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30-Day SBO Kit Program

Introduction

As the understanding of gut microbiota has expanded in recent years, there is now a growing recognition of the extensive influence it has on every system of the body. More than simply contributing to digestion and nutrient metabolism, the microbiota plays an active role in cardiometabolic health and function through a variety of mechanisms, including bile acid metabolism and short-chain fatty acid (SCFA) synthesis.[1] It influences systemic immune function and tolerance, and communicates with the central nervous system via the "gut-brain axis."[2,3] In a healthy individual, the gut microbiota performs essential tasks and is a partner in a mutually beneficial relationship. Yet when there is an imbalance in either the functionality, density, or composition of the microbiota, i.e., dysbiosis, it can be a driver for a broad spectrum of dysfunctions. The close ties established between dysbiosis, intestinal permeability, and systemic inflammation have highlighted pathways that may underlie seemingly disparate disorders, ranging from cardiovascular to gastrointestinal to neurological dysfunctions.[4-6]

Normally the concentration of bacteria increases along the intestinal tract, from a low of 10^3 CFU/mL (colony forming unit per milliliter) in the stomach to as high as 10^{11}-10^{12} CFU/mL in the colon, with the small intestine having an intermediate range of 10^2-10^5 CFU/mL.[7] At bacterial concentrations exceeding this in the small intestine, the risk for multiple clinical symptoms and conditions escalates. For example, the risk for overgrowth among people with functional dyspepsia (characterized by pain, bloating, nausea, etc., following meals) was found to be 2.8 to 4.3-fold greater than among healthy controls, with a prevalence as high as 53%.[8] Indeed the most common symptoms reported as a result of overgrowth include watery diarrhea, bloating, abdominal pain, and distension, with an increased risk for multiple vitamin and mineral deficiencies, including vitamins B_{12}, D, A, and E, and iron and calcium.[9] The prevalence of overgrowth among people with irritable bowel syndrome (IBS) has been estimated to be nearly 5-fold higher compared to healthy controls (with many overlapping symptoms, and IBS subtypes may be predicted by breath gas analysis), and this prevalence is nearly 10-fold higher among those with inflammatory bowel disease.[10-12]

Given the close ties between cardiometabolic function and the microbiota, overgrowth in the small intestine could be predicted to have a potential influence on cardiometabolic health. Here, too, the evidence supports a connection; a nearly 4-fold risk for non-alcoholic fatty liver disease (NAFLD) was observed among study participants with bacterial overgrowth in the small intestine.[13]

SBO Kit includes 1 bottle each of **A.D.P.®**, **DYSBIOCIDE®**, and **FC-CIDAL™** (#1098)

Analysis of individuals living in Western countries found that among those with obesity, the risk for overgrowth was approximately 3.5-fold greater.[14] A systematic review of 14 studies found that among people with diabetes, the prevalence of overgrowth was nearly 40%, a nearly 3-fold risk compared to healthy controls.[15] Bacterial overgrowth has also been associated with neurodegenerative diseases, particularly Parkinson's disease, and has the potential for promoting (or preventing) neurodegeneration via several mechanisms, including the production of inflammatory mediators and disruption of the integrity of the intestinal barrier.[16,17]

Restoring a Healthy Bacterial Balance

The initial approach when overgrowth is suspected should be to identify and address contributing factors, primarily any changes to gut anatomy, secretions, motility or immunity.[18] Risk factors include medications used to inhibit gastric acid (proton pump inhibitors (PPIs) and H2 blockers), antibiotics, and motility-altering drugs (e.g., anticholinergics, prokinetics, and opioids), as well as conditions that may alter gastrointestinal motility, such as diabetes and systemic sclerosis.[7,19]

Perhaps the most well-studied and often employed approach to reducing the bacterial burden is the medication Rifaximin, a non-systemic antibiotic. However, between 30-40% of people treated with Rifaximin do not see improvement, and approximately 44% experience a recurrence within 9 months of initial treatment.[20,21]

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This may be due to underlying factors which have not (or cannot) be addressed, such as PPI use or abdominal surgery. Additionally, antibiotic use in general has been associated with microbial resistance, as well as the long-term persistence of antibiotic-resistant genes.[22] For this reason, antibiotics that are rotated and have different mechanisms of action appear to be more effective than a single antibiotic alone.[23]

Clinical Trial

In a 4-week clinical trial (*Herbal Therapy Is Equivalent to Rifaximin for the Treatment of Small Intestinal Bacterial Overgrowth*) involving over 100 participants struggling with an overgrowth of bacteria in the small intestines, several approaches were examined.[24] One group of participants received a commonly used medication for bacterial overgrowth, while others were given an herbal protocol, which included both **Dysbiocide®** and **FC-Cidal™**, administered as one serving of each, twice per day.

