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*CALCIUM DISODIUM EDTA CHELATION SUPPOSITORIES:
A NOVEL APPROACH FOR REMOVING HEAVY METAL TOXINS
IN CLINICAL PRACTICE*

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ABSTRACT

Heavy metals accumulate in various tissues and are associated with increases in today's biggest killers: cardiovascular disease and cancer. Reducing these heavy metals from the body has been a challenge to modern day medicine. With the advent of intravenous EDTA chelation, it was possible to remove heavy metals, but this invasive method of heavy metal removal is burdensome and expensive. This review examines the rectal suppository method of chelating and removing toxic metals from the circulation and deposits in tissue storage sites. In preclinical experiments CaNa₂EDTA (Detoxamin) rectal suppositories were compared to intravenous (IV) administration of C14-labeled calcium disodium ethylenediaminetetraacetate (CaNa₂EDTA) in order to evaluate the absorption, brain and prostate tissue distribution, and excretion in rats. The absolute bioavailability of CaNa₂EDTA in blood following rectal dosing was 36.3% of the IV doses route, which confirmed that rectal dosing is an efficient method for delivering EDTA to tissues. Following IV or rectal dosing of C14 labeled CaNa₂EDTA, the ratio of radioactive EDTA in tissues compared to blood, showed negligible brain localization. However, prostate tissues were found to have a mean ratio of 3.69 via the IV and 13.6 for the rectal route. The half-life of IV administration was found to be approximately 1.5 hours whereas the half-life of rectal administration was over 8 hours. The total recovery of C14 EDTA expressed as percent of administered EDTA IV and rectally was a mean of 47.3% and 30.3%, respectively at eight hours. The suppository formulation of CaNa₂EDTA was well absorbed; delivering high levels of EDTA to the tissues, prostate in particular (3.5-fold increase over IV administration). In human subjects, adult men with chronic prostatitis and with benign prostate hyperplasia and/or prostate cancer and prostate calculi were treated in an outpatient setting with tetracycline and EDTA suppositories (Detoxamin) for 90 days, and their symptoms and lab results were analyzed. Using the NIH Chronic Prostatitis Symptom Index, statistically significant post-treatment mean

reductions in symptoms and pain were found, along with a significant improvement in mean quality of life. Use of the International Prostate Symptom Score also indicated significant reductions in 5/7 symptom categories and significant reduction of mean overall scores. Analysis of blood and stool post-treatment indicated significant changes in mobilized, secreted cations (cadmium, copper, boron, lead, molybdenum, magnesium, and calcium). The blood cholesterol/high density lipoprotein ratio was also significantly decreased. Use of rectal suppositories has proved to be an innovative, effective and simple approach, saving time and money for the patient, and its efficacy and safety have been validated in pre-clinical and clinical studies.

INTRODUCTION

Some of the most dangerous emerging diseases facing society today are directly related to exposures to environmental oxidative toxins. One of the most important sources of oxidative toxins is heavy metals. For example, forty-five states have issued mercury advisories from coal-fired plants and mercury fish advisories exist for nine or more of the waterways in this country.^{1,2}

The numbers of toxins released into the air, water, and land are increasing at a record rate, and we are paying the price. There are dangerous levels of oxidizing heavy metals, such as lead, found in more homes today than ever before in history.³ Early exposure to heavy metal toxins, such as lead, is linked with a 46 percent increase in the mortality rate, according to the Centers for Disease Control in Atlanta.⁴

The Multifactorial Impact of Heavy Metal Toxicity

Heavy metals in the environment have both an economic and medical cost. For example, Men in the fishing industry in California have sued the state over heavy metal contamination that is damaging the source of their livelihood.⁵ This has reached levels where pregnant women are now warned not to eat certain fish, such as tuna, because of the mercury content.⁶ Heavy metal exposures are especially taking a toll on young children and even the unborn. Government agencies are becoming increasingly concerned about the relationship of thimerasol, a mercury-containing bacteriostatic chemical, in vaccines and their related neurological deficit impact and apparent relationship to autism. The Environmental

Protection Agency has now doubled its estimate of children with toxic levels of mercury in their blood.^{7,8} In the home, arsenic has been found in the wood used for construction.⁹

Since heavy metal toxins have been found in a variety of locations and products, it is imperative that avoidance is incorporated into a daily lifestyle. This includes eliminating or reducing exposure to heavy metal-associated agents such as aluminum cookware; amalgam dental fillings; antiperspirants; baking powder; batteries; bleached flour; fish (such as tuna); fertilizers; fluoridated water; paint pigments and solvents; and tobacco smoke.

Some of the most toxic and commonly found heavy metals are mercury, lead, cadmium, aluminum, arsenic, and nickel. Many of these heavy metal/oxidizing agents impact the nervous system and are linked to Alzheimer's and other neurodegenerative diseases, while others can harm the kidneys, immune system, and cardiovascular system.¹⁰ There is even a relationship between heavy lead levels and bone demineralization (osteoporosis).¹¹

In reviewing archaeological studies of ancient bones and comparing them to ours today, experts have found about one thousand times the amount of certain heavy metals deposited into inner tissues, fat, bones, and ligaments of people today. The result may explain the surge in gastrointestinal-related adverse health symptoms, such as fungal mycotoxins, gut dysbiosis and a host of other disorders.¹²

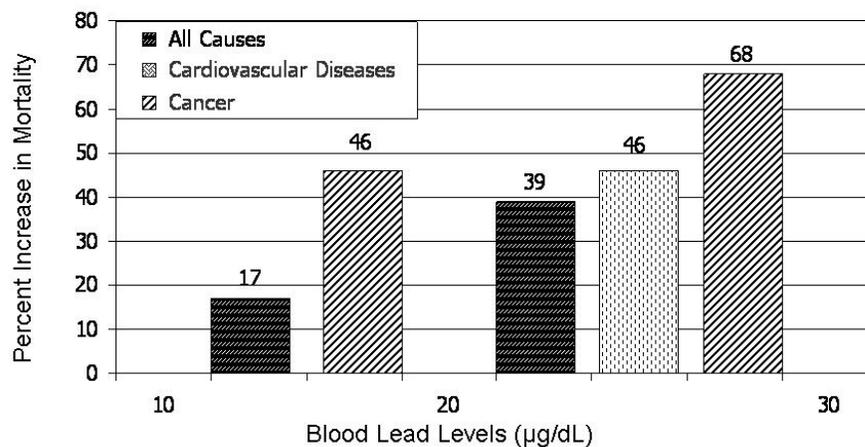
Loss of Mitochondrial Function and Vascular Insufficiency

Free radicals cause the dissolution of cell membrane surfaces over time. Starting out as healthy tissues, these cell membrane surfaces erode in the presence of oxidative agents, such as heavy metals. These oxidizing agents can modify (oxidize) membrane lipids, making them less fluid and allowing an increase in spontaneous leakage of ions across the membrane. Heavy metal toxins can also damage the inner sanctum of the cells themselves, interfering with mitochondrial function and DNA structure, and can set the stage for malignancy and cancer progression. For example, when inner membrane mitochondrial membrane lipids are oxidized, as also occurs naturally during aging, mitochondrial function is impaired and the cell's ability to produce energy is dramatically reduced.^{13, 14}

Heart Disease and Cancer Death Increases Associated with Chronic Low Lead Levels

Chronic low levels of lead exposure have been linked to hypertension, as reported in Current Hypertension Reports (August 2004). This heavy metal damages the delicate and fragile endothelial linings of blood vessels and damages nitric oxide synthetase, the enzyme responsible for healthy vasodilatation and signaling. Nitric oxide was discovered in 1986 and a Nobel Prize was given for its discovery. Free radicals resulting from chronic low lead exposure harm the production of nitric oxide synthetase in this tissue that is responsible for proper vascular performance.¹⁵ When toxic metals accumulate in the bones, fat, ligaments, and other tissues, they are in equilibrium with the intra-vascular compartment, and this continually disturbs the homeostasis of the entire cardiovascular system by maintaining chronic lead levels in the blood.

Death Rates of Participants with Low Pb Levels in NHANES III Survey



Ref: Lustberg, Mark and Silbergeld, Ellen. Blood lead levels and mortality. Arch Intern Med, 2002, 162: 2443-2449

Figure 1. Results of the NHANES III Survey revealed a relationship between blood lead levels and the incidence of death from cancer and cardiovascular disease.

Because of findings from the National Health and Nutrition Study (NHANES), a study conducted every five years, thirty micrograms of lead per deciliter is now the new, reduced cut-off concentration for a toxic lead blood level. In this study, the association between people who were dying from cardiovascular

disease, cancer, and all other causes, with chronic “low” lead levels was examined. Researchers discovered that about 70 percent of cancer deaths were associated with chronic low-level lead concentrations. That parallel is very significant. In addition, nearly 50 percent of cardiovascular deaths are associated with chronic low levels of lead.¹⁶ (Figure 1)

Bioaccumulation is a Core Issue that Needs to be Addressed

The measurement of chronic low levels of heavy metals in the body is a core issue in preventing heavy metal toxicities. Thus instead of crisis management and attempted removal of heavy metals from blood and tissues, there is a need to concentrate more on preventive methodologies. Unfortunately, there are no “safe” or “acceptable” levels of these oxidizing agents in blood. Low levels are dangerous because they allow tissue accumulation and can therefore become stored for long periods of time in the body. Since the blood levels of heavy metals are likely in equilibrium with tissue levels, the tissue levels become higher as toxic heavy metal concentrations increase in the blood circulation.

There are various sources of heavy metals in blood circulation that eventually accumulate in tissues. One exposure source of this heavy metal is the nearly ubiquitous amalgam dental filling. According to the American Dental Association, the life of amalgam material in the mouth is seven to eight years and recently the United States Food and Drug Administration (FDA) finally acknowledged that we need to start addressing this issue. After eight years the physical properties of a filling start to change, resulting in micro-leakage of mercury into surrounding tissues and eventually into the blood circulation. In some patients this can cause adverse neurobehavioral effects.¹⁷ Thus there is a need to rethink the old patterns of dentistry and use of heavy metal amalgams, including the difficulties involved in removing mercury and other metals.

In our clinic, we perform random blood samples on most patients. None of our patients are exempt of the presence of heavy metals in their blood. Thus every one of our patients has toxic heavy metals present in their blood and very likely in their tissues as well. The vast majority of those that are screened exhibit an excess over normal blood levels of at least three or four heavy metals. Most patients have multiple heavy metal concentrations that are in the elevated range, and several of them even reach potentially toxic ranges. (Figure 2) Consider how concerned a physician would be, if in every patient

blood sample, he found two to four different pathogenic bacteria! This could result in bacteremia, which can be a serious, even fatal, disease.

Random Blood Sampling of Dr. Ellithorpe's Patients: Presence of Heavy Metals

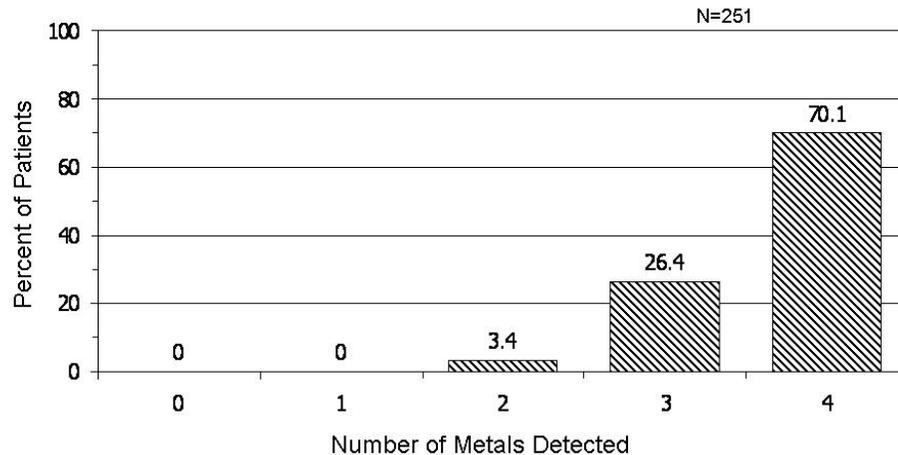


Figure 2. Random blood sampling revealed that the vast majority of those that are screened exhibit an excess over normal blood levels of at least three or four heavy metals.

REMOVAL OF HEAVY METALS BY EDTA CHELATION

Chelation is a modality that effectively eliminates heavy metals systemically: initially from the blood circulation and then the tissues in which they are sequestered. The standard method for eliminating heavy metals uses IV chelators, such as calcium disodium EDTA or DMPS. There are transdermal methods of treatment using DMSA, as well as oral chelating agents, such as penicillamine; however intravenous IV EDTA chelation is probably the best-known approach.

In contrast to oral EDTA, IV EDTA is well absorbed and this method of delivery been the gold standard of treatment for more than 70 years. However, newer non-invasive approaches, such as rectal suppository EDTA chelation, are effective and less expensive than IV EDTA, and there are studies validating the effectiveness of this modality. The rectal delivery method is simple and eliminates the need

to spend four hours at a time in an IV room. Rectal Suppository chelation ensures that EDTA is absorbed and bioavailable to all tissues and organs.

In our practice, we specifically use Detoxamin calcium disodium EDTA suppositories from World Health Products of Draper, Utah. We have confidence in this particular brand because its efficacy has been proven through clinical and pre-clinical studies. We have been using this modality clinically for nearly ten years, with tens of thousands of dosing experiences. It is quick, easy to use, safe, and inexpensive for the patient – approximately one-fourth or less the cost of IV treatments. Calcium disodium EDTA chelation supports broad-spectrum heavy metal removal and is approved by the United States Food and Drug Administration.

Rectal suppository chelation has been proven effective in pre-clinical and clinical studies. In one animal study, we used C14 radioactive-labeled EDTA and a carbon-based amino acid, and compared rectal suppository and IV methods of delivery in rats. Blood samples were drawn at various times from five minutes to eight hours and tissue samples were harvested at one and eight hours in both groups of animals.¹⁸ The study showed that although IV administration yielded high initial blood levels of EDTA that peaked within minutes, by one hour almost all of the EDTA had been excreted. In contrast, eight hours after insertion of anal suppositories there were still significant levels of C14 radioactive-labeled EDTA in the blood. When the tissue levels of EDTA were compared, there were also differences. For example, after eight hours there was greater than three-times the level of EDTA in prostate tissue from animals containing rectal suppositories than in animals given EDTA by IV administration.

The half-life of EDTA in suppository form has been compared to IV administration in animal studies. A half-life pharmacokinetic study of the trans-rectal and IV delivery systems was conducted, and we found blood-to-tissue ratio absorption almost 3.5 times higher with the trans-rectal delivery than the IV delivery of EDTA. IV EDTA showed a typical spike of delivery within minutes in the blood, with rapid removal pharmacokinetics and a half-life of approximately 1.5 hours. In contrast, the rectal suppository pharmacokinetics in the blood revealed a biphasic, more gradual rise and decrease with a half-life of over eight hours (Figure 3).

Pharmacokinetic Results of IV vs Rectal Suppository Administration

	Intravenous	Rectal (Suppositories)*
Absolute Bioavailability	100%	36.3 %
Blood to Tissue Ratio**	3.7	13.6
Half-Life	1.5 hours	8 hours +

* Detoxamin

** Prostate tissue

Figure 3. Pharmacokinetic results of IV EDTA versus rectal EDTA suppository administration.

The rectal admission of medicine is well established. However, the absorption of drugs has always been an issue. Some of the best transrectal medications only achieve 20-25 percent bioavailability. However, our animal studies revealed an EDTA absorption level from the calcium disodium EDTA suppositories of 36.3 percent compared to IV administration (Figure 3). The slow and constant movement of EDTA from the suppositories to the blood to various tissues is likely to have less toxicity than IV bolus administration. It delivers EDTA in a continuous, lower concentration for longer periods of time, allowing the EDTA to bind metals more efficiently and effectively.

Note that other EDTA suppositories may not be able to make the above claim, since they were not tested in similar animal studies. The research performed here used Detoxamin™ chelation suppositories and we can only recommend this suppository formula based on our studies.

Case Studies Using Calcium Disodium EDTA in Rectal Suppositories

The presence of heavy metals has been studied by us in over 3,000 patients using Doctor's Data (St. Charles, IL) to perform the meta analyses. Packed red blood cell analyses of one hundred percent of

these patients show the presence of heavy metals above threshold levels (Figure 2). When these patients use the CaNa_2EDTA chelation suppositories, their circulation is enhanced, in part probably due to a sparing effect on their endothelial cell nitric oxide synthetase. This is typically translated into a subjective improvement in expression of general well being, which we believe is due to improved perfusion throughout the body.

Other benefits include increased energy and endurance, and better mental clarity from enhanced nutrient delivery and detoxification. These patients also experience reduced blood pressure levels and improved erectile function. Laboratory studies for inflammatory markers also show reductions and HDL cholesterol improvements are noted.

K.M.

K.M. (5 foot, 6 inches tall, 131 lbs) was in her early fifties when she first sought treatment. She had gone on disability from teaching due to severe low back pain, chronic fatigues, postmenopausal symptoms, and hypothyroidism. She was on several prescription medications. She was seeking natural therapies and detoxification to improve her energy and menopausal symptoms. During her evaluation for oxidative stress, red blood cell analysis indicated the excess presence of four heavy metals: lead, arsenic, mercury, and cadmium. We initially gave her standard I.V. treatment (1.5 grams CaNa_2EDTA , 1.5 hours infusion time) plus oral 500 mg DMSA challenge, with a six-hour urine collection for heavy metal analysis. Her heavy metal analyses are shown in Figure 4. We then prescribed 750 mg of rectal CaNa_2EDTA suppositories three nights a week (total of 90 suppositories) and she completed this regimen within 7.5 months, after only using the suppositories twice a week. After 9.5 months, she returned for a repeat IV challenge identical to the first treatment. Analysis showed that she had a large drop in mercury and lead levels in her blood cells. Although CaNa_2EDTA is primarily an approved chelator for lead, it will chelate mercury and other metals. CaNa_2EDTA was chosen for its broad spectrum of chelating several metals and its long safety record over the past 70 years.

K.M. remained on a maintenance dose of one suppository a week for one year. When tested at that time, she continued to maintain reduced levels of heavy metals, despite a protein-rich diet, often consuming fish with probable mercury exposure. With exercise three times a week she has stable,

improved low back pain on fever pain medications and improved energy. This patient is typical of those who continue to use CaNa_2EDTA suppositories for over six months on at least an average of twice a week.

Practical Clinical Case Study

Patient K.M.

55 y/o • W • F • 131 lbs. • School Teacher • Chronic LBP • Fatigue • Hypothyroid

Date	Cadium	Mercury	Lead	Nickel
5/03	1.7	30	43	9.5
2/04	1.0	2.6	27	17
2/05	1.0	18	27	13

Outcome: 7/04 – Excellent energy • Exercise 3x/day – water aerobics • Back pain stable • Reduced need for medications.

Figure 4. Results of a clinical case study show that this patient's blood levels of cadmium, mercury, and lead dropped significantly after treatment with rectal CaNa_2EDTA suppositories, even though the patient did not use the treatment as regularly as prescribed.

F.K.

F.K. is a 42 year-old perimenopausal woman (height 5 foot, 5 inches, 145 lbs), who worked in photography and developed chronic fatigue, hypothyroidism, and insomnia. She also sought as natural as possible means to improve her energy, sleep, and oxidative stress. As expected, she also had above threshold levels of several toxic heavy metals, including arsenic, on a random red blood cell analysis. She was given the same IV CaNa_2EDTA (1.5 gm) challenge with 500 mg oral DMSA and her urine was collected six hours later. At six hours her arsenic levels were elevated, along with significant elevations in cadmium, lead, mercury, and nickel (Figure 5). She then received rectal suppositories CaNa_2EDTA (750 mg), three nights a week. F.K. was a very compliant patient and kept up with the three nights per week treatment, and the challenge was repeated as above five months later. We normally treat for at least six

months or a minimum of 60 suppositories, which most patients usually accomplish by the sixth or seventh month. F.K. was motivated since she knew her photography work exposed her to heavy metals and other toxins and she was concerned about the elevated arsenic levels. Interestingly, arsenic is found in chicken meat which she primarily consumed as her main source of protein. According to *Chemical & Engineering News*, an arsenic-based additive used in chicken feed is linked to multiple health risks in humans.¹⁹

Practical Clinical Case Study

Patient F.K.

42 y/o • W • F • 145 lbs. • Photographer • Fibromyalgia • Chronic Fatigue • Hypothyroid

Date	Arsenic	Cadium	Lead	Mercury	Nickel
8/02	220	2.5	20	24	49
12/02	4.5	2.1	7.4	15	25
5/03	45	3.2	12	8.9	18

Outcome: 11/04 – Energy good • Exercises daily (45 min.) with mild to moderate pain of fibromyalgia • Increased daily activities

Figure 5. Results of a clinical case study show that the patient's blood levels of arsenic, cadmium, lead, mercury, and nickel dropped significantly after treatment with rectal CaNa₂EDTA suppositories.

By four months, her arsenic level had dropped dramatically, as well as her other toxic metals (Figure 5). She continued on a maintenance dose of one 750 mg suppository weekly. Her 10-month challenge showed fairly good maintenance of the reductions in heavy metals (Figure 5). On follow up, K.M. admitted she skipped some doses and continued to enjoy chicken, although she used free range chicken more often. She reported improved energy and was able to exercise daily for 45 minutes. She reduced her need for pain medications, had improved sleep, and was experiencing reduced perimenopausal symptoms.

M.O.

M.O. is a 52-year-old male, (5 foot 8 inches, 175 lbs) electrician. He presented with palpitations and anxiety. He began to visit emergency rooms more often as his symptoms worsened, despite normal cardiology consultations. He was placed on antidepressant and anti-anxiety medication. He was also given a medication to reduce palpitations.

Because of the high association of heavy metals with cardiac and neurological disease, we also did a random red blood cell analysis and found above threshold levels of four heavy metals (Figure 6). The same IV challenge was administered. He expressed an aversion to using rectal suppositories but was compliant at least half of the time. Instead of the recommended three nights a week he used one or two on the average, at most. Nevertheless, he showed reductions in heavy metals upon his repeat challenge five months later. The challenge was repeated four months later as he wanted reassurance that this was, in fact, reducing these toxins, despite not using the recommended dose per week. He found that his anxiety and palpitations were notably reduced and did not have any more emergency room visits.

Practical Clinical Case Study

Patient M.O.

52 y/o • M • 175 lbs. • Electrician • Chronic Anxiety Panic Attacks • Hypertension • LBP

Date	Cadium	Mercury	Lead	Nickel
10/02	1.2	5.2	27	8.4
2/03	0.9	4.4	18	3.6
10/03	1.4	9.8	20	1.6
5/04	0.7	3.8	16	7.7
12/04	1.0	1.6	12	12

Outcome: 10/04 – Anxiety greatly improved • Reduced need for auxiolytic medication • Improved BP • Reduced anti-hypertensive medication • LBP improved • Exercises daily (30 min.)

Figure 6. Results of a clinical case study show that the patient's blood levels of cadmium, mercury, lead, and nickel dropped after initial treatment with rectal CaNa₂EDTA suppositories, despite poor compliance. Poor results on a subsequent IV challenge motivated the patient to follow the prescribed treatment and results improved at later challenges.

M.O. continued with maintenance rectal CaNa₂EDTA suppositories once a week or less for eight months and another challenge was performed with mixed results (Figure 6). Mercury showed an increased level above his initial reading. However, he had his amalgams partially removed, which we felt caused some mercury contamination, in addition to his exposure in food and possibly work materials. Subsequently, his motivation to use the CaNa₂EDTA suppositories increased, and he used them at least twice a week. Seven months later, we found reductions again in heavy metals in his blood. We noted that his nickel levels varied, and we concluded that his exposure to nickel in his occupation also varied. With major reductions in the lead and mercury, this may have allowed for the CaNa₂EDTA to remove more nickel with continued use of the suppositories.

Practical Detoxification

In our patients, the IV CaNa₂EDTA (1.5 gm) and oral 500 mg DMSA challenge is a stress test for the amount and ease with which we can chelate heavy metals on a uniform challenge. This is similar to the concept of a stress treadmill to evaluate the performance of the heart muscle according to a standard Bruce protocol for concerns about circulation to the heart muscle.

A positive stress treadmill can suggest the potential for serious circulatory problems in the coronary vessels and may indicate which vessels are most likely involved. But the stress treadmill does not define exact degrees of blockage nor can it assess blockage within other areas such as the carotid vessels in the neck, which also can be significantly blocked. Nevertheless, the stress treadmill is a useful tool to assess for poor circulation in the coronary vessels.

Similarly, we know the bioaccumulation of oxidative toxic metals is primarily in more inert or slow-turnover tissues such as fat, bone, and ligaments. The actual amounts of heavy metals in these tissues never can be accurately known. Therefore, about one-half of the patients on repeat testing need a minimum twelve months of CaNa₂EDTA suppositories three nights a week until maintenance dosing of once a week can be employed. This can be reduced to twice a month maintenance treatments if repeat challenges show that the reductions in blood levels of heavy metals are maintained.

All patients are unique, and their ability to detoxify toxic metals varies. Some patients tolerate suppositories as often as seven nights a week, for up to three months, whereas others do not. We have used both the 750 mg and 1500 mg CaNa₂EDTA suppositories, and we have not found any adverse reactions to the treatments. Of course, we always do complete histories, physicals, and comprehensive chemistries to establish normal kidney function. The CaNa₂EDTA is primarily removed by the kidneys and secreted in the urine. For training on the use of EDTA chelation therapy using the standard IV administration, interested clinicians can attend EDTA chelation courses sponsored by the American College for the Advancement of Medicine (www.acam.org)

In my clinical experience, more severely ill patients, chemically sensitive or on dialysis, have been successively treated with CaNa₂EDTA suppositories, as the dosing can be reduced and/or extended over time intervals as suits the patient or clinician.

Generally, patients report a sense of improved wellbeing that progresses to notable mental clarity, less brain fog, more energy, warmer extremities, faster healing, and improved skin color. Even visual improvements are noted, such as reduced eye pressures and optics in eye glasses.

All of this could be due to reducing damage to the endothelial lining, improved nitric oxide synthetase activity, better vasodilatation and hence cell nutrition and toxic waste removal. Most encouraging are my male patients who experience remarkable erectile performance after six months of 1500 mg CaNa₂EDTA suppositories used three nights a week.

We also accumulate biofilm over the years. Various types of bacteria enjoy living in stressed and overused tissues. The poor perfusion, pH changes, and cell breakdown products provide food substrates for these pathogens. They are described as attracting calcium deposits and are, over decades, seen as calcifications in the prostate, breast, joints, vessels, etc.

The combination of CaNa₂EDTA, which begins to reperfuse these regions and the tetracycline 500 mg capsule on the nights a suppository is used, will destroy this biofilm according to some studies.²⁰

²¹ These studies were the basis for our research of chronic prostatism with established prostate calcifications on ultrasound. This therapy was shown to reduce both the symptoms and the calcifications.

CaNa₂ CHELATION SUPPOSITORIES SHOW PROMISE FOR PROSTATE DISEASE

Prostate disease is related to heavy metal toxicity. Prostate cancer, the most common type of cancer in the United States, kills a quarter of a million men each year. It occurs in one in six men and the number of diagnosed cases is rising rapidly. Prostatitis is a disorder related to an aging vascular system under oxidative stress.

Prostate problems can start with bacterial infiltration: urological infections involving biofilms, such as ureaplasma and mycoplasma. There is no effective treatment for pain, disorders of urinary/ejaculatory systems, and calcification. A variety of pathogens have been implicated in prostatitis.²² We know that we are dealing with bacteria, mycoplasma, urea, and Chlamydia biofilms and that these bacteria embed themselves in the cell wall lining of the vasculature. From coronary atheromatous plaque culture, they obtained antibody antigen identification and eventually cultured nanobacteria.

These biofilms contain salts, calcium, and other metal cations. They exhibit adhesion clustering, which causes localized infection and increased resistance to antibiotic treatment. The biofilms stress host immune responses because of their tenacious calcium covering.^{22, 23}

We conducted a study with 31 men, ages 40 to 73 (mean age 61).²⁴ A color Doppler transrectal ultrasound of the prostate established that all participants had calcification in that tissue. We assumed there was an inflammatory response in the tissue because when it cannot clear an infection, the body seals it off with calcium. In this study, all subjects exhibited symptoms of mild to severe benign prostatic hyperplasia (BPH). Seventeen of the participants had prostate cancer, and all of them had calcifications confirmed by ultrasonography. Treatment consisted of a CaNa₂EDTA (Detoxamin) 750 mg suppository, four nights a week at bedtime.

The subjects also took a multi-mineral vitamin and one probiotic each morning to offset the negative effects of tetracycline (500 mg/day), which was administered. Our understanding was, if there is a biofilm containing calcium salts it could be reduced by chelation suppository therapy to expose the escaping bacteria with a potent antibiotic. We conducted this study for three months and after conducting fasting chemistry blood panels, found no significant changes in the subjects' pre-comprehensive chemistry and post-90 day comprehensive chemistry. Thus, all safety parameters were established.

Results

We found that HDL cholesterol increased significantly and uric acid decreased significantly. The blood cholesterol-to-HDL ratio was improved. No significant differences in prostate specific antigen (PSA) levels were seen. We are currently completing a study involving longer treatment time and higher dosing 1500 mg of Detoxamin. At the lower-dose studies, we noted decreasing levels of lead, arsenic, and cadmium in the red blood cell analysis. We also saw excretion of heavy metals in fecal samples.

In the chronic pain syndrome scores for prostatitis pain symptomology, we found significant pre-versus post-treatment reduction in their pain, as well as a reduction of urinary and pain symptoms and increase in quality of life scores. The subjects said they felt better overall. Probability values (P) reached significant levels of less than 0.05 within all of the parameters stated above.²⁵ (Figures 7 and 8).

Treatment with CaNa₂ Suppositories Chronic Prostatitis Symptom - Total Scores

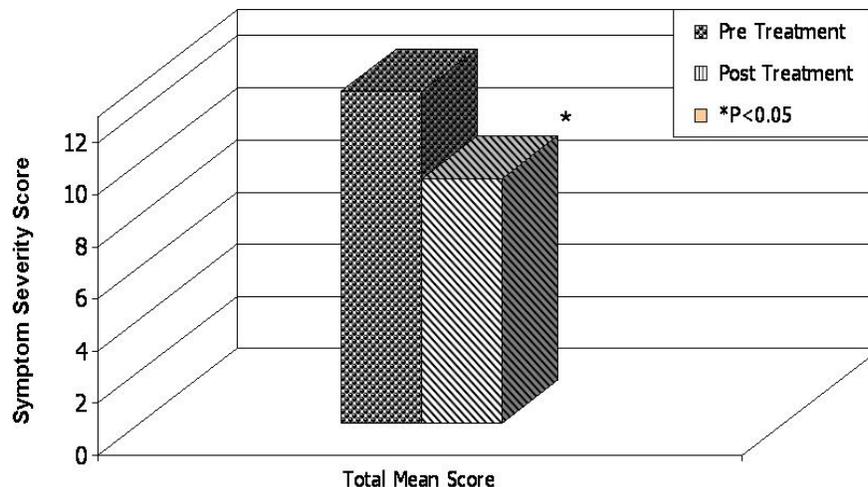


Figure 7. Treatment with CaNa₂EDTA suppositories led to a significant decrease in symptoms of chronic prostatitis.

There was a trend towards erectile function improvement in the first three months. However, we are seeing even better results, in about half of the individuals, on the second half of the study on the higher dose of 1500mg of CaNa₂EDTA suppositories that we are now completing. There was significant

laboratory data from red blood cells and fecal samples showing a decrease in lead, cadmium, arsenic, and tungsten (a heavy metal that originates from non-stick cookware).

Treatment with CaNa₂ Suppositories International Prostate Symptom Score (IPSS) Results

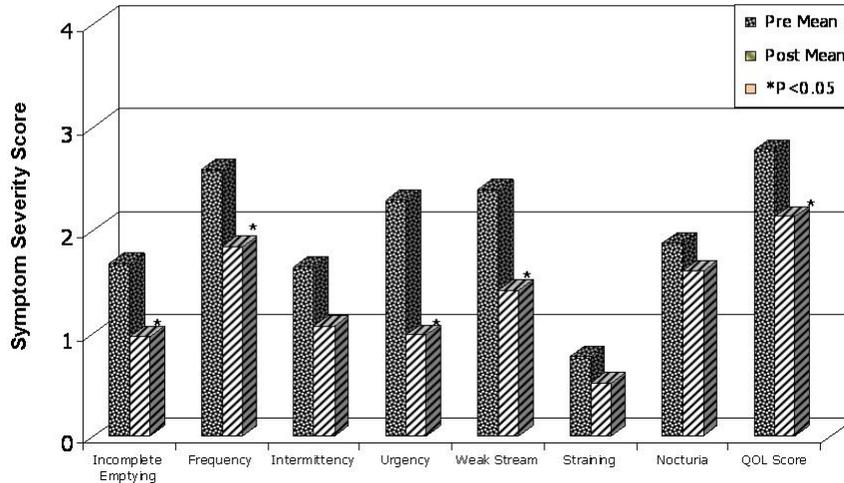


Figure 8. Treatment with CaNa₂EDTA suppositories markedly reduced the severity of symptoms of chronic prostatitis.

Summary

These observations were obtained from my private patients' experience in a general medical practice and validated with the pre-clinical animal studies using radioactive labeled carbon CaNa₂EDTA suppository and IV CaNa₂EDTA. The clinical trials have established the functional outcomes for prostatism with statistical significance. Also, laboratory pre- and post-heavy metal reductions, lipid profile improvements, of statistical significance and near statistical significance of erectile performance on the low dose arm of the trial. The higher dose 1500 mg CaNa₂EDTA arm of the clinical trials are pending publication but I can share even more superior results in all the earlier reports with erectile performance the most impressive in my experience.

This is due, I believe, to the unique ability to deliver CaNa₂EDTA at 750mg or 1500mg, with or without tetracycline, depending on the presence of calcium deposits in chronically damaged tissues, to people in an affordable, time-conserving method. Everyone is accumulating heavy metal toxins. Everyone needs to reduce them.

The relationship between diseases such as cancer and heart disease and oxidative heavy metals is clearly linked. Now we have to recognize that a lifetime of “low” chronic levels is as damaging and concerning as acute ingestions.

Fortunately, a solution is already available and studied. I see CaNa₂EDTA as “the” antioxidant for the 21st century. Just as vitamin C opened our understanding to oxidative stress in the 20th century, CaNa₂EDTA is opening our 21st century eyes.

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