Necrotic leg ulcers secondary to hydrophilic polymer gel emboli

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ABSTRACT
A 63-year-old man presented with left lower extremity ischemia and pain. Left lower extremity angiography revealed calcification throughout the superficial femoral artery, prompting atherectomy and angioplasty with a drug-coated balloon. About 1 week after the procedure, he developed angulated ulcers with central eschar on the left lower extremity and was referred to the dermatology clinic. A biopsy showed cutaneous intravascular foreign material consistent with hydrophilic polymer gel. In patients who develop retiform purpura and ulcerations after endovascular procedures, the diagnosis of hydrophilic polymer embolus should be considered. Treatment consists of supportive care, making early identification vital to avoid unnecessary amputation. (J Vasc Surg Cases and Innovative Techniques 2019;5:310-3.)

Keywords: Hydrophilic polymer gel; Revascularization; Emboli; Ulcers; Purpura; Angioplasty

During the past 20 years, polymer gel-coated endovascular devices have become more ubiquitous as physicians in various specialties use minimally invasive procedures for revascularization. Both hydrophilic and hydrophobic polymer compounds have been used to decrease friction between vessels and endovascular devices. The hydrophilic polymer compounds, because of their ability to absorb water, have an overall lower coefficient of friction, allowing smoother movement through the vasculature. In contrast, hydrophobic polymers do not absorb water and glide less easily. The hydrophilic polymer coating was first introduced by Cook Medical (Bloomington, Ind) on arterial introducer sheaths to minimize friction between vessel walls and endovascular sheaths to decrease vessel spasm and pain. In a bilaminar hydrophilic polymer system, the base coat adheres to the surface of the device and is chemically bonded to the top layer. Weakness of these chemical bonds can cause the coating to lift away from the device and embolize intravascularly to other vessels and organ systems, including the skin. In 1997, Barnwell et al first reported the histologic presence of a foreign material consistent with hydrophilic coating of a catheter used in neurointerventional procedures. Physicians in other specialties soon began considering iatrogenic polymer emboli in patients experiencing a sterile inflammatory response at access sites after radial artery catheterizations. Case reports of hydrophilic polymer emboli manifesting cutaneously show an average onset of lesions 24 hours to 2 weeks after a procedure and with various clinical features. We describe a unique case of necrotic leg ulcers and retiform purpura secondary to iatrogenic hydrophilic polymer gel emboli and the utility of skin biopsy in confirming this diagnosis. The case was discussed with the patient, and permission was obtained for teaching purposes.

CASE REPORT
A 63-year-old man presented with left lower extremity pain at rest. He reported a surgical history of right below-knee amputation secondary to complications of peripheral artery disease and a medical history of stage IV small cell lung cancer, atrial fibrillation, chronic obstructive pulmonary disease, hypertension, and type 2 diabetes mellitus. The patient denied a history of renal disease, and laboratory values showed normal kidney function. Left lower extremity angiography revealed significant calcification and stenosis in the left superficial femoral artery, most heavily at the adductor canal. An atherectomy device was placed with intraoperative improvement of the area of greatest calcification. Subsequently, angioplasty was performed with a drug-coated balloon. The patient experienced an unremarkable postoperative course and was discharged 1 day later. About 1 week after the procedure, an ulcer developed on the left posterior calf with red granulation tissue, moderate serosanguineous drainage, surrounding eschar, and reticulate purpura. A sharp debridement with curettage was performed down to subcutaneous tissue, and the patient was referred to the dermatology clinic for further evaluation.

Physical examination revealed multiple angulated ulcers with central eschar and a peripheral rim of erythema as well as reticulate nonblanchable purpura on the left lower extremity (Figs 1 and 2). A 4-mm punch biopsy was performed, showing an ulcer with underlying...
cutaneous intravascular foreign material consistent with hydrophilic polymer gel (Fig 3). The patient completed a 2-week course of trimethoprim-sulfamethoxazole for a superimposed methicillin-resistant *Staphylococcus aureus* wound infection and was later treated with clobetasol 0.05% cream twice daily for 4 weeks with consistent wound care clinic visits. The ulcers healed significantly during the next 4 months.