By the end of the study, breath test results indicated normalization in 46% of participants who had been assigned the herbal regimens. The likelihood of improvement in this group was found to be 1.85-fold higher. This study suggests that herbal products like **Dysbiocide®** and **FC-Cidal™** may provide beneficial effects in balancing microorganisms in the small intestines.*

Botanicals — Diverse Mechanisms

Dysbiocide® & FC-Cidal™

Dysbiocide® and **FC-Cidal™** are proprietary blends of 16 botanicals with a range of complementary biological effects. Many of these botanicals have direct antimicrobial activity in experimental models through a variety of different mechanisms, including thyme, stemona, yarrow, stinging nettle, olive leaf, and cutch tree.[24-29] Many also have additional biological effects likely to support gastrointestinal health. For example, wormwood and yarrow have also been shown to have gastroprotective effects in experimental models, by maintaining the integrity of the mucosal barrier and upregulating antioxidant enzyme expression (via upregulation of nuclear factor-erythroid 2 related factor 2 (Nrf2)), respectively.[30,31]

Given that intestinal inflammation has been strongly associated with the overgrowth of bacteria in the small intestine, many of these botanicals were chosen for their anti-inflammatory effects.[32] Diverse models indicate this occurs through multiple mechanisms, including inhibition of NF-κB activation by Java brucei and hedyotis, and inhibition of multiple prostaglandins and inflammatory cytokines by Pau d'arco.[33-36] Several of these botanicals support healthy inflammatory pathways and bacterial equilibrium, including French tarragon, which has been shown to have an immunomodulatory influence on neutrophils as well as bactericidal and anti-biofilm effects.[37,38] Similarly, horsetail has been shown to have anti-biofilm and antimicrobial effects along with localized immunomodulatory and anti-inflammatory actions.[39-41] Indian Tinospora has been reported to have both immunomodulatory and anti-inflammatory actions, and provide berberine and palmatine, well-recognized for their antimicrobial and anti-fungal effects, respectively.[42] Thyme also appears to have pluripotent effects; it has been shown to regulate gut microbiota, suppress TLR4/NF-κB-NLRP3 inflammasome pathways, and provide protection to the intestinal epithelial barrier.[43-45]

In addition to anti-inflammatory and antimicrobial effects, the botanicals in **Dysbiocide®** and **FC-Cidal™** support gastrointestinal health through other mechanisms as well. Dill has a long traditional use for indigestion and possesses notable antispasmodic effects, mediated in part by high concentrations of quercetin and rutin. In models of ulcerative colitis, Chinese pulsatilla was found to both decrease activation of the NLRP3 inflammasome, and increase the colonic concentration of SCFAs, as well as shift the abundance of bacteria to a more favorable balance.[47,48] Jamaica quassia has long been used as a bitter herb, and may promote gastric acid secretion through this mechanism.[49,50]

A.D.P.®

In addition to the botanicals used in the clinical trial, **A.D.P.®** provides a sustained-release form of micro-emulsified oregano oil. Oregano oil has been shown to directly kill or inhibit the growth of intestinal microbes, and contains multiple active compounds responsible for antimicrobial activity, including carvacrol, γ-terpinene and p-cymene.[51-53] These compounds act through multiple mechanisms, including inhibition of microbial enzymes and efflux pumps, as well as disruption of biofilm formation.[54] Oregano oil also has anti-fungal actions, inhibiting the germination and development of C. albicans, as well as each phase of Candida biofilm synthesis, i.e., adhesion, formation, and the mature state. It also provides an antioxidant benefit, in part by upregulating Nrf2 activation.[56]

