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SHOEMAKER PROTOCOL: SURVIVNG MOLD
12 Steps to a Healthier YOU

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Upon presentation to clinic, patients may not be aware of the complexity of why they are not feeling well. They may have seen multiple other providers before finding their way to my office. They may have been feeling off for a long period of time and have never gotten to the bottom of the mystery. The key to being an exemplary physician/healer/clinician is being able to recognize a series of syndromes (CIRS) that are far too common in patients today from the myriad of symptoms they present. Typical symptoms that will set off my radar for a biotoxin illness include: fatigue, headache, light sensitivity, difficulty with word finding, concentration at home and at work or school, joint stiffness that is worse in the morning, muscle cramps, tingling in the extremities, skin sensation changes, shortness of breath that worsens with activity, sinus congestion, cough, excessive thirst, difficulty with body temperature regulation, increased urinary frequency, blurred vision, mood swings, diarrhea, numbness, tearing, vertigo or increased dizziness, metallic taste, static shocks combined with a history of being in a water damaged building. This is the cluster analysis of symptoms that is positively correlated with CIRS and is a part of my intake questioner.

An important part to any physician-patient interaction is the history. This is the time where the story behind the symptoms may be gleaned from simple interview questions such as “Have you ever lived in a moldy building? Does your home smell musty? Does your office have good air circulation? Have you noticed these symptoms get worse when you go anywhere? Or better? Do you have a basement? Do you have crawl spaces in your home? Have you ever had a plumbing leak? A tick bite? Do you have a summer cottage in Wisconsin? When was the last time you had a round of antibiotics? For what? When was the last time you felt really great?”

If the patient presents with a series of symptoms that clue me in to possible CIRS my first step would be to obtain a VISUAL CONTAST SENSITIVITY TEST (VCS) in my office. This is such a great screening test because it is quick, cost effective and easy to do in the time of a regular office visit. If this is negative a CIRS diagnosis is much less likely. If this is positive it will lead me to start the process of diagnosing CIRS.

If the VCS is positive in my office I will proceed to order lab testing. To have this done properly I have laminated the order sheets from Dr. Shoemaker to give to my lab staff or if the patient is having them drawn elsewhere due to insurance concerns then my staff may copy them to give to the patient before leaving.

Recommended Initial Lab Tests (in no particular order):

HLA DR
Alpha MSH
Leptin
Anticardiolipin Antibody
Antigliadin Antibody
MMP-9
VEGF
C3a
C4a
ADH/Osmolarity
ACTH/Cortisol
VIP
CRP
ESR
TGF-B1
CBC
CMP
TSH
Willebrand's profile
HgbA1c
Fe
TIBC
Ferritin
Lipase
Vitamin D3 (25-OH)
Lipid Panel

MARCoNS analysis – sample taken in office during second office visit
HERTSMI/ERMI analysis from Mycometrics – instructions given on how to obtain

I would next plan on seeing the patient back to discuss the results of the lab work. At this time we would discuss the treatment plan based on the 12 step Shoemaker Protocol.

1. Remove From Exposure
2. CSM/Welchol
3. Eradicate MARCoNS
4. Correct Antigliadin
5. Correct Androgens
6. Correct ADH/Osmolality
7. Correct MMP9
8. Correct VEGF
9. Correct C3a
10. Correct C4a
11. Correct TGF Beta-1
12. VIP if needed

REMOVE FROM EXPOSURE:
GOAL: ERMI less than 2
HERTSMI 2 less than 10

The first step is the hardest. Hopefully the patient has had time to discern when the mold exposure may have occurred and whether the place in which they are residing is safe from mold. Unfortunately with 50% of residences having mold per the National Institute for Occupational Safety and Health it is unlikely that they are free from mold in their current home environment. I always recommend an ERMI/HERTSMI of the home because the patient cannot heal in a sick environment. This is an easy and quick test that will give results in a short period of time (as quickly as 2-3 days with expedited processing). I would also question their workplace and all other environments where they spend time on a regular basis (gym, library, etc). It is prudent to have the workplace tested for mold at the same time although it is sometimes difficult to convince patients due to economic concerns. I do discuss whether their symptoms improved over the weekend when they are away from the office or during times of vacation out of town. If this is the case a culture from the work environment may be prudent because it is likely they are being exposed at their office.

