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Prosthetic Hip-Associated Cobalt Toxicity (Phact) Reversal through Nutrition Supplementation and Dietary Intervention

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Abstract

Cases of Prosthetic Hip-Associated Cobalt Toxicity (PHACT) are becoming more prevalent in medical literature. Conditions associated with cobalt toxicity include cardiac issues, thyroid dysfunction, and neurological afflictions [1]. This case report presents positive results in a patient with PHACT after supervised supplementation therapy and ongoing adherence to a whole foods diet with 'Low Glycemic Load Through Paleolithic Principals' (LGLPP).

Keywords

Prosthetic hip-associated cobalt toxicity, Cobalt toxicity reversal, Chromium toxicity reversal, Metabolic syndrome reversal, Vitamin D deficiency reversal, Nutrition intervention, Functional medicine, Diet, Paleo diet

Introduction

A 62-year-old Caucasian male patient presented to an integrative medicine clinic in February 2017 with heavy metal toxicity, Metabolic Syndrome (MetS), and low vitamin D status, seeking nutrition advice to support the reduction of Cobalt (Co) and Chromium (Cr) biomarkers associated with 2010 and 2011 hip replacements. His current medications include Flonase. The patient diagnosis and treatment are outlined in the timeline.

Patient Case

This 62-year-old male came in with heavy metal toxicity, MetS, and low vitamin D status. His past medical history is significant for hip resurfacing operations on both hips in 2010 and 2011. These prostheses appear to pose a risk of excess cobalt and chromium release due to debris created by wear and tear [2].

At the time of his February 2017 visit, he was taking Flonase and a vitamin D supplement as directed. He followed a whole foods diet with 'low glycemic load through Paleolithic principals', (LGLPP; Appendix 1) which was previously integrated in his nutrition intervention in June 2016 for improvement of blood sugar regulation. His nutrition plan also included the avoidance of dairy, which had resulted in the reversal of previous symptoms of bloating, loose stools and itchy skin.

The patient was evaluated at an integrative nutrition clinic that uses a functional medicine approach guided by laboratory testing and a whole foods diet with LGLPP intervention (Appendix 1). Foods with a high Glycemic Index (GI) are those which rapidly digest and absorb, creating fluctuations in blood sugar levels. Low-GI foods, by virtue of their slow digestion and absorption, produce gradual rises in blood sugar and insulin levels and have proven benefits for health. Furthermore, adhering to a whole foods diet with LGLPP promotes food choices with increased nutrient density. Increased intake of nutrient-dense foods discourages mineral deficiencies which, when paired with increasing vitamin D levels, can promote the accumulation of toxic metals [3].

He was a runner but had recently eased up on his active lifestyle out of concern for metal ion elevation and the potential risks of excess exposure. He came in for a follow-up visit after two months.

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Table 1: Nutritional visit timeline (with diagnostic evaluation and interventions).

Past medical history: 2010/2011 hip resurfacing, heavy metal toxicity, blood sugar dysregulation, MetS, low vitamin D status. Current history: Heavy metal toxicity.

Three visits over three months			**Nutritionist visit dates**	
			2/6/17	4/10/17
Medications				
Flonase			Yes	Yes
Dietary recommendations				
LGLPP			Yes	Yes
Dairy free			90%	Yes
Dietary supplements				
Metal-X-Synergy™			Advised	Yes, advised to discontinue
Vitamin D			Yes	Yes
Lifestyle recommendations			No running	No running
Vital signs				
Height			5'9"	5'9"
Weight (pounds)			157.01	157.4
BMI			23.6	23.6
Fat mass			20.21	18.0
Fat free mass			137.01	139.4
Body fat %			12.8	11.4
Total body water			100.2	102.01
Laboratory biomarkers				
Dates collected	06/18/16	9/17/16	1/14/17	4/1/17
Glucose (mg/dL)	106	106	105	97
HgA1C (%)	5.9	5.7	5.8	5.7
Vitamin D (ng/mL)	27.3	55.8	-	-
Sodium (mmol/L)	145	142	143	146
LDL (mg/dL)	103	109	116	117
Cobalt, urine (ug/L)		6.8	10.8	2.9
Cobalt/creatinine ratio (ug/g)		7.8	7.3	6.9
Chromium, urine (ug/L)		4.0	6.6	2.0
Cobalt, plasma (ug/mL)		2.9	2.9	2.6
Chromium, plasma (ug/mL)		5.1	7.1	4.2

