

**Self-expanding foam for prehospital treatