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Hydrophilic polymer embolism: An under-recognized iatrogenic cause of ischemia, inflammation and coagulopathy

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Dear Dr. Lloyd

In 2009, we published in *Human Pathology* a report detailing an endovascular complication in a patient who died from widespread intracranial dissemination of hydrophilic polymer microparticles [1]. The foreign materials originated from the surfaces of microcatheters, guidewires and endovascular coils used in a recent aneurysm coiling procedure, and contributed to significant postoperative cerebral infarction. To our knowledge, this was the first documented case of mortality and the phenomenon of hydrophilic polymer embolism (HPE) was reported to the U.S. Food and Drug Administration and hypothesized to be an under-recognized iatrogenic cause of ischemia and infarct [2].

In our current publication entitled “Hydrophilic polymer embolism and associated vasculopathy of the lung: prevalence in a retrospective autopsy study” [3], we analyzed the histologic frequency of HPE at autopsy. In this comprehensive investigation, nearly 5000 hematoxylin and eosin-stained autopsy slides originating from 136 patients were screened for HPE. We found that (a) the autopsy prevalence of HPE was higher (at least 13%), and the burden of pulmonary involvement in some patients was greater than we had initially anticipated; (b) most iatrogenic microemboli were overlooked on initial autopsy evaluation; (c) among patients with multifocal pulmonary involvement, clinical reports sometimes documented constitutional changes, suspected pulmonary embolism, vasculitis and coagulopathy of unclear etiology; and (d) these unexplained clinicopathological changes occasionally contributed to morbidity.

Accumulating reports now highlight diverse vascular reactions associated with embolization of foreign polymeric materials and implicate various catheters and endovascular devices in this phenomenon. Although surface irregularities of drug-eluting cardiac stents have been evaluated extensively after deployment *in vivo* [4], the integrity of other coated vascular devices has not been investigated to the same extent [5], despite their greater surface areas and more abundant coating materials. Moreover, preliminary scanning electron microscopic analyses conducted by our group show that prominent delamination (Fig.), including multifocal linear scrapes (Fig. B), cracks (Fig. C), and surface craters (Fig. D) are typically

found on the surfaces of various brands of coated catheters and microcatheters tested following routine use in experimental swine models, suggesting further that this phenomenon of HPE may be substantially under-recognized.

Progress on this subject is pertinent to the medical community at large. Our current publication highlights the prevalence of HPE among hospital autopsies [3] and illustrates potential relevance of its occurrence to pathologists, radiologists, pulmonologists, neurologists [6], cardiologists, interventionalists, immunologists, and hematologists, among other physicians, engineers, manufacturers, polymer chemists, and regulatory agencies. Through our current report, we hope to bring an increased awareness of this phenomenon to the broader clinical community. A heightened recognition of this potential complication should hopefully lead not only to improvements in pre-mortem diagnosis and reporting of this under-recognized iatrogenic event, but also to advancements in the design and regulation of novel vascular devices and emerging nanotechnologies.

Sincerely,

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Figure. Scanning electron microscopic images of coated microcatheters as control (A) and tested in swine models (B-D). Delamination patterns include scrapes (B), cracks (C), and craters (D); scale bars 200 μm .