

TITLE: INCIDENCE OF ANTI-PROTAMINE ANTIBODY IN VASECTOMIZED MALES
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Acute reactions to protamine include rash, urticaria, bronchospasm, pulmonary artery hypertension, and systemic hypotension, leading at times to cardiovascular collapse and death. Several putative high risk populations for serious protamine reactions have been identified. We have previously shown that in protamine-insulin dependent diabetics, the presence of anti-protamine antibodies is a significant risk factor for life-threatening reactions when iv protamine is used (N Engl J Med 1989; 320:886-92). Two severe reactions to iv protamine occurred in the same vasectomized male within the same week. The first reaction followed cardiopulmonary bypass (Fig. 1) and the 2nd occurred at cardiac catheterization. At the time of his reactions his serum contained anti-protamine IgG but no IgE antibody. To determine if vasectomized males have increased incidence of protamine specific antibodies, we compared the prevalence and quantity of serum protamine IgG and IgE antibodies in vasectomized men and age matched controls.

Following institutional approval, sera of 55 men, who had vasectomies, along with 13 age matched control males with no history of vasectomy, infertility, or prior exposure to protamine were evaluated. Each serum was pre-incubated with buffer and 1.4 mg/ml of a commercial protamine preparation before addition to an agarose-based solid phase radioimmunoassay using either ¹²⁵I radiolabeled *Staph* protein A in the IgG assay or ¹²⁵I

radiolabeled rabbit anti-human IgE antibody in the IgE assay as the detection protein. The absolute quantity of antibody as well as the % inhibition of antibody binding by soluble protamine was determined. Positive serum samples were defined as those with a count per minute ≥ 2.5 times that of negative serum samples and inhibited $\geq 50\%$ by soluble protamine. Data were analyzed by the Kruskal-Wallis test.

19 of the 55 vasectomized patient's sera contained anti-protamine IgG antibody. 34.5% of sera from vasectomized patients and 0% of the sera from age matched controls contained circulating anti-protamine IgG antibody. No anti-protamine IgE antibody was found in the study population or in the control group.

Our study shows that vasectomized males have a significantly increased incidence of anti-protamine IgG antibody in their sera compared to the controls. Vasectomized males with high anti-protamine IgG levels may be at increased risk for the development of severe life-threatening reactions to iv protamine.

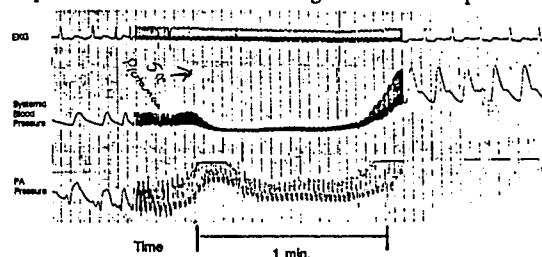


Fig. 1: Hemodynamic profile in a vasectomized male following protamine administration and subsequent treatment of the reaction.

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TITLE: CIRCULATORY, NEUROLOGIC, AND BLOOD GAS CHANGES DURING TOTAL KNEE REPLACEMENT. ROLE OF THE INTRAMEDULLARY ALIGNMENT ROD.
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The use of an intramedullary alignment rod in the distal part of the femur is an important step in performing total knee replacement arthroplasty. We observed a sudden decrease in oxygen saturation in some patients after insertion of the rod. This prompted a prospective study of the circulatory and blood gas changes and neurologic manifestations that were associated with rod insertion in forty patients.

We examined the effects of the use of an 8 mm solid alignment rod, with and without venting; an 8 mm fluted alignment rod, with venting; and an 8 mm fluted or solid alignment rod, inserted through a 12.7 mm drill hole, but without other venting.

A statistically significant reduction in O_2 saturation, PaO_2 , and end-tidal CO_2 tension ($PETCO_2$) occurred after insertion of both solid and fluted 8 mm alignment rods through an 8 mm hole in both vented and unvented femoral canals, in association with a significant increase in intramedullary

pressure (from 36 ± 7.9 to 656.4 ± 63.6 mm Hg, $P < 0.001$). Bone marrow contents and fat were retrieved from samples of blood from the right atrium, indicating that embolization of marrow contents had occurred during insertion of the alignment rod. A small decrease in systemic blood pressure and heart rate also occurred. These changes were completely eliminated by the use of a 12.7 mm drill hole as the entry site of the 8 mm fluted rod. Three patients in whom a solid rod without venting was utilized had changes in mental status suggestive of encephalopathy. Two additional patients (not included in the study) had similar postoperative neurologic sequelae, despite a stable blood pressure intraoperatively.

We conclude that insertion of an intramedullary alignment rod in the femur causes embolization of marrow contents, which decreases PO_2 , O_2 saturation, $PETCO_2$, arterial blood pressure, and heart rate. Neurologic manifestations may well be related to fat embolism. Embolization of fat in trauma patients can cause diffuse encephalopathy or encephalopathy with focal features.¹ This embolization in total knee arthroplasty, can be prevented by making the drill hole that is used as the entry site of a fluted alignment rod at least 4.7 mm larger than the diameter of the rod to allow for drainage of marrow contents. Our findings may help explain the fatalities reported with this procedure.

References:

1. Jacobsen et al. Neurology 36:847, 1986.