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EPISTULALETTER

Respiratory RCTs: What Are We Missing?

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Original abstract: 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.

Received

Dear Editor:

We read with interest the paper titled '*Respiratory RCTs: What are we Missing*?' in a recent volume of the Asia-Pacific Chiropractic Journal. (Masarsky, 2025)

In that paper, Masarsky outlines some valuable points about the limitations of randomised controlled trials, in particular, their experimental nature, ability to control variables that may unintentionally influence results and low generalisability to real-world populations.

The 1988 case study (Masarsky and Weber, 1988) of a COPD patient clearly shows that Masarsky has been managing patients with chronic respiratory conditions for a considerable time. Our foray into the field of COPD has been more recent. We have been treating patients with COPD since 2005. The main difference between our work and that of Masarsky is the scale. While Masarsky has conducted cohort studies of up to 16 participants on non-respiratory patients (Masarsky and Todres-Masarsky, 2011), his only report on patients with respiratory disease appears to be his 1988 case study on a patient with long-term COPD (Masarsky and Weber, 1988). Meanwhile, we have reported the results of a series of RCTs involving cohorts of 15 (Engel et al, 2013), 33 (Engel et al 2016) and 71 (Engel et al, 2024) participants across various stages of COPD.

With respect to the strengths and weaknesses of the two designs, RCTs have high internal validity, unbiased distribution of confounders and can evaluate the efficacy of an intervention but may not represent true performance of any one participant (Lobo et al, 2017). As compared to an RCT, a

single case study has questionable internal validity, poor generalisability but clearly reflects the effect on the participant.

Given Masarsky's conclusion, that '*the experimentalist can help save the clinician from generalising individual encounters, mistaking the tree for the forest* ...' and '*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*', it would appear that Masarsky has sided with the clinician in formulating his three suggestions for improving clinical research. While the suggestions are interesting, they would have carried more weight if supported by some evidence. Our considered thoughts on the suggestions by Masarsky are as follows.

1. Including trauma history for asthma patients.

   While the suggestion to include trauma history in the data of asthmatic patients undergoing symptom exacerbation may be novel, there is currently no evidence linking trauma and asthma exacerbation. Rather than using an RCT design to test this hypothesis, interrogating readily available longitudinal data sets could provide valuable information on any potential link. (AIHW, 2009; Tan et al, 2023; TAHS, 2024)

2. Incorporate 20 or more Chiropractic adjustments over eight or more weeks for patients with COPD.

   This suggestion appears to be based on patients with more severe COPD and does not factor in patients with less severe forms of the disease. Our results show that patients with mild COPD do not respond to chiropractic intervention in the same manner as those with moderate or severe forms of the disease (Engel et al, 2016; 2024). Furthermore, resolving the question of dosage requires a graded approach where different regimes are tested for their efficacy over different time frames. For example, we reported improvements in lung function on 9 patients with moderate COPD at 24 weeks following 16 Chiropractic treatments over an 8-week period (Engel et al, 2016). What is the basis for Masarsky's suggestion of administering 20 or more Chiropractic adjustments over eight or more weeks?

3. Adopt a holistic rather than reductionist approach to administering chiropractic intervention.

   Masarsky's suggestion implies that researchers adopt a restricted perception of the role of the chiropractic adjustment. He makes this suggestion without offering any evidence to support it. Furthermore, when considered within the field of chronic respiratory disease, the view appears to rely heavily on the findings from a single case study.

Given the above, we argue that the three suggestions put forward are based on flawed assumptions and hence not tenable. This view is supported in part, by Masarsky's own comments where he acknowledges that '*the results of a pilot study must be approached with caution*'. (Masarsky, 2011)

Understanding levels of evidence (Sackett, 1989) and how they are incorporated into evidence-based practice is critical to the successful management of patients. Clinician researchers strive to blend clinical and research knowledge in trying to formulate the best course of action for their patients. However, not all researchers appear to be on the same page. Adopting Masarsky's metaphor on intellectual bifocals, maybe it is time for some researchers to have their vision re-checked.

