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Comment

Metallic debris from orthopaedic implants

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Total hip replacement has revolutionised the management of patients with endstage arthritis of the hip. It is the second most common elective surgical procedure in the UK. In the 1960s and 1970s, total hip replacement was reserved for elderly and substantially disabled people. Now, ever-younger patients seek replacement surgery to deliver quality-of-life aspirations.¹

An implant of metal coupled on ultrahigh-molecular-weight polyethylene (a resilient plastic) was the globally preferred articulation throughout the 1970s and 1980s. Aseptic loosening caused mainly by osteolysis emerged as the major cause of failure of total hip replacement.² The osteolysis was attributed to the cytochemical response to the generation of micron and submicron particles of polyethylene.³

Recognition of the problems associated with polyethylene resulted in a striking increase in the use of metal-on-metal implants, especially for younger patients (<50 years of age). More than 300 000 metal-on-metal (cobalt chrome on cobalt chrome) couples have been inserted in the past 10 years. Two types of metal-on-metal implants are in use: total joint replacement and the bone-conserving surface replacement endorsed by the UK National Institute of Clinical Excellence.⁴

Although the volumetric wear of metal-on-metal bearings is substantially less than that with metal-on-polyethylene, a far greater number of much smaller particles are produced. Increased concentrations of metal ions have been widely reported in the peripheral blood and urine of patients with metal-on-metal couples.^{5,6} The changes in patients' demographics and the materials used for the articulation will increasingly result in younger patients being exposed to higher

amounts of metal ions and particles for extended periods. Both particle-mediated and metal-mediated diseases could have long latency periods. Therefore, health and safety assessments are essential to monitor changes in the very long term.

The long-term risk of cancer has been examined in several epidemiological studies,⁷⁻¹¹ especially from Scandinavia, where there are good records and hip registries. Thus far, no consistent risks have been identified. However, many of these studies were underpowered and the follow-up period was short and less than the accepted latent period for metal-induced cancers. The International Agency of Research on Cancer reviewed the evidence of 14 epidemiological cohort studies in six countries in 2000.¹² Because of insufficient evidence, the Agency assigned orthopaedic implants of complex composition to a group 3 classification (not classifiable for carcinogenicity in human beings).

Metal ions in solution or in particulate form have been shown to cause delayed type IV T-cell hypersensitivity,^{13,14} dose-dependent cell necrosis,¹⁵ and mutagenic changes.¹⁶ The Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment released a statement in July, 2006,¹⁷ which concluded that "there was good evidence for an association between cobalt chrome on cobalt chrome and cobalt chrome or titanium-aluminium-vanadium on polyethylene hip replacements and increased genotoxicity in patients". The implications of these mutagenic changes are unclear.

Metals are known to produce complex biological actions with immunological, mutagenic, and toxic effects. Both the law and health-and-safety committees provide a clear and exacting framework for the control of exposure and monitoring of human beings, should they be in contact with chromium and cobalt from the environment or as a result of working in industry. However, no corresponding guideline or legal requirement exists for the control of exposure of orthopaedic patients to these same metals if a surgeon has implanted a joint replacement. Different countries provide guidelines or acceptable limits of environmental and industrial exposures, with thresholds which, if exceeded, require a change in industrial practice to limit the exposure. But no corresponding exposure limits exist for metals released from orthopaedic implants, although concentrations have frequently been recorded that exceed the thresholds established in industry. Currently, no practical notion of biomonitoring can be applied to orthopaedic implantation surgery, as it is in industry for a worker exposed to the same metals.

However, joint replacement surgery has revolutionised the management of patients with endstage arthritis, and will remain to be the treatment of choice for the foreseeable future. Therefore risks should be carefully weighed against benefits. Risks associated with strategies introduced to reduce the occurrence of revision surgery need to be assessed against a 2.6% risk of death within 90 days after total hip revision.¹⁸ Notwithstanding the huge benefits of joint replacement, a system should be introduced to monitor any putative (so far untested) clinical side-effects of the procedure.

The establishment of a National Joint Registry in England and Wales is to be applauded. However, all requisite information regarding composition of the component and materials used for the bearing surfaces must be available either from the registry or from the clinical records. Data generated from this registry should be readily cross-correlated with other medical data to assess various short-term and long-term effects.

Little is known about the transport, distribution, and excretion of metal ions in the body. The long-term biological implications of the systemic dissemination of metallic debris and toxic-effect thresholds have not been characterised, nor has the risk of exposure to metallic debris for 20–60 years. However, ignorance is no cause for complacency. Although these concerns are currently theoretical, our lack of knowledge dictates that we urgently need to implement a programme of research that will address these issues.

We declare no conflict of interest.

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