

7/20/18

Amy Herdy and Kirby Dick

Update on Alaska Study of Arthroplasty Cobalt Encephalopathy (ACE): corrected version

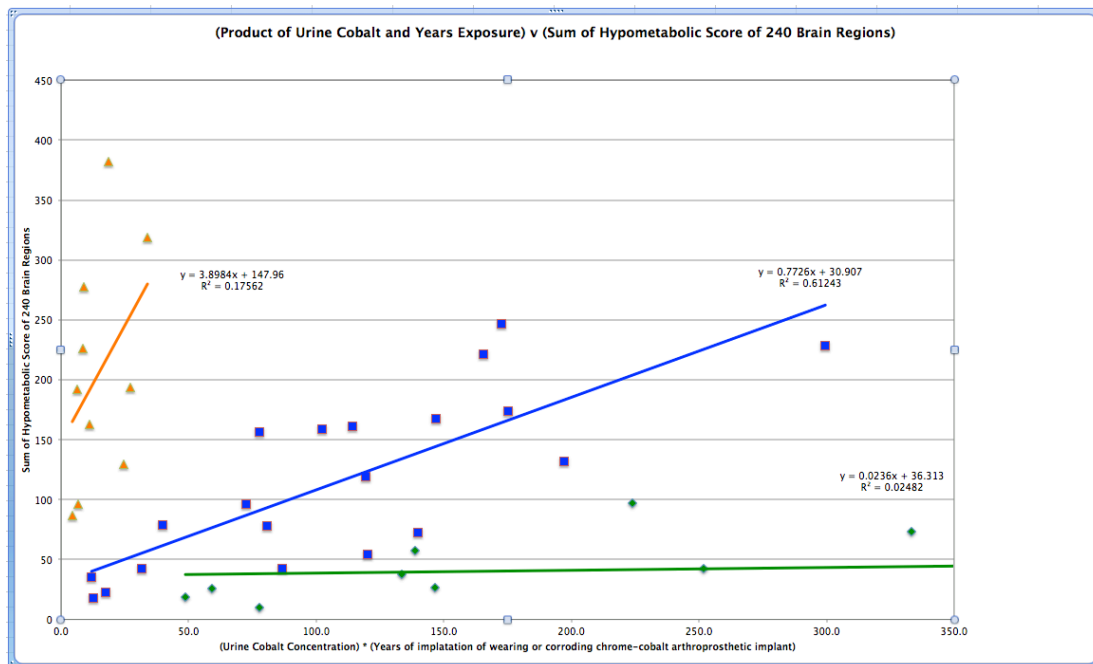


Dear Amy and Kirby,

Since you visited Anchorage in March 2017 our understanding of ACE has substantially increased. Our screening program of patients with an “at-risk-hip” (any chrome-cobalt part) that began March 2015 now encompasses 161 patients ... over half are peeing cobalt. Only a quarter of the cobalturic patients have the benighted Metal-on-Metal hips known to be problematic, most have currently popular Metal-on-Plastic hips.

81 percent of the 86-cobalturic patients have 2 or more symptoms of ACE as opposed to only 19 percent of the 74-non-cobalturic patients. This is an extremely statistically significant finding ( $p < 0.0001$ ). 40 of our cobalturic patients without confounding neuropathology have undergone FDG-PET Brain Studies. All scanned patients show the same pattern of brain hypometabolism consistent with Chronic-Toxic-Encephalopathy (CTE). Other heavy metals, solvents, chemotherapeutic agents, and carbon monoxide also cause CTE. Our findings indicate that cobalt accelerates brain aging, the areas of the brain affected by CTE are notably different from those affected by Alzheimer's, Lewy Body, or Frontotemporal dementias.

FDG-PET scan is a quantitative and sensitive measure of brain metabolism. Analysis of the data from our 40 scanned patients confirms that the severity of brain hypometabolism is a function of both the degree of cobalt exposure (concentration of cobalt in the urine), and the duration of exposure (number of years that the corroding or excessively wearing chrome-cobalt implant as been in place).



