Adverse Events Noted With Polyalkylimide Fillers

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Polyalkylimide dermal fillers can produce delayed adverse immune effects, including chronic inflammatory and granulomatous reactions, investigators reported in the Archives of Dermatology.

This is the first report of histologic granulomas related to polyalkylimide implants (PAIs) described in the literature, according to Dr. Jaume Alijotas-Reig of Vall d'Hebron University Hospital, Barcelona, and associates.

"Considering the increased use of polyalkylimide fillers in European countries and the United States, physicians should be aware that …delayed effects can occur with polyalkylimide implants just as they can with collagen, polyacrylamide, polylactic acid, or methacrylate," the researchers wrote.

PAIs are used for a variety of facial defects, including anatomic or traumatic deformities as well as aesthetic defects. They also are being used increasingly in lipodystrophy related to antiretroviral therapy in patients with HIV.

According to manufacturers PAIs do not change over time, do not move or migrate, and will not be reabsorbed, unlike other dermal implant materials. However, recent reports refute these statements, according to the investigators.

A voluntary registry of patients with delayed adverse effects related to implants was designed jointly by the Spanish Society of Cosmetic Medicine and Surgery and Dr. Alijotas-Reig and associates at the hospital's clinical immunology unit.

The researchers reported on 25 patients in the registry who had delayed adverse effects related to PAIs. Of the three study patients who were HIV-positive, two were not undergoing treatment with antiretrovirals.

"Multiple inflammatory tender nodules of different sizes, facial edema and/or angioedema, and swelling and/or skin induration were the most frequent local and/or regional complaints. …In six cases, distant or systemic manifestations appeared," including Sjögren's syndrome, they reported (Arch. Dermatol. 2008;144:637-42).

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Pseudoabscesses were also common. "Recovered material looks like pus, but bacterial cultures are usually negative for organisms," Dr. Alijotas-Reig and associates wrote.

The mean interval between implantation and symptom onset was 13 months (range, 1-60 months).

Other factors—such as smoking status, personal or family history of autoimmune disease, and "triggering" events such as infection or trauma—did not contribute to granulomatous reactions in these patients.

Of the 17 patients who had laboratory assessments, 12 had at least one abnormal result. These included elevated levels of C-reactive protein and fibrinogen in 11 of the 12, "so underlying inflammatory processes in different stages had to be present."

Five patients also showed elevated lactate dehydrogenase levels, which probably indicated lymphocyte or macrophage activation. Six patients had elevated levels of angiotensin-converting enzyme, which also might be secondary to macrophage and granulomatous immune responses.

Biopsy of facial and distant nodules was performed in three patients, and all showed nonspecific foreign-body granulomas.

All patients were treated with NSAIDs, and some also received hydroxychloroquine or low-dose prednisone. At least 15 had previously received antibiotics, which were ineffective.

After an average of 21 months of follow-up, 11 patients had achieved remission, 10 had recurrent or residual nodules, induration, or edema, and 4 were lost to follow-up.

"Although infrequent, delayed, moderate to severe immune-mediated adverse effects may be caused by PAIs, occasionally with systemic manifestations," the investigators concluded. ■

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