Dietary Approach

The most elemental and valuable dietary approach would be to begin with a foundation that focuses on unprocessed, whole foods. In addition to reducing sugar intake and smoking cessation (as well as identifying gluten-intolerance), perhaps the most often utilized dietary change is a reduction in FODMAPs, fermentable oligosaccharides, disaccharides, and monosaccharides and polyols. These are poorly absorbed carbohydrates that are rapidly fermented by intestinal microbiota.[18] However, a low FODMAP diet has primarily shown efficacy for reducing symptoms among those with IBS, which often presents concomitantly with bacterial overgrowth of the small intestine. Because these two conditions frequently occur together, there is likely a subset of people that will show improvement, but for those without IBS, a low FODMAP diet may have unfavorable effects on bacterial composition.[57] An alternative may be an elemental diet, which has been shown to improve markers of overgrowth in the majority of study participants.[58] Other dietary approaches that may provide benefit include mindful eating, avoidance of snacking, and increasing dietary fiber content.[58]

SBO Kit 30-Day Program

The dosage used in the clinical trial cited above was 1 serving (2 capsules) of **Dysbiocide®** along with 1 serving (1 capsule) of **FC-Cidal™**, taken twice per day. Due to the success of **Dysbiocide®** and **FC-Cidal™** in the clinical trial, clinicians have experimented with administration options. This has led to an updated protocol that combines **Dysbiocide®** and **FC-Cidal™** with **A.D.P.®**. The revised protocol includes the use of each of the three antimicrobials at a dose of 2 capsules/tablets three times per day for 30 days.

Directions for Use

Take two (2) tablets/capsules of each product three (3) times daily as a dietary supplement or as otherwise directed by a healthcare professional.

This product is gluten, dairy, and GMO free.

A.D.P.®
#1105

Supplement Facts
Serving Size: 2 Tablets
Servings Per Container: 90

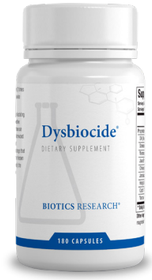
	Amount Per Serving
Oregano Oil (*Origanum vulgare*) (extract from leaf)	100 mg*

*** Daily Value not established**

Other ingredients: Cellulose, modified cellulose gum, potassium sorbate, silica, water and gum arabic.

A.D.P.® supplies oregano oil which is emulsified and processed in a gradual release form for optimal effectiveness.

Patent #5,955,086



DYSBIOCIDE®
#7859

Supplement Facts
Serving Size: 2 Capsules
Servings Per Container: 90

	Amount Per Serving
Proprietary Blend	950 mg
Dill (*Anethum graveolens*) (seed) *	
Stemona (*Stemona sessilifolia*) (root) (extract) *	
Wormwood (*Artemisia absinthium*) (shoot & leaf) (extract) *	
Java Brucea (*Brucea javanica*) (fruit) (powder & extract) *	
Chinese Pulsatilla (*Pulsatilla chinensis*) (rhizome) (powder & extract) *	
Jamaica Quassia (*Picrasma excelsa*) (bark) (extract) *	
Hedyotis (*Hedyotis diffusa*) (herb) (extract) *	
Cutch Tree (*Acacia catechu*) (heartwood & bark) (powder & extract) *	
Yarrow (*Achillea millefolium*) (leaf & flower) (extract) *	

*** Daily Value not established**

Other ingredients: Capsule shell (gelatin and water), cellulose and magnesium stearate (vegetable source).

FC-CIDAL™
#6311

Supplement Facts
Serving Size: 2 Capsules
Servings Per Container: 90

	Amount Per Serving
Proprietary Blend	1000 mg
French Tarragon (*Artemisia dracunculus*) (leaf) *	
Indian Tinospora (*Tinospora cordifolia*) (stem & root) *	
Horsetail (*Equisetum arvense*) (whole herb) *	
Thyme (*Thymus vulgaris*) (leaf) *	
Pau D' Arco (*Tabebuia impetiginosa*) (inner bark) *	
Stinging Nettle Extract (*Urtica dioica*) (root) *	
Olive (*Olea europaea*) (leaf) *	

*** Daily Value not established**

Other ingredients: Capsule shell (gelatin and water), cellulose and magnesium stearate (vegetable source).

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.