Laboratory testing from January 2017 was indicative of heavy metal toxicity, blood sugar dysregulation and dyslipidaemia (Table 1). It disclosed high plasma and urine cobalt and chromium, cobalt/creatinine ratio, glucose, hemoglobin A1c, and LDL cholesterol. Vitamin D biomarker showed improvement in the previous laboratory testing from September 2016.

In his first visit made specifically to address the heavy metal toxicity in February 2017, Metal-X-Synergy™ by Designs for Health (DFH) was recommended to chelate and reduce the severity of heavy metal load; starting dose was recommended at three capsules twice per day with meals. This was accepted by the patient, who signed an informed consent and was willing to embark on this case study. Absence of remarkable renal issues supported the safety of this intervention. He was also advised to continue 2000 IU of vitamin D throughout the winter months as well as continue the whole foods diet with LGLPP and avoidance of dairy.

One week later, the patient's wife reported side effects of extreme drowsiness, so he was advised to lower the dose by half to three capsules in the evening with dinner. The drowsiness may be due to rapid clearing and detoxification.

In April 2017, the patient showed dramatic reduction in both cobalt and chromium plasma and urine levels within a three-month period, as well as stabilization of blood sugar and vitamin D level within normal range (Table 1). He was advised that he may discontinue the Metal-X-Synergy™ and continue his exercise regimen of walking during the day and a gym routine; he had discontinued running for exercise. He reported a maintenance dose of vitamin D at 5,000 IU per week and was advised to increase to 10,000 IU per week, a dose which better approaches the level projected to maintain almost 80% of the population at optimum vitamin D levels [3]. He was also advised to continue and improve adherence to the whole foods diet with LGLPP and avoidance of dairy to support optimal blood sugar, reduction of HgA1c levels, and reversal of MetS markers, sufficient mineral intake, and maintenance of improved symptoms of bloating, loose stools and itchy skin.

Patient Perspective

"I had two surgeries on my hips, one in 2010 and one in 2011. I have always been a very active runner and athlete. I have taken care of my body my whole life through what I perceived to be decent nutrition and exercise. I am a high school teacher by profession. I came to the NHC center originally to have my low vitamin D issue addressed and also some signs and markers of a borderline blood sugar issues. The NHC staff worked with my wife for Hashimoto's Thyroiditis and Rheumatoid Arthritis (RA). They had great success with her case, actually improving her RA and reversing the Hashimoto's symptoms. Within a couple of months, my blood sugar appeared better, and my vitamin D increased. At this point I approached the staff at the NHC with my PHACT concerns. We evaluated the potential of a supplement designed by DFH called Metal-X-Synergy™. The staff investigated the science and potential side effects of using this product. After their positive evaluation, I was comfortable using it short-term. Initially I had some symptoms, but after adjusting the basics of dosing, everything seemed to go smoothly. The blood results were astounding; I was very happy. I am not sure I will use the supplement long-term, but am willing to intermittently try it as long as the numbers are measured and improving".

Discussion

De Smet, et al. [4] and Langton, et al. [5] indicated that cobalt and chromium concentrations in the blood, serum, and urine appear to be reliable indicators of hip resurfacing arthroplasty. The FDA issued a public health update in January 2017 on both total hip replacements, which are metal-on-metal, and metal ball procedures (hip resurfacing). Issues that were investigated and discussed were metal ion testing, failure rates, complications, patient risk, and imaging methods. The bearing surfaces of these prosthetic hips are made of a mixture of cobalt and chromium or ceramic, polyethylene, and stainless steel. The consistent friction on these bearing surfaces and some corrosion over time of these non-moving parts may be the cause of some systemic heavy metal build-up in the patient. De Smet, et al. [4] further indicate that when the procedure fails, these hip prostheses will lead to elevated cobalt and chromium levels, and the result might be cardiomyopathy or even fatality. The FDA further recommended that orthopedic surgeons not perform this type of surgery on patients with renal insufficiency, suppressed immune systems, known chemical sensitivities, on corticosteroids, and females of child-bearing age. The major point of concern is that cobalt and chromium serum levels are easily measured, however, when these heavy metals deposit in the tissue, only invasive biopsy can determine the extent of toxicity.

There have been reported cases of Prosthetic Hip-Associated Cobalt Toxicity (PHACT). In a review, Devlin, et al. [1] investigated 10 cases. Conditions associated with cobalt toxicity were investigated, including cardiac issues, thyroid dysfunction, and neurological afflictions. The neurological associations to symptoms were most common. The review showed the average time between arthroplasty and symptoms from 3 to 72 months, with the median at 19 months. Various measures of toxicity indicated that all patients in one or more matrices had elevated cobalt levels. Chelation therapies and detoxification methods for these metal elevations were not clearly defined in the review but were suggested by authors to receive further attention. An extensive review of the medical literature was undertaken to characterize cobalt toxicity from prosthetic hips.

As an objective approach to making the diagnosis of PHACT, Pizon, et al. [6] suggest the following criteria: (1) Elevated serum or whole blood cobalt levels due to a prosthetic hip, (2) At least two test-confirmed findings consistent with cobalt toxicity and (3) Exclusion of other etiologies.

In a case review by Grant, et al. [7], they found that a Therapeutic Plasma Exchange (TPE) was able to temporarily lower cobalt levels due to the fact that cobalt is albumin-bound and was removed by TPE. In their case, a 61-year-old female was able to reduce her cobalt by two-thirds in this removal but unfortunately returned to pre-TPE levels within 8 hours. She was unfortunately already suffering from blindness, deafness, and endocrine disruptions due to cobalt toxicity. These researchers further comment on chelation therapy as an option, but only in patients with no kidney damage.

There are currently class action lawsuits pending on the cobalt toxicities from these hip replacement surgeries and the harm done to patients. One such lawsuit recently settled with DePuy Orthopedics, a division of Johnson and Johnson, for about 8,000 cases for approximately 2.5 billion dollars. Injuries stemming from metallosis, cobalt toxicity, and general implant failure include heart failure, bone loss, swelling, inflammation, infection, tissue death, loss of vision and hearing, general organ damage, and neurological disorders like dementia, memory loss, and severe migraines.

Metal-X-Synergy™ was recommended to chelate and reduce the severity of heavy metal load. The active combined ingredients in the Metal-X-Synergy™ showed promising results in this case. They are discussed below by investigating the evidence-based data supporting each ingredient.

Chlorella (*Chlorella regularis*) is a green alga which is an extremely nutrient-dense food. It aids in circulation, digestion, and detoxification. It is well researched in its

ability as a heavy metal chelator [8]. It seems to have an affinity for mercury, lead, cobalt, and cadmium.

Chlorella falls into the category of alginates, so it plays an integral role in the prevention of reabsorption of minerals that were released from tissues [9]. Metal-X-Synergy™ contains an organic form of chlorella, but it is also in a "broken cell" form, which has converted the normally impenetrable cell wall through a patented process to make the inner part more bioavailable.

N-Acetyl-Cysteine (NAC), comes from the amino acid cysteine, and it is the precursor to Glutathione (GSH). It is the most powerful antioxidant known to man, especially in its liver-protection capacity. GSH is the antidote to free radicals and oxidative stress [10]. NAC has been shown helpful in the restoration of liver damage due to these heavy metals. Research indicates that NAC is a biomonitoring provoking agent for heavy metals such as mercury [11].

Alpha lipoic acid is another antioxidant. Its uniqueness lies in the protective properties for both water- and lipid-based tissues. Alpha lipoic acid has been shown to penetrate cell membranes into the intracellular space [12]. Thus, the postulation is formed that it can aid in the chelation process. In supplemental form, it is in an unbound form which gives it the potential to bind to heavy metals [13,14]. This unbound form can further cross the blood brain barrier which is of vital importance, because glial cells in the brain have been shown to accumulate lead and mercury [15].

Fulvic Acid is a component of humic substances, which are known as some of the most important organic soil constituents. Fulvic acid is also known to be an antioxidant and has been used in Chinese medicine for centuries as a chelator. Fulvic acid is unique in its ability to bind to and remove metal ions by forming water-soluble complexes. Its benefit stands out in the mobilization of metal ions that are heavy and normally difficult to transport [16].

Garlic (*Allium sativum*) is one of the richest sulfur-containing compounds. Sulfur oxidizes heavy metals, which renders them water-soluble and allows for excretion. Garlic is also known to stimulate the production and recycling of GSH [17].

Cilantro (*Coriandrum sativum*) acts on the central nervous system by mobilizing mercury, cadmium, aluminum, lead, and other metals. It works in a complex way within the cell wall where it appears to disrupt the metal ions that have an affinity for various receptor sites. This botanical appears to "pull" metals that are deep-rooted in tissues [18].

Finally, the proprietary science of Metal-X-Synergy™ demonstrates several additional patterns in conjunction with utilizing the above-mentioned nutrients. Metal-X-Synergy™ contains patented complexes of modified citrus pectin (PectaSol-C®) and alginate (Algimate®), two naturally-occurring complex polysaccharides called polyuronides. These polysaccharides work together to safely remove heavy metals without depleting essential minerals from the body.

Pectin is found in the cell wall of many citrus fruits [19]. While pectin is normally too large to work at the cellular level, PectaSol-C® was developed using a unique proprietary process which allows for the correct low molecular weight and structure necessary to chelate toxic metals [9,20].

Alginates are the carbohydrates that make up the cell wall of seaweed and have the distinct capability to bind heavy metals to their own molecules. Alginates work mainly in the gastrointestinal tract to prevent reabsorption of toxins as they are being pulled from tissues. This is a critical step, as other chelation methods may only bind toxins from tissues, releasing them into the intestinal tract. In the gastrointestinal tract, they become easily reabsorbed, creating a potentially vicious cycle that never allows for the complete elimination of the heavy metals [9].

Before the final publication of this case report, the patient was seen for a routine follow-up in August 2017. The only observable difference in the treatment plan was the discontinuation of Metal-X-Synergy™. Laboratory testing from July 2017 showed that urine cobalt had increased to 6.0 ug/L, urine chromium to 4.5 ug/L, plasma cobalt to 2.7 ug/mL, plasma chromium to 4.3 ug/mL, and cobalt/chromium ratio to 7.1 ug/g. The trend reversal of toxicity markers after discontinuation of Metal-X-Synergy™ introduces the need for further investigation into the safety of long-term use for patients with on-going toxin exposure.

Conclusion

The patient showed dramatic reduction in both cobalt and chromium plasma and urine levels within a three-month, as well as stabilization of blood sugar and vitamin D level within normal range. Metal-X-Synergy™ and adherence to a whole foods diet with LGLPP appear to have had a positive clinical effect in this patient. The improvement in the heavy metal load in his body while taking Metal-X-Synergy™ warrants further investigation of this product's use in patients with PHACT. The trend reversal of toxicity markers after discontinuation of Metal-X-Synergy™ supports the efficacy of the supplement while introducing the need for further investigation into the safety of long-term use for patients with on-going toxin exposure.

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