Notably, our scanned patients sort into three distinct clusters relating to the patients' degree of sensitivity to arthroprosthetically generated cobalt as expressed by global and focal brain hypometabolism. A quarter (**Orange Group**) is exquisitely sensitive showing profound brain hypometabolism in response to a relatively low product of their urine cobalt concentration and the number of years implanted with a chrome-cobalt hip or shoulder implant. In contrast, another quarter

**4100 Lake Otis Parkway, Suite 300, Anchorage AK 99508 | TowerOrthopedic.com | P: 907-222-2924 | F: 907-222-2934**

(Green Group) are comparatively immune to the adverse affects of systemically circulated cobalt ... showing only minor brain hypometabolism despite a high urine cobalt levels and decades of exposure. Half (Blue Group) fall between, the slope of the regression lines shows that the each group differs by an order of magnitude in degree of sensitivity to the ill effects of arthroprosthethically generated cobalt to its immediately adjacent group.

Collaterally, we found five patients with ACE whose shoulder replacements were the major sources of the patients' systemically circulated cobalt. We have yet to identify a patient whose prosthetic knee is solely responsible for elevated urine or blood cobalt levels but prosthetic chrome-cobalt knee components may contribute to the elevated blood and urine cobalt levels in our patients who also have hip or shoulder chrome-cobalt arthroprosthetic components.

Most but not all of our patients with ACE confirmed by brain imaging who have undergone revision surgery to remove the source of systemically circulated cobalt have improved neurologically within a year.

In a nutshell ...

- One million Americans are at extreme risk for ACE from now disfavored Metal-on-Metal hip replacements and resurfacings. Most of these patients are not aware that they are at risk for systemic cobalt poisoning.
- 5-10 million Americans are at indeterminate risk (likely varies by brand and model) for ACE from presently popular Metal-on-Plastic hips. Neither patients nor surgeons are aware of the potential for cobalt poisoning from non-Metal-on-Metal hip replacement.
- One million Americans are at indeterminate risk for ACE from their replaced shoulders. Nearly all-prosthetic shoulder systems employ modular chrome-cobalt implants. Patients and surgeons are unaware of the risk of cobalt poisoning from shoulder replacements.
- People fall into three markedly different groups concerning their sensitivity to the ill effects of arthroprosthethically generated cobalt: exquisitely sensitive, relatively immune, and an intermediate group. Each group is separated from its neighbor by a ten-fold difference in dose-response to U[Co] and duration of exposure.
- Dr. Tower's decade of experience attempting to raise awareness of the risk of cobalt poisoning from chrome-cobalt arthroprosthetic implants indicates that industry and the orthopedic surgeons that collaborate with industry appear inclined to turn their blind eye and a deaf ear to the problem. The FDA in the US and the MHRA in the UK appear disinterested, this likely indicates that they have been "captured" by industry.
- Dr. Tower no longer implants any chrome-cobalt arthroprosthetic components because proven safe alternatives exist. Dr. Tower monitors all of his patients already implanted with chrome-cobalt hip or shoulder arthroprosthetic parts with a yearly urine cobalt level. Those patients with a U[Co]  $\geq$  1 part per billion (ppb) are queried about the symptoms of arthroprosthetic cobaltism.
- FDG-PET brain scan is the entity of choice to diagnose Arthroplasty-Cobalt-Encephalopathy (ACE). Dr. Tower recommends patients with a  $\geq$  2 ACE symptoms and an U[Co]  $\geq$  1 ppb get an FDG-PET-Brain-Scan (FPBS). If the FPBS confirms brain hypometabolism with the Chronic-Toxic-Encephalopathy (CTE) pattern Dr. Tower discusses the alternatives, risks, and benefits of revision arthroplasty to remove the source of the systemically circulated cobalt.
- Dr. Tower's decade of experience revising hips and shoulders for cobalt complications suggests that most patients with ACE experience neurologic improvement within a year of revision surgery involving exchanging excessively wearing or corroding chrome-cobalt components for stainless steel, plastic, or ceramic alternatives. Six of our revised patients show improved brain metabolism on repeat FPBS 6-12 months post remediation with documentation of decline in urine cobalt levels. Two patients that deferred remediation show progression of brain hypometabolism 1-2 years after their index scan.