ANECDOTAL AUTONOMIC MONITORING RESULTS PRE- AND POST-LIFE VESSEL™ APPLICATION IN LONG-TERM CHRONICALLY ILL PATIENTS

J. Colombo

The Life Vessel™, a novel relaxation device, was first described in a paper by Barry McNew and Valerie Donaldson that was presented at the Science of Whole Person Healing 2003, First Interdisciplinary International Conference, Bethesda, Maryland.

INTRODUCTION

The Life Vessel™ is a holistic, alternative medicine approach to health care. The Life Vessel™ (Cottonwood, AZ) employs a patented technique to non-invasively interact with a patient's autonomic nervous system (ANS). The technique is based on light and sound frequencies that have been found to adjust the ANS to restore a proper balance and improve patients' health. The Life Vessel™ has employed the ANSAR (Philadelphia, PA) autonomic monitoring technology to evaluate and document autonomic changes resulting from Life Vessel therapy.

ANSAR technology was selected based on the fact that it is the only commercially available, FDA certified, non-invasive, quantitative, independent, simultaneous measure of the two ANS branches the parasympathetic and the sympathetic nervous systems; PSNS and SNS, respectively. As The Life Vessel™ founders discovered, all other ANS measures, merely measured whether or not the patient's ANS was functioning. Physicians already know whether their patient's ANS is functioning. If the patient came into the office and was breathing, of course their ANS is functioning. The question for which The Life Vessel™ founders required answers was whether the PSNS or the SNS was functioning properly and, to a certain extent, more importantly, was there an appropriate balance between the two branches.

They understand the need for balance in life in general and how balance in the ANS is a reflection of the patient's whole life balance (disease, therapy, lifestyle, environment, and genetics). ANSAR is the only ANS monitoring technology that can provide them a true measure of ANS balance. ANSAR provides the measure as sympathovagal balance (SB) which is a ratio of the SNS measure (LFa, or the low frequency area) to the PSNS measure (RFA, or the respiratory frequency area) [Aysin, et al., IEEE EMBS, 2006; Aysin et al., IEEE BME, 2007].

This treatise provides data from seven patients tested pre- and post-Life Vessel application on the same day as The Life Vessel™ therapy. Five of the patients (3 female, ages 15 to 65 years, average of 40 years, 5'3", 149#) present, pre-Life Vessel therapy, with autonomic symptoms and signs of orthostatic hypotension (OH). One patient (male, age 15, height 5'10, weight 150#) presents with symptoms and signs of postural orthostatic tachycardia syndrome (POTS). One patient (male, age 46, height 5'10, weight 145#) presents at rest as normotensive, but as hypertensive to a stress response as modeled by a series of short Valsalva maneuvers, suggesting that their hypertension is not well managed. On average these patients' ANSs were normalized as a result of The Life Vessel™ therapy.

ORTHOSTATIC HYPOTENSION

The patients that presented with OH, had an average decrease in systolic BP of 16.4 mmHg (range: 14 to 19 mmHg drop in systolic BP, sBP, upon standing) prior to The Life Vessel™ therapy. The PSNS response to upright (stand) challenge was normal, but their sympathetic response was abnormal. The five OH patients presented with an average 1.64 bpm2 decrease (range: 0.49 to 3.78 bpm2 decrease) in (alpha-) SNS activity upon standing. Normally, an increase is expected to drive the vasoconstriction required to defeat orthostatic abnormalities and the dizziness and lightheadedness that can be associated. (see Table 1)

After The Life Vessel™ therapy, on the same day as the therapy, a second ANSAR was administered to these 5 patients. Their average sBP change upon standing was significantly different (corrected). On average the 5 patients presented with a 1.6 mmHg drop in sBP (range: +9 to -6, where a positive (+) change is normal). Overall not yet totally normal (only 3 of 5 patients normalized), but an average 14.8 mmHg correction in a positive direction, indicating that the patients were less dizzy upon standing. The concurrent average change in SNS activity was a (normalized) +0.49 bpm2 increase (range: -2.68 to +3.77, where a positive (+) change is normal) in sympathetic activity upon standing. (see Table 1)

Table 1: Summary of systolic BP and alpha-sympathetic changes with standing pre- and post-Life Vessel application on the same day.

Averages Over 5 Patients	Systolic BP Changes Upon Standing	Alpha-Sympathetic Changes Upon Standing

Pre-Life Vessel	-16.4 mmHg	-1.64 bpm2
Post-Life Vessel	-1.60 mmHg	+0.49 bpm2

A negative (-) indicates a decrease upon standing (abnormal). A positive (+) indicates an increase (normal).

The lag in sBP correction is expected. As it is known, the SNS drives the baroreceptor reflex, which drives BP changes. So SNS changes will occur first, followed by baroreceptor reflex changes, then followed by BP changes.