This first step is extremely difficult. If mold is found in a home, the patient has two choices. They can obtain a certified mold remediation service to remove the mold from the home while living elsewhere or they can move to a new location. If they chose to move it would be recommended that they have an ERMI or HERTSMI on their new place before buying as mold is very pervasive in the environment even in newly built homes due to the changes in building materials that have occurred over the last few decades and the advent of energy conserving environments (i.e., minimizing air flow to reduce heating expense, etc.) and sloppy construction practices. They would also have to face giving up most of their things that are porous (furniture, clothing, books) and basically start over in their new location.

There are new generation HEPA filters by a variety of different manufacturers that have been introduced to the market that are able to filter out the small size particles of mold and toxic spores and reduce them from air flow. These are an adjunct for people that are not able to leave their office or homes in order to remove a portion of exposure but are not a substitute from having a home or work space remediated by a trained professional who is able to remove the majority of the pathogens.

CHOLESTYRAMINE/WELCHOL:
GOAL: VCS – Pass

The second step of the protocol is using a bile acid sequestrant – cholestyramine (CSM) – to bind to the toxic ionophores which are responsible for CIRS in the intestine and remove from the body. As the CSM binds to the toxins that are present and removes them from the body, it creates a diffusion gradient whereby the toxins stored in tissues move to the lower concentration areas – intestines – and then may be bound by CSM in subsequent doses.

Treatment:
Cholestyramine is the best option for binding mold toxins and removing them from the body. This is because of its chemical structure – it is an anion binding resin with an ammonium side chain which has a positive local charge leading to its ability to bind with high affinity to the negatively charged ionophores which lead to CIRS. The dose of CSM is 4 grams four times daily for an adult that is greater than 120 pounds. For children greater than 60 pounds but less than 120 pounds the dose is 4 grams three times daily. For children less than 60 pounds the dose is 60 mg/kg per dose three times daily. This must be taken 30 minutes prior to meals or one hour after meals, supplements and other medications. This prevents it from binding to the food and/or supplements and instead binds to the toxins located in the intestines, thus removing them from enterohepatic circulation.

CSM may be compounded by compounding pharmacies to reduce any additives which may help with the side effect profile in select patients.

Welchol is another option which is more expensive and less successful in the removal of toxic ionophores from the body. Some patients cannot tolerate the cholestyramine due to side effects such as gastrointestinal bloating or change in bowel status or a sensitivity to the yellow coloring or sugar which is added to the cholestyramine. For these patients welchol is an option. The dose for welchol is 3 tabs 625 mg twice daily. This is a more expensive option but for some is the only choice they have due to the side effect profile.

This step should be taken for at least 30 days or until the VCS normalizes before moving onto the next step of the protocol.

There are minimal side effects to the CSM due to its local effects. It is not absorbed systemically and thus does not have systemic side effects. The most common side effect is constipation due to binding to substrates in the colon. This can be handled by increasing water intake daily, adding a magnesium supplement or taking a daily fiber supplement like Benefiber or Miralax. The second most common side effect is bloating and it tends to resolve naturally over a few days. If the patient exhibits a detox reaction in response to the CSM, the dose can be lowered or halted and actos or omega-3 fatty acids can be started to help rid any side effects of the detoxification.

In order to test for response to treatment VCS is recommended at days 2, 7 and 14.

Typical duration of treatment for CSM is dependent on the compliance of the patient. If the patient is compliant with treatment, they have removed themselves from dangerous home and work environments, they are taking the CSM four times daily on an empty stomach they may only need a few months of CSM before their symptoms have resolved completely. If they are still in a water damaged building or are not able to fully comply with treatment it will take longer.

ERADICATE MARCoNS:
GOAL: Negative nasal culture

The next step depends on the presence of MARCoNS in the nasal mucosa. These are resistant bacteria that are not destroyed by normal mechanisms – i.e. oral antibiotics. These bacteria produce a biofilm (slime) which protects them from our normally functioning immune system.

In patients with low alpha MSH, 80% will show the presence of MARCoNS. This leads to a "turning on" of cytokine attacks around the clock. Patients that have a normal MSH rarely have MARCoNS.

Treatment: BEG spray – bactroban, EDTA and Gentamicin. EDTA is present to eradicate the biofilm in order to allow the antibiotics to penetrate to the actual bacteria. Have the patient blow his/her nose. 2 squirts of BEG spray in both sides of the nose three times daily. Treat for one month and then reculture.

The best place to order this spray is from Hopkinton Drug. They offer a convenient iphone application to make the ordering process simplistic.

It seems that treatment times have been increasing and it may take 2-3 months of nasal spray to fully eradicate the MARCoNS from the nasal mucosa.

TREAT ANTIGLIADIN:
GOAL: 0-19 AGA IgA/IgG

If the patient was positive for antigliadin then a tissue transglutaminase antibody test should be performed. If this is positive the patient has celiac disease and must no longer consume gluten. Typically with CIRS patients the TTG test is negative and the next step of treatment is to remove all gluten from the diet. This is to be done for a minimum of three months but may continue indefinitely. After three months the antigliadin should be retested. If it is negative at that time the patient may reintroduce gluten. With reintroduction of gluten they should monitor their body to see if they notice any change in their symptom profile. If so they may consider keeping gluten out of their diet until further notice.

CORRECT ANDROGENS:
GOAL: Normal testosterone, estrogen, pregnenolone for age and gender

At this time it is prudent to correct any androgen deficiency.

Using testosterone has been shown to worsen symptoms. It is most efficient to correct the overexpression of aromatase in order to decrease the symptoms. If we reduce the aromatase overexpression the testosterone deficiency will correct by itself.

Treatment: Supplement can be accomplished with the use of DHEA typically 25 mg three times daily or human chorionic gonadotropin injections 125 mg week for 5 weeks or vasoactive intestinal polypeptide nasal spray four times daily and recheck levels in 4 weeks. This may help with insomnia due to the increased production of melatonin.

CORRECT ADH/VASOPRESSIN:
GOAL: ADH: 1-13.3 pg/ml; Osmolality 280-300 mOsm

The treatment for the dehydration caused by mold exposure is DDAVP, a synthetic form of ADH. The starting dose is 0.1 mg 1-2 tabs nightly. Typically I would use desmopressin 0.2 mg every other night for 10 nights. I would plan on rechecking labs within two weeks in order to determine what dose adjustments still need to be made. The patients typically notice a change in static shocks with the use of desmopressin and appreciate the need to use the bathroom less frequently. These changes are noticed almost immediately after the first nightly dose.

CORRECT MMP9:
GOAL: 85-332 pg/ml

High MMP9 indicates the endothelial response to ongoing inflammation. This is involved in regulating pathological tissue remodeling. It directly degrades the extracellular matrix proteins and activates cytokines and chemokines to regulate tissue remodeling[3]. High MMP-9 levels are associated with headaches, neurological issues, cognitive issues, muscle pain and decreased lung function. If the leptin level is less than 7, I use EPA/DHA instead of the actos to regulate the MMP9 levels.

Treatment for high MMP-9 is a low amylose diet, Actos 45 mg once daily. If the patient cannot tolerate Actos I would use 2.4g/day EPA and 1.8 g/day of DHA instead.

CORRECT VEGF:
GOAL: 31-86 pg/ml

Upon re-exposure to a water damaged building VEGF will initially increase and then crash within 48 hours.

Low VEGF leads to capillary hypoperfusion. This may also be diagnosed through a pulmonary stress test. The anaerobic threshold is decreased with low VEGF. Correcting low VEGF leads to better blood flow and oxygen delivery, decreased brain fog, decreased fatigue, decreased shortness of breath, muscle pain and post exercise exhaustion.

Treatment: High dose Omega-3 can help with low VEGF and is a safer alternative.

CORRECT C3A:
GOAL: 55-486 ng/ml

C3a is part of the complement cascade – complement split product – which causes neutrophil activation and leads to capillary hypoperfusion. This is only present in some biotoxin patients. C3a promotes pathological inflammation and leads to many of the symptoms found in both Lyme and CIRS patients [1,2].

