Fibrin sealant, aprotinin, and immune response in children undergoing operations for congenital heart disease.

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Abstract:

OBJECTIVE: Most commercially available fibrin sealants contain aprotinin in doses of 1500 kallikrein inactivator units per milliliter. They are used in many operative disciplines. An elevated risk of hypersensitivity reactions exists at reexposure to aprotinin. Our aim was to examine the immunogenic potency of aprotinin as a fibrin sealant content.

METHODS: We investigated 49 children with operatively treated congenital heart disease. All patients received aprotinin only topically as contained in fibrin sealant. Serum samples were drawn preoperatively, 1 week, 2 weeks, 6 weeks, and approximately 1 year after operation. They were analyzed for aprotinin-specific immunoglobulin G antibodies with a standard enzyme-linked immunosorbent assay and a fluorescence enzyme immunoassay for aprotinin-specific immunoglobulin E antibodies.

RESULTS: At 1 week, 2 weeks, 6 weeks, and 1 year, we found prevalences of 8% (2 of 26), 8% (2 of 24), 6% (3 of 49), and 0% for aprotinin-specific Immunoglobulin E, and for aprotinin-specific immunoglobulin G 8% (2 of 26), 17% (4 of 24), 39% (19 of 49), and 12% (5 of 41). The doses of aprotinin given did not differ significantly in antibody-negative and antibody-positive patients; no significant factors could predict the immune response.

CONCLUSIONS: Our findings show the existence of a subgroup of patients who had

aprotinin-specific antibodies develop after topical aprotinin application. Any use of aprotinin must be carefully documented. If aprotinin use is planned in patients who previously underwent a surgical procedure, preexposure to aprotinin in any form must be sought to avoid unexpected anaphylactic reactions. The necessity itself and alternatives for aprotinin as a stabilizing agent in fibrin sealants merit consideration.