As an example from this cohort shows (Figure 1, a 45 y/o Male, 5’6”, 165#), the patient pre-Life Vessel (“Pre”) presents with: a normal looking HR plot (cardiogram for the 15.5 minutes of the ANASR study), 2) a normal looking breathing plot, but 3) a seemingly, mildly abnormal autonomic trends plot, more parasympathetic (blue) activity early in the test, during resting baseline, and no (red) sympathetic response to stand, just after the last vertical broken line. From the data table, the challenge responses are drawn against normal population data (the gray areas of the second row of graphs). The left most (resting) baseline response plot shows that the patient presents with normal autonomic levels, but a Vagal or parasympathetic dominance. His SB is too low (0.39, normal is 0.4 < SB < 3.0; for young adults the preferred range is 1.0 < SB < 3.0). His age adjusted parasympathetic response to deep breathing is low indicating autonomic dysfunction. His age adjusted sympathetic response to Valsalva is high which can be associated with (pre-) hypertension, pain, anxiety, etc. His sympathetic response to stand is abnormal indicating sympathetic withdrawal (SW) which can be associated with orthostasis. Since (from the table in the figure, his BP drops from 163/99 to 146/93 mmHg upon standing, his SW can be associated with pre-clinical, orthostatic hypotension. His parasympathetic response to stand is normal.

After The Life Vessel™ therapy, on the same day, his HR and Breathing plots still look normal. There is less (excess) parasympathetic (blue) activity in his trend plot. His resting BP is now 146/100 mmHg, a 17 mmHg drop in sBP. His autonomic activity at rest is still normal, and now so is his SB (0.93). His deep breathing response still shows autonomic dysfunction and his Valsalva response still shows excess sympathetic activity, associated with hypertension. His stand response plot has normalized and his drop in BP has reduced to only 7/5 mmHg. The patient is less dizzy upon standing.

ORTHOSTATIC HYPOTENSION

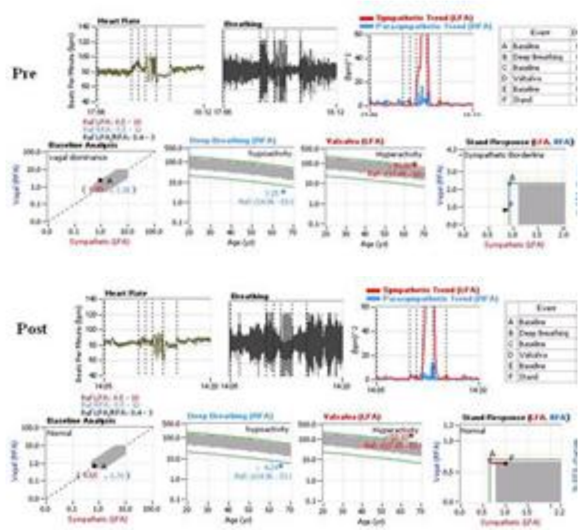


Figure 1: Orthostatic Hypotension (OH) example. A 45 y/o, Male, 5’6”, 165#.

POSTURAL ORTHOSTATIC TACHYCARDIA SYNDROME

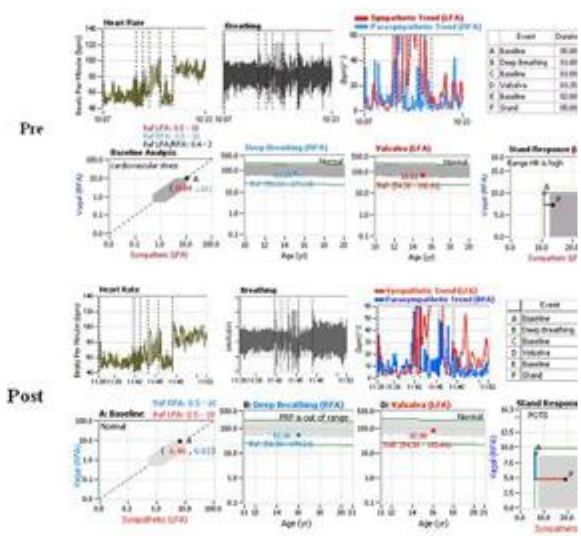
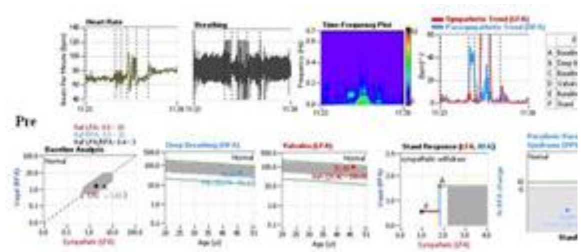


Figure 2: Postural Orthostatic Tachycardia Syndrome (POTS) example. A 15 y/o Male, 5’10”, 150#.

NORMOTENSIVE PATIENT WITH HYPERTENSIVE STRESS RESPONSE



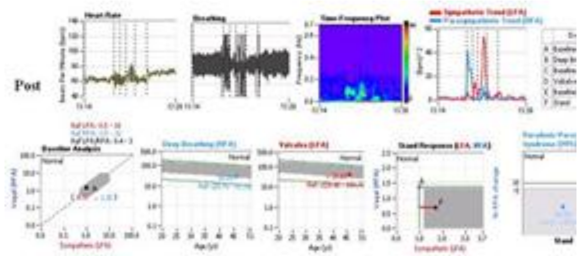


Figure 3: Resting normotensive patient example with hypertensive stress response. A 46 y/o Male, 5’10”, 145#.