Treatment of high C3a levels involves the use of high dose statins. Due to the risk of side effects with high dose statins, I begin Coeq10 150 mg 1 week prior to starting high dose statin therapy in order to mitigate any side effects.

CORRECT C4A:
GOAL: 0-2830 ng/ml

C4a is another complement split product that is found in CIRS. A level greater than 2,800 is concerning. C4a elevated within about 10 minutes of entering a water damaged building.

Treatment: EPO 8,000 IU twice weekly x 5 doses has been shown to be beneficial at increasing oxygen delivery to tissues that are hypoperfused. Procrit has a black box warning and must be used with extreme care. Informed verbal and written consent must be obtained before proceeding.

Treatment: VIP nasal spray has also been found to be very beneficial to decreasing C4a levels. The dose for this is four times daily x 30 days then twice daily x 30 days, then daily x 30 days. VIP may only be used if the patient is out of the water damaged building, they have screened negative for MARCoNS, MMP-9 is less than 320, VCS is normal and lipase levels are normal. The first dose is given in the office and a TGF-Beta is checked after dose.

CORRECT TGF-BETA:
GOAL: Normal is less than 2,380 pg/ml.

TGF Beta 1 is involved in maintaining tight junction adhesions, impairs normal T regulatory cell function, prevention of auto immunity.

TGF Beta 1 leads to transformation of the lungs by remodeling and abnormal collagen cross-linking, fibrosis in tissues, nasal and vocal polyps and auto-immunity.

Fixing TGF Beta 1 leads to the symptoms of auto-immunity disappearing.

Treatment: losartan 25 mg twice daily in adults and 0.6 mg/kg/day divided BID in children or VIP 50 mcg four times daily if losartan is not a possibility due to low blood pressure or intolerance.
Recheck TGF-Beta 1 monthly.

CORRECT VIP:
GOAL: 23-63 pg/ml

Low VIP is demonstrated by an absence of fall of pulmonary artery pressure during and after exercise. This may be diagnosed by a pulmonary stress test with low VO2 max and a low anaerobic threshold.

VIP regulates vasodilation in the pulmonary artery tree. It regulates inflammatory responses and is the regulator of hypothalamic responses.

Treatment of low VIP is a lifesaver for victims of CIRS as it can correct multiple steps in the pathway including C4a, TGF beta-1, MMP-9, VEGF and androgen levels.

REQUIREMENTS BEFORE BEGINNING VIP SPRAY:
Normal VCS
No exposure to water damaged building
MARCoNS negative
Normal serum lipase levels

Treatment is 50 mcg four times daily for a month then twice daily for a month and then once daily for a month. The first dose of VIP is administered in the office with pre and post labs taken. Patient must remain in the office for 15 minutes at least after the first dose and have a repeat lipase done at that time. After that point patients are able to self-titrate to symptom profile.

And finally – stay away from moldy buildings!!! If that is not a possibility, initiate the treatment sequence as soon as possible to minimize sequelae. I recommend to my patients that if they are traveling and unsure of their environments they should pre-treat with CSM twice daily to prevent any reoccurrences a few days before leaving home.

12 steps – it does not seem like much but is an intensive and rigorous program developed by a genius of a man (Dr. Ritchie Shoemaker) to detoxify a body and potentially a whole family from a load of serious health consequences caused by mold and mycotoxins. Detoxification length can range in time depending on how quickly each sequential step is conquered – for some just getting out of the mold into a new living condition may take upwards of two years. For others they are not able to remove themselves from the moldy condition as it is at their place of employment and they must just limit their exposure and do the best they can to stay healthy. Their health condition will be more dire the longer it takes to finish the protocol. The good news is that many will feel better as soon as they are out of the moldy situation and taking the cholestyramine daily. For some true healing will not be complete until they finish all of the steps.

This is truly a great example of patient centered medicine because it truly is individualized. Each patient may show different signs and symptoms and have a different course of recovery. Some may feel better in weeks and others it may take months or years. It is truly a beautiful partnership between patient and physician that leads to whole body wellness and getting through this pervasive illness. This partnership is the basis of healing and is what we as clinicians do very well. I am honored to be helping my patients achieve ultimate health working with them to remove toxins from their environment and their bodies and striving towards living the healthiest lives possible. Every day.

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