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In reply:

I am of course pleased that my recent paper attracted the interest of Engel and Vemulpad. (Masarsky, 2025). I am also puzzled that this accomplished research team somewhat missed my point in several important respects. This response is intended to clarify.

Trauma and Asthma

Engel and Vemulpad state there '*is currently no evidence linking trauma and asthma exacerbation*'. Here I can only reiterate the instructive experiences discussed in Killinger, (1995) Bachman and Lantz, (1991) and Peet. (1997) In each of these case reports, physical trauma immediately preceded exacerbation of asthmatic manifestations, strongly suggesting a provocative role for trauma. Furthermore, at least one non-chiropractic research group found a history of slip-and-fall accidents to be a statistically significant risk factor in a study of 6,372 asthmatics. (Chung et al, 2018)

I applaud Engel and Vemulpad's suggestion regarding '*interrogating readily available longitudinal data sets*', and I think they may be just the people to undertake this task. However, this need not be a replacement for incorporating trauma history in RCTs. This does not have to be burdensome. Adding a few questions about history of slip-and-fall accidents, motor vehicle accidents, work and sports injuries, etc to an intake form would enable scientists to demonstrate the role of Chiropractic Adjustments in post-traumatic asthmatic exacerbation.

More Adjustments and more time in COPD Studies

Engel and Vemulpad ask '*What is the basis for Masarsky's suggestion of administering 20 or more chiropractic adjustments over eight or more weeks*'? These numbers were not intended to be precisely prescriptive. They were intended to illustrate the general idea that improvement in a chronic condition such as COPD can take more time and more intervention than is often provided in RCTs.

As I mentioned in my recent paper, we did not see significant change at all during the first seven weeks of our COPD case study. (Masarsky and Weber, 1988) We would have missed significant improvement in our patient if we abandoned the study prematurely. My suggestion was intended to help design RCTs in a way that could accurately capture the effect of chiropractic adjustments.

A constellation of innervation

Here I mentioned that several RCTs studying COPD restricted their intervention to a limited spinal area. For example, the Chiropractic intervention described in the papers by Engel and Vemulpad's team is a manoeuvre designed to relieve hypomobility at multiple thoracic levels simultaneously. (Engel et al 2013, 2016, 2023)

Of course, I understand the significance of ameliorating rib cage stiffness for COPD patients. I would add that relieving thoracic subluxation may be beneficial for the autonomic innervation of the bronchi and the somatic innervation of the intercostal muscles.

However, I must reiterate that innervation relevant to respiration ranges all the way from the cranial nerves to the lumbar spinal nerves. Consider a hypothetical COPD patient in whom control of the diaphragm is disturbed by a subluxation at the origin of the phrenic nerve at C3-5. Manipulation of the thoracic spine would be unlikely to correct this problem. Likewise with lumbar subluxation disturbing expiration due to its influence on the lower abdominal muscles.

In my practice, we have experienced improved respiration following adjustments anywhere from cranium to sacrum. (Masarsky and Weber, 1986; 1989; 1991) Recently, we have observed this improvement in a COVID-19 long hauler. (Masarsky and Todres-Masarsky, 2023) I believe limiting Chiropractic intervention to the thoracic spine when studying COPD is tantamount to studying the problem with tunnel vision.

To take into account the neurophysiological individuality of COPD patients, I suggested that adjustments not be restricted to one region, but to take a more holistic approach to Chiropractic intervention. At a minimum, I believe cervical, thoracic, lumbar and sacroiliac adjustments should be included in COPD RCTs. The criteria indicating the need for adjustment should of course be specified at the beginning of the study based on input by the treating researcher.

Conclusion

For some reason, Engel and Vemulpad seem to have concluded that I am 'siding' with clinicians against scientists. Dr Engel, Prof Vemulpad, I assure you that the idea of an intellectual jousting tournament was the furthest thing from my mind. The practicing clinician and the academic scientist have little to gain by acting like adversaries on opposing teams. We serve in different divisions of the same team. Learning as much as possible from each other is in the best interest of the patients under our profession's care.

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