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Respiratory RCTs: What Are We Missing?

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Narrative: To date the RCTs reporting the response to Chiropractic care by patients with asthma, COPD and related pulmonary disorders have omitted real-world factors which in turn produces biased results.

Based on my own considerable experience with such patients I recommend that RCTs now (i) record the detail of any injury about the time of asthma onset, (ii) allow for a reasonable period of continuing care and measurements, for example for more than one year, to enable investigators to better account for the influence of seasonal changes, such as pollen count, temperature and humidity, among other factors, and (iii) recognise the complex neurology associated with such conditions and take a more holistic, full-spine approach instead of just a short period of care with an unacceptably low number of care visits.

Indexing terms: Chiropractic; chiropractic RCT; asthma; COPD; respiratory disorders

Introduction

Many chiropractic practitioners have cared for patients with asthma or chronic obstructive pulmonary disease (COPD). It is not unusual to witness significant improvement in respiratory function and general wellness during chiropractic care. Yet, when formal experiments such as randomised controlled trials (RCTs) are conducted, the results are often ambiguous if not downright disappointing.

> *'... the are three recommendations to improve the design of RCTs examining the response to Chiropractic care with pulmonary issues; add trauma history, provide ample care, and take a more holistic view ...'*

When taking care of an individual patient, it is of course possible to be misled by a myriad of factors. Perhaps the patient was misdiagnosed with respiratory disease to begin with. The practitioner's outcome measures may have been inaccurate. Patient-centred outcomes may have been confounded by the placebo effect or the Hawthorne effect or the Pygmalion effect, and so on. The RCT can be effective in filtering out such hopeful but misleading informational noise.

However, no clinician competently assessing and successfully managing an asthma or COPD patient can accept that the above confounders are always (or even usually) the explanation for their results. Clearly, some practitioners encounter asthma and COPD patients who experience real, sometimes profound, respiratory benefit from the Chiropractic Adjustment. Perhaps the RCT is not only filtering out informational noise. Perhaps the RCT can also filter out real information that is accurate and valuable. Both the clinicians and the patients they serve deserve access to this information.

Aren't there ways to plan RCTs in such a way that the influence of the chiropractic adjustment on respiration does not get dismissed as a statistically insignificant artefact? Is there not a way to craft the RCT in such a way that successful cases are not submerged in a fog of mathematical obscurity?

In this paper, I will point to some factors that controlled experimental research in this area may have been missing. Introducing those factors into RCTs going forward may help clarify issues that are now ambiguous.

Asthma and trauma

A number of experimentalists have found Chiropractic care to be of no benefit to asthmatics. (Balon et al, 1998) This is very much at odds to what has emerged from case reports and case series.

The real world - 1

An 18-year-old man with a two-year history of medically diagnosed asthma presented for Chiropractic care at the clinic of a Chiropractic College (Killinger, 1995). This patient's first attack occurred shortly after a sports injury. At the beginning of Chiropractic care, he was experiencing daily attacks that left him exhausted. The results of medical intervention were disappointing. Adjustments to correct upper cervical subluxations were administered three times over a period of four months. The patient was then monitored by correspondence and annual visits to the chiropractic college clinic over a five-year period.

Asthma attacks dropped sharply in frequency and severity during this period. Eosinophil counts were elevated at presentation and reverted to normal levels during Chiropractic care. By the second year of the study, attacks were strictly nocturnal and relatively rare, with intervals of several months sometimes separating them. Concurrent improvement in subluxation related outcomes including palpation, paraspinal temperature readings, and x-ray findings were reported.

The real world - 2

An instructive case report involving paediatric asthma was presented at a paediatric conference (Bachman and Lantz, 1991). After three Chiropractic adjustments delivered to T3, T12, and the sacrum a 34-month-old patient experienced eight weeks of freedom from symptoms. During the previous year, the patient had weekly asthma attacks, 20 of which were severe enough to require visits to the hospital emergency department. An exacerbation at the end of this eight-week period of relief followed a fall from a step ladder. This time, the asthma symptoms were accompanied by nocturnal enuresis. Both sets of symptoms resolved after three adjustments to the previously mentioned levels. After a full year of freedom from symptoms, the boy fell from a horse and experienced a return of asthma and enuresis. This time, a single adjustment resolved the exacerbation. At two years of follow-up, no recurrence was reported.

Real world - 3

Peet presented the case of an eight-year-old girl medically diagnosed with asthma three years before initiation of chiropractic care (Peet, 1997). Interestingly, this patient exhibited no evidence of respiratory disease until she suffered a traumatic injury. This injury was severe enough to cause dislocation of the left elbow. An inhaler was used by this patient one to three times per day prior to chiropractic care.

Chiropractic analysis included postural assessment and x-ray examination. Cervical and thoracic subluxations were identified, with the signs clustering at the upper cervical area. After eight adjustments during a period of less than three weeks, the mother stated that the child had not used her inhaler for two days, her wheezing had ceased, and she could run without gasping. Postural reassessment indicated substantial improvement. Follow-up x-ray at the eleventh visit

verified these improvements in subluxation signs. At the time of publication, the patient was reported to have been free of asthmatic attacks for four months without medication.

What does this mean?

What the above three papers have in common is physical trauma as a provocative factor in asthma. This connection has also been observed by non-chiropractic investigators. For example, a recent study of 6,372 asthmatics found a history of falls to be a statistically significant risk factor. (Chung et al, 2018) Of the 788 patients who required emergency medical treatment for an asthma attack in the previous year, 32.7% reported a history of trauma due to at least one fall.