**DISCUSSION**

It is estimated that >200 million individuals worldwide experience peripheral artery disease, with a gradually increasing prevalence.\(^{10}\) Advancement in revascularization procedures performed by vascular surgeons during the last 20 years has played a significant role in management of the most severe form of peripheral artery disease, including critical limb ischemia and tissue necrosis.\(^{10}\) The addition of hydrophilic polymer coatings to the surfaces of catheters, stents, balloons, guidewires, and other revascularization devices decreases the coefficient of friction, which therefore allows for easier passage and less vessel spasm through narrow vascular spaces.\(^{11-14}\) Similar devices are used by interventional cardiologists and radiologists, neurosurgeons, and nephrologists in addition to other subspecialists in the revascularization and repair of vessels of the lungs, heart, brain, and kidneys.\(^ {14-17} \) Despite its utility, the polymer gel coating can become a problem if weakness in the chemical bonds of the bilaminar structure leads to separation of the base coat from the metallic surface of the device.\(^5\)

The polymer material can then embolize through the vasculature and travel to distant organ systems, including the small vessels of the skin located in the dermis.\(^ {5,18} \) Many causes of polymer separation have been described, including overmanipulation of devices in small and tortuous vessels, heavily calcified atherosclerotic vessels, repeated interventions, and multiple attempts at vascular cannulation.\(^3\) In other circumstances in which revascularization devices were exposed to 0.9% saline for anywhere between 15 and 60 minutes, hydrophilic coating was shed from the surface of the catheter. The U.S. Food and Drug Administration (FDA) acknowledged in a 2015 Safety Communication that there is an increasing concern of polymer coating separation. The FDA is developing testing strategies to evaluate coating performance and to improve device standards.\(^2\)

Polymer coating emboli in the dermal vasculature can appear clinically as nonpalpable petechiae and purpura, reticulate purpura, acute and chronic ulcerations, hyperkeratotic and lichenified nodules, and hemorrhagic panniculitis.\(^ {3,5,7-9,19} \) Similar findings can also be seen in conditions such as vasculitis, venous stasis ulcers, cholesterol emboli, and calciphylaxis. The absence of kidney disease and normal kidney function on laboratory studies decreased the likelihood of calciphylaxis as a cause of the leg ulcerations. Typically, cutaneous lesions appear anywhere from immediately after the procedure to about 2 weeks later; however, cases reported by
Goto et al. and Hamidi et al. also indicate cutaneous sequelae occurring 4 to 6 months later. Although the patient in this case experienced an uneventful postoperative course with successful intraoperative revascularization, about 1 week later he was seen in the outpatient vascular surgery office with new onset of necrotic ulcers, which prompted referral to the dermatology clinic as repeated imaging confirmed patency of the vessels. A punch biopsy of the affected skin was performed, and findings were consistent with those presented in other case reports: polymer gel emboli appearing as nonrefractile, basophilic, amorphous material occluding vessels of the mid-dermis (Fig 4). In other cases, colloidal iron staining has been used to identify the polymer material within vessels, but it is not necessary for diagnosis as it can be visualized with hematoxylin-eosin.

Treatment of hydrophilic polymer gel emboli in the cutaneous vasculature consists of supportive care as the gel material will gradually degrade during a period of weeks and does not require additional surgery, which is why early identification is vital to avoid unnecessary amputation. In addition, a high-potency topical steroid was prescribed once the infection resolved to alleviate inflammation, in addition to regular visits to a wound care clinic. Although there is no one specific treatment, various topical medications can be prescribed by a dermatologist to alleviate the symptoms of the associated skin findings and secondary infections.

CONCLUSIONS

In patients with new onset of necrotic ulcers and retiform purpura about 1 to 2 weeks after an endovascular procedure, the diagnosis of iatrogenic hydrophilic polymer gel embolus should be considered. A multidisciplinary approach and application of clinicopathologic correlation in the identification of these lesions will ultimately improve patient outcomes.

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