E19 ARMD and Dangerous: Adverse Reaction to Metal Debris, Metal on Metal Joint Replacements, and Present Toxicological and Legal Challenges

Karl G. Verebey, PhD, Ammon Analytical Laboratory, 1622 South Wood Avenue, Linden, NJ 07036; and Samuel L. Davis, JD*, 375 Cedar Lane, Teaneck, NJ 07666-3432*

After attending this presentation, attendees will learn about a newly identified complication of joint replacement surgery currently identified by a number of different and confusing names. The information gap on the toxicology of low levels of heavy metals will have short term and long term consequences for clinical medicine, public health, medical device innovation, and regulatory policy.

This presentation will impact the forensic science community making attendees aware of data that is currently lacking on the biological effects of long term low level heavy metal concentrations in the body. Legal, political, public health, and regulatory debates are filling this vacuum with polemics and speculation. It is recommended that attorneys in this medico-legal debate be mindful of the potential harm yet recognize the limits of current knowledge. Clinicians and researchers should seize upon this opportunity to advance the state of knowledge and fill this vacuum.

Hypothesis or Proposition: Shedding of metal microparticulates from so-called metal-on-metal joint prostheses is a clinical phenomenon with potentially toxic consequences. Toxicologists must identify the biomedical significance of elevated levels of metals used in joint replacement surgery. Inconsistent naming conventions for the phenomenon are hampering clinical assessment of its import to patients, physicians, and regulators.

Synopsis of Content: Medical science has been experimenting with suitable materials for human joint replacement since 1891 when a German doctor tried to substitute ivory for the head of the femur in a hip joint. Since then, various mundane and ultra sophisticated materials have been tried and tested with varying degrees of success. Use of cobalt-chrome surfaces to replace both the hip and femoral sides of the ball and socket hip joint, so-called "metal-on-metal (MoM)", began in the 1950's and continues today with the application of harder alloys and precision surfacing equipment.

Yet friction forces that degrade the metal surfaces are inevitable. The tribology of friction, wear, and lubrication in these anatomical bearing surfaces dictate the toxicological potential of the bearing materials. Micro particulates and metallic ions migrate from the immediate joint space throughout the body and across the placental barrier. Blood and serum levels of cobalt and chromium that equal or exceed EPA and OSHA permissible exposure limits (PELs) are increasing in frequency. Certain devices using the MoM design are reported with higher than expected failure rates due to component loosening.

Toxicological screening now measures heavy metal levels in the low parts per billion ranges. The pathological significance of these findings is uncertain, but they have become an indication for costly and risky revision surgery in the absence of other signs or symptoms of prosthetic failure.

Local tissue toxic reactions are identifiable by gross visual inspection and characterized by frank tissue necrosis and cellular organization into pseudotumors. Variously names are used to link their pathological features to their identified cause: metallosis, adverse reaction to metal debris (ARMD), arthroplasty-related metal disease (ARMD), periprosthetic cobaltism, aseptic lymphocytic vasculitis- associated lesions (ALVAL), and others. No uniform set of diagnostic criteria has yet been devised.

The actual number of U.S. patients that have received or will have joint replacements with metal-on-metal joint couples is unknown. Medicolegal concerns about alleged design defects and inadequate warnings to patients and physicians have discouraged but not eliminated use of the metal-on-metal design. Public health policies recommending medical monitoring for affected patients will be valued in the millions of dollars.

Diverging, if not conflicting, regulatory pronouncements by the FDA and its European counterparts leave device manufacturers and their customers at a loss to decide what is or is not safe and effective. Political debate over a stricter or more lenient regulatory policy governing device approval reflects the contest between the free market and the public health. Litigation, rather than science, is now driving research into the toxicology of metallic ions widely disseminated throughout the human body.

General Statement of Conclusion: The science of toxicology needs to re-capture the initiative on the biological consequences of a body burden of metallic ions and microparticulates. Pending litigation that is seeking damages for short term and long term medical monitoring is based in part on extrapolation from existing industrial exposure investigations. Defining what are safe and unsafe heavy metal levels have tremendous economic and medical consequences for individual patients, health care providers, medical device innovators third party benefit payors, and litigants.

Metal-on-Metal, Joint Replacement, Cobalt Poisoning

 ** Presenting Author*