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Hydrophilic polymer embolism: past obstacles and future progress

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Dear Editor

In 2009, we published in *HUMAN PATHOLOGY* a case of cerebral infarction and death due to embolization of hydrophilic polymer vascular device coatings [1]. Subsequently, we showed that embolization of polymeric device coatings occurs throughout the body and is associated with various devices and interventional procedures [2]. A retrospective analysis recently published in the journal demonstrated that the histopathologic frequency of this iatrogenic phenomenon at autopsy was at least 13% [3]. Moreover, the article entitled “Polymer-induced central nervous system complications following vascular procedures: spectrum of iatrogenic injuries and review of outcomes” [4], published in the current issue, highlights diverse clinical sequelae associated with cerebral polymer phenomena, including neuroinflammation, cerebral volume loss, chronic hydrocephalus, immunosuppressive dependency, ischemic and hemorrhagic stroke, and systemic inflammatory response syndrome. In some cases, these iatrogenic complications necessitated additional medical procedures, contributed to increased cost and length of hospitalization, and caused death of patients.

The evolution and significant advancements in interventional technologies over the past 3 decades have allowed for treatment of patients in cases where previously impossible. With novel nanotechnologies, however, have come novel nanodiseases that require vigilance and underscore the important role of diagnostic physicians and medical autopsies in this modern era. Despite publication of serious polymer reactions several years ago, progress on this topic has been slow, and dissemination of these findings to a broader clinical audience has been fraught with difficulties.

Differences in opinion among diagnostic physicians who have not previously encountered these foreign materials and cautiousness on the part of treating physicians to disclose details of unexpected negative outcomes have prevented and delayed reporting of these cases. Among numerous other factors, lack of research funding in this area has also greatly contributed. Furthermore, manufacturers have been reluctant to openly discuss proprietary ingredients and specific coating processes. Skepticism and conflicts of interest led to lengthy, inconsistent reviews at clinical journals, and some editors and reviewers at clinical

journals asked, “If these polymer complications truly occur, shouldn't we already know about them?” whereas others questioned the overall significance and whether publication of associated findings would actually lead to changes in regulation, manufacturing or clinical practice. Without widespread recognition or accepted guidelines, a lack of information on this topic contributed to further uncertainty and confusion as to how to diagnose and manage affected patients. Even when accurately identified on postmortem exams, many pathologists have been unsure how to interpret adjacent tissue changes, and in some cases, risk management specialists have been wary to communicate details of these complications to patients and their families.

We thank HUMAN PATHOLOGY for the important role it has played in disseminating knowledge on this topic to the medical community [1·3–5]. Although the impact of these findings remains to be determined, formal documentation and reporting of these cases and their sequelae were an important step toward raising public awareness on this issue. The US Food and Drug Administration has received around 500 medical device reports (MDR) describing separation of coating materials from vascular devices over the past 2 years, and increased knowledge on this subject has recently triggered a new Food and Drug Administration Safety Communication [6]. Further studies on polymer phenomena are needed to identify etiologic, preventative and therapeutic strategies. In light of numerous competing interests, progress will likely continue to be slow. However, more open discussions among and between manufacturers, engineers, researchers, administrators, diagnostic and treating physicians and regulatory agencies would help shed light on these issues. Improvements in this area may ultimately lead to refinement and advancements in the next generation of vascular technologies, and to additional opportunities for improved patient care.

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