Caring for victims of such traumata as motor vehicle accidents, sports injuries, work-related injuries, and slip-and-fall incidents is part of a chiropractor's normal day at the office. Such traumatic events commonly generate the subluxations that Chiropractic adjustments are designed to correct. Given the widespread innervation of the respiratory musculature, it would not be surprising to find that pre-existing respiratory illnesses can be exacerbated by such accidents.

Suggestion one for RCT Design

Include trauma history in the data set when conducting clinical trials of asthma patients under Chiropractic care. Included in this data should be any history of asthma exacerbation following trauma. In addition to analysing the data for the subject population, analyse the subpopulation of subjects with trauma history and subjects with history of exacerbation following trauma.

Chronic Obstructive Pulmonary Disease and time

The situation with COPD is similar to that with asthma. For example, one clinical trial found no benefit from chiropractic care. (Engel et al, 2023) On the other hand, a similar study (by many of the same investigators) involving patients with severe COPD found robust improvement in forced vital capacity. (Engel et al, 2016)

A systematic review of the literature on the use of spinal manipulative therapy in COPD management was reported in 2015. (Wearing et al, 2015) These authors considered randomised controlled clinical trials to be the highest form of evidence, with case reports and case series vulnerable to risk of bias. They also noted the randomised controlled clinical trials in the area of Chiropractic care for COPD were limited by small sample sizes. Evidence for spinal manipulation was found to be somewhat promising but ambiguous, prompting the authors to urge further research.

In the experimental studies, Chiropractic care is usually limited to as little as four weeks, with observation frequently continuing for some time after Chiropractic care has been completed. It must be remembered that the pathological changes in the pulmonary viscera and the musculoskeletal adaptations to those visceral changes usually develop gradually. It may not be reasonable to expect a month of correction to set in motion the interruption of the relatively glacial progress of this stubborn pathological process.

In this regard, it is instructive to consider a case report of a COPD patient under more than a year of Chiropractic care (Masarsky and Weber, 1988). After a two-week baseline period, diversified Chiropractic Adjustments were administered, usually including the upper cervical and upper thoracic regions. The precise levels adjusted varied from visit to visit according to palpation and Applied Kinesiology challenge findings. The frequency of visits was three times weekly for more than 14 months. Motorised intersegmental traction, vitamin C supplementation, cranial adjusting, and neurolymphatic reflex stimulation for the lungs and diaphragm were also included in the Chiropractic regimen.

Outcome measures included forced vital capacity (FVC), forced expiratory volume in one second (FEV-1), a ten-point severity scale with 10 being the most extreme for coughing, dyspnea and fatigue, and a daily count of laryngospasms. Up to three laryngospasms per week had been the norm for this patient for 17 years prior to Chiropractic care.

Mean scores during the last seven months of this study were compared with the mean baseline scores. FVC increased by more than 1 litre, and FEV-1 scores increased by more than 0.3 litres. Coughing intensity, dyspnea, and fatigue all decreased sharply. The patient reported no laryngospasm during the final five months of the study.

An important aspect of this case is the lack of any significant change during the first seven weeks of the Chiropractic care. In fact, we were very much tempted to terminate the study at that point. We were dissuaded from this course by the patient's report of a dream he had the night before a visit. He dreamed that he took the spirometer in hand and '*blew it right off the meter*'. He did indeed demonstrate a robust improvement in FVC and FEV-1 at that visit compared to previous measurements. It seems plausible that measurable improvement in COPD under Chiropractic care often takes more time and more visits than previous RCTs generally allow.

Suggestion two for RCT Design

Consider incorporating 20 or more Chiropractic adjustments or more over a period of eight weeks or more in future RCTs. In fact, continuing care and measurements for more than one year would enable investigators to better account for the influence of seasonal changes, such as pollen count, temperature and humidity, among other factors. It should be noted that the natural history of COPD tends towards steady exacerbation, rather than the ups and downs of '*good days'* and '*bad days*' experienced by many asthma sufferers. Furthermore, lung capacities tend to decline with age with or without pulmonary disease.

Therefore, any improvement during a long trial of Chiropractic care is significant for such a patient. In fact, simply preventing the patient from worsening over time is worthy of note.

A constellation of innervation

The muscles of respiration are not controlled by a simple scheme of innervation. The nerve supply ranges all the way from Cranial Nerves such as the *Accessory* (innervation to the sternocleidomastoid muscle) to the lumbar spinal nerves (innervation to the *quadratus lumborum* and inferior portions of the abdominals). Restricting chiropractic care to a limited portion of the vertebral column seems to miss this point. For example, in several of the RCTs studying COPD, the Chiropractic procedures were sometimes restricted to a mobilisation of the thoracic area to ameliorate rib cage stiffness.

Suggestion three for RCT design

Acknowledge the constellation of innervation that the respiratory system employs. By avoiding a reductionistic restriction to one or another spinal region and adopting an attitude of neurological holism, a more realistic perception of the role of the chiropractic adjustment may emerge.

Conclusion

The clinician and the experimentalist do not occupy different realities. They both study the same natural world. The experimentalist can help save the clinician from generalising individual encounters, mistaking the tree for the forest as it were.

The clinician can help save the experimentalist from a blurred perception of the tree, cautioning the scientist against ignoring the insights of the individual clinical encounter. Moving

beyond both nearsighted and farsighted perception of reality seems possible by crafting a long-overdue set of intellectual bifocals.

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Dr Masarsky writes a frequent feature in the *Journal* called '*The Wide Angle Lens*' in which he takes a broader than usual perspective on one issue or another, and has contributed much on clinical aspects of COVID.

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