers' Association) on the Therapeutic Goods Advertising Complaint Resolution Panel and the Therapeutic Goods Advertising Code Council. He is also an Executive member of Friends of Science in Medicine.

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