The Role of the Autoimmune Protocol (AIP) Diet to Improve Health Related Quality of Life and Disease Activity in Autoimmune Disease: A Review of the Current Clinical Evidence

Robert D Abbott[1], Angela Alt, CHC, NTP[2], Mickey Trescott, NTP[3]

1. Resilient Roots: Functional and Evolutionary Medicine
Medical Director, Charlottesville, VA

2. Autoimmune Wellness
Co-Owner, McMinnville, OR

3. Autoimmune Wellness
Co-Owner, McMinnville, OR

Contact Information/Degrees/Credentials

Robert Abbott, MD
901 Preston Avenue
Suite 402/3
Charlottesville, VA 22901
(757) 320-9383
rda4zf@virginia.edu

Angela Alt, CHC, NTP
9264 Red Cart Court
Columbia, MD 21045
(503) 487-0044
angela-alt@hotmail.com

Mickey Trescott, NTP
2135 NE McDonald Lane Suite A
McMinnville, OR 97128
(503) 487-0044
mickeytrescott@gmail.com

Introduction:

Due to the emphasis for pharmaceutically based clinical research and the focus on epidemiologic, observational studies aimed at assessing dietary patterns in large populations, the scientific community has suffered tremendously with a paucity of well-designed, interventionally-directed clinical trials utilizing dietary and lifestyle therapies. With funds in most academic settings already limited to discrete areas of lifestyle medicine or observational research, it has been exceedingly difficult for clinicians to conduct meaningful dietary and lifestyle-based interventions on any scale. With the growing global burden of chronic disease, including conditions such

as autoimmune disease, cancer, cardiovascular disease and diabetes, coupled with the ever-growing cost of marginally effective pharmaceuticals, we are reaching a crisis point in chronic disease management, where we must begin to employ rigorous scientific inquiry into cost-effective and readily available dietary and lifestyle therapies (1). In this extended abstract, we provide a brief review of recent interventional research examining the role of the Autoimmune Protocol (AIP) diet to improve quality of life and disease activity in three autoimmune diseases. We will also propose, as evidenced by the nature of the most recent AIP interventional research study, practical solutions for clinician scientists and academic organizations to conduct more dietary and lifestyle research of an interventional nature.

The Role of Diet in Autoimmune Disease:

Outside of the removal of gluten in celiac disease, a pathology directly linked to an immune reaction to gluten and gluten-self immune complexes, there are inconsistent and often vague dietary and lifestyle recommendations provided to individuals affected by the over 80 recognized autoimmune diseases. To date, dietary and lifestyle-informed research has focused disproportionately on Inflammatory Bowel Disease (IBD), with most other autoimmune diseases lacking specific dietary guidelines or rigorous evidence for any particular dietary pattern (2). While there continues to be a charged debate concerning the inclusion and balance of animal versus plant products in a given individual's dietary pattern, research continues to demonstrate the deleterious health effects of a diet high in ultra-processed refined foods (3). Given the inherent complexity in trying to study the effects of a single food or nutrient as compared to wider nutritional patterns, clinicians will likely continue to face challenges in providing rigorous and evidence based nutritional recommendations to both health and diseased populations (4).

Recognizing that the simple prescription of a whole foods diet that minimizes refined foods is likely insufficient for all symptomatic individuals affected with mild to moderately severe autoimmune disease, Sarah Ballantyne, PhD outlined an extended set of dietary principles for those with autoimmune disease that took into consideration the nutrient density of specific whole foods, the likelihood of a food to be implicated in immune dysregulation, and the likelihood for a food to cause disruption to either the gut microbiota ecosystem or the mucosal gut barrier, and thus established a theoretical basis for the inclusion or exclusion of certain foods (5). This theoretically developed dietary approach, known as the Autoimmune Protocol (AIP) has gained significant anecdotal recognition in a wider clinical community as an effective nutrient-dense diet that is able to address quality of life and disease activity across a wide spectrum of autoimmune diseases.

In 2017, the first clinical trial involving AIP was conducted by Konijeti et. al.

where they studied the effectiveness of AIP alongside community based health coaching for 15 individuals with long-standing IBD (6). The researchers noted that 11/15 participants (5 with Ulcerative Colitis and 6 with Crohn's Disease) achieved clinical remission by week 6 of the study and maintained remission by study end at week 10. In addition, they noted decreases in the inflammatory marker fecal calprotectin and even noted changes to the gastrointestinal mucosa for a subset of patients as part of follow-up endoscopy or colonoscopy. While there were obvious limitations to the study given its small, single arm design, the subjective and objective changes were rather staggering and provided the first scientific evidence for the efficacy of the AIP diet for two common autoimmune diseases.