POSTURAL ORTHOSTATIC TECHYCARDIA SYNDROME

Figure 2 presents an example of a POTS patient. During the pre-Life Vessel study the patient presented with elevated level of HR variability as evidenced in the HR plot and the Trends plot. This, in part, is due to the young age of the patient. Children and teenagers have elevated levels of HRV due to the higher parasympathetic activity associated with development. This elevated, young state typically transitions to the adult state between the ages of 18 and 21. The patient presents at rest with low HR, normal BP, high autonomic levels indicating cardiovascular stress and normal SB. His deep breathing and Valsalva responses are normal for his age. His average autonomic responses to stand are within normal limits, but his standing HRV is high, potentially inflating his autonomic results and masking the evidence for orthostasis. His standing BP response is weak and his standing HR response is borderline high. The elevated instantaneous autonomic activity after the gravitational response during standing (the last section of the Trends plot after the last vertical broken line) is further evidence that the autonomics are abnormal during stand. Normally, there should not be more activity after the gravitational response than before.

The lower half of Fig. 2, post-Life Vessel therapy on the same day, presents the patient’s responses to The Life Vessel™ therapy. Although his HRV is still elevated, due to his age, his autonomic levels are now normalized. His SB remains normal, and his HR and BP remain about the same. His deep breathing and Valsalva responses remain normal. His respiratory frequency (FRF) during deep breathing is high. This is associated with his reported symptoms of pulmonary stress due to mold infection. His average autonomic responses to stand remain normal, but his instantaneous responses are high, even during the gravitational response to standing. His standing BP response is stronger, but his HR response is still high. This patient is an example of how ANS therapy is often a function “peeling back layers” before getting to the core of the matter. As the patient progresses towards a more normal autonomic balance, at rest and during challenge activation, underlying processes are uncovered. Once they present, they can be treated more directly and further the recovery process. Ultimately, it is expected that this patient will normalize, be weaned of medication, and be enabled to carry forward with his re-trained ANS properly balanced and supporting him in all of his metabolic activities.

MASKED AUTONOMIC DYSFUNCTION

Figure 3 presents another common autonomic abnormality. This patient is thought to be a well managed hypertensive. From his pre-Life Vessel study (top panel), his resting BP is normal. His resting HR, autonomic levels and BP are all normal as well, but the patient still reports feeling poorly. His parasympathetic response to deep breathing is normal for his age. His (beta) sympathetic and parasympathetic responses to Valsalva are high and his (alpha) sympathetic response to standing is low. High parasympathetic responses during sympathetic challenges are expected to decrease. Parasympathetic excess during sympathetic challenge is known to destabilize patient responses to disease and therapy, and causes excessive sympathetic responses. The difficulty is that without ANS monitoring the patient presents as continued excess or difficult to control BP or HR from the secondary sympathetic excess. Further sympathetic therapy actually further destabilizes the patient because it acts to remove more of the extant sympathetic balance over the parasympathetics. In spite of this sympathetic excess, the patient still presents with sympathetic insufficiency or sympathetic withdrawal (SW) upon standing which is associated with orthostasis. SW with a 7/1mmHg drop in BP upon standing is associated with pre-clinical OH. His standing HR response was normal. Post-Life Vessel therapy (the lower half of Figure 3) presents a normalized (adult) autonomic nervous system. His standing BP response is still weak, but as stated before, BP takes longer to correct than the ANS.

CONCLUSION

Overall The Life Vessel™ therapy can help patients’ ANSs to normalize. Once normal, the primary disease can be treated more aggressively. Follow-up reports from patients suggest that the long term effects of The Life Vessel™ therapy can remain. Apparently, this is due to the plasticity of the ANS and its ability to “learn” or “be re-trained”. Once re-trained, the ANS can carry forward in its new state without the need for further therapy. Proper ANS balance is associated with improved wellness and improved outcomes. Proper ANS balance, however does not immediately or always correct the end-organ dysfunction. End-organ dysfunction would be the reason for needing continued therapy or maintenance dosing to help maintain ANS balance once established.

Chronic disease leads to autonomic neuropathy. Autonomic neuropathy is associated with a five-fold increase in mortality. Autonomic dysfunction precedes autonomic neuropathy, but is asymptomatic, except in cases of dizziness and abnormal sweating. Therefore, the chronic disease itself is the indication for ANS testing. This point has been supported by the medical leadership (AAN1, AHA2,3, ADA2-5, AAFP6, JDIF2 and NIH2) is supported by Medicare which encourages (reimburses) periodic testing to detect autonomic decline early to intervene prior to end-organ dysfunction or failure forces catastrophic conditions that require expensive procedures. The Life Vessel™ therapy has been shown to normalize patients with long standing chronic disease. ANS monitoring shows that there is an autonomic effect associated with The Life Vessel™ therapy which seems to help to contribute to the patients overall improvement in health.

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J. Colombo, Ph.D.
Medical Director and Executive V.P.
Ansar Medical Technologies, Inc.
Email: joe@ans-hrv.com