In 2018, we sought to expand on Konjeti's pilot study and examine the efficacy of a similar multidisciplinary diet and lifestyle intervention involving health coaching and the AIP diet for individuals with an autoimmune thyroid disease known as Hashimoto's Thyroiditis (7). We enrolled 17 non-obese women between the ages of 20-45 with a history of Hashimoto's Thyroiditis and no other active autoimmune disease. The 17 women participated in a 10-week online, community based health coaching program focused on implementing the AIP diet. The study's primary outcome was a change in quality of life as measured by the Short Form 36 Health Survey (SF-36), which measured multiple subdomains of quality of life. Secondary outcomes included changes in symptom burden, thyroid function including thyroid hormones and thyroid antibodies, a differential white blood cell count and the inflammatory marker high sensitivity C-reactive protein (hs-CRP). As a modification to the single arm study performed by Konijeti et. al., study participants also received personalized care and communication from the lead study physician at 3 time points during the 10-week study.

Following the 10-week program, we noted statistically and clinically significant changes in health related quality of life with changes in all 8 subdomains of the SF-36 survey. There was also a statistically and clinically significant decrease in symptom burden as measured by the Institute for Functional Medicine's Medical Symptoms Questionnaire. 6/13 women who began the study on some form of thyroid hormone replacement medication were able to decrease their medication by the end of the study. Statistically significant decreases in self-reported weight and BMI were also noted even though we did not instruct participants to count or restrict calories.

When examining changes in thyroid hormones and thyroid antibodies, there were no clinically or statistically significant changes. Given the small cohort size, a normal mean TSH at baseline, and the clinically low initial mean for anti-thyroid peroxidase (TPO) antibodies, it was going to be rather difficult to see any significant changes in thyroid hormones or thyroid antibodies during the relatively short study. Further longer term studies examining larger populations of individuals with Hashimoto's Thyroiditis and higher TPO

antibodies or higher thyroid stimulating hormone (TSH) levels may be more fruitful with regards to determining the impact of AIP on these lab markers. Additional unsuspected results from our study included a clinically and statistically significant decrease in hs-CRP and a clinically significant decrease in the white blood cell (WBC) count. These findings were particularly interesting and support further inquiry into the effect of AIP on various immune and inflammatory markers in Hashimoto's Thyroiditis.

Future Considerations:

While Konjeti et al.'s study in 2017 was institutionally funded by the Scripps Clinical Medical Group, our 2019 study had no such institutional funding. In order to raise the money necessary to conduct the study, we utilized internet-based crowdfunding and community engagement from interested citizens. In just under 3 weeks, over $10,000 was raised from over 100 contributing individuals from the larger citizen-scientist community. From the initial design of the 2019 intervention, through community crowdfunding, the study intervention itself and our final publication efforts, the entire study process lasted less than 1 year. This rapid, but rigorous approach to interventional dietary research that leverages the power of community engagement and crowdfunding appears to be a viable option for accelerating the implementation of further dietary and lifestyle informed research. Given the numerous limitations to conducting interventional research involving dietary and lifestyle elements as cited in the introduction of this article, our innovative crowdfunding model should be strongly considered by other independent researchers seeking to conduct similar research employing dietary and lifestyle interventions such as AIP.

Conclusions:

The scientific community is missing the valuable data that well-designed, interventionally-directed clinical trials utilizing dietary and lifestyle therapies could offer for addressing the growing crisis of chronic disease management and costly, but marginally effective pharmaceuticals. A main factor in this missing data is the lack of funding for conducting large-scale dietary and lifestyle-based interventions. In this extended abstract, we have provided a review of recent interventional research examining the role of one such dietary and lifestyle-based intervention, the Autoimmune Protocol (AIP) diet and demonstrated practical solutions in terms of funding for clinician scientists and academic organizations to conduct similar, future research.

References

1. Raghupathi W, Raghupathi V. An Empirical Study of Chronic Diseases in the United States: A Visual Analytics Approach. *Int J Environ Res Public Health*. 2018;15(3):431.

2. Knight-Sepulveda K, Kais S, Santaolalla R, Abreu MT. Diet and Inflammatory Bowel Disease. *Gastroenterol Hepatol (NY)*. 2015. 11(8):511–520.

3. Costa CS, Del-Ponte B, Assunção MCF, Santos IS. Consumption of ultra-processed foods and body fat during childhood and adolescence: a systematic review. *Public Health Nutr*. 2018;21(1):148-159.

4. Tapsell LC, Neale EP, Satija A, Hu FB. Foods, Nutrients, and Dietary Patterns: Interconnections and Implications for Dietary Guidelines. *Adv Nutr*. 2016;7(3):445-454.

5. Ballantyne S. The Paleo Approach: Reverse Autoimmune Disease and Heal Your Body. *Victory Belt Publishing.* Las Vegas, US. 2014.

6. Konijeti GG, Kim N, Lewis JD, et al. Efficacy of the autoimmune protocol diet for inflammatory bowel disease*. Inflamm Bowel Dis*. 2017. 23(11):2054–2060.

7. Abbott RD, Sadowski A, Alt AG. Efficacy of the Autoimmune Protocol Diet as Part of a Multi-disciplinary, Supported Lifestyle Intervention for Hashimoto's Thyroiditis. *Cureus*. 2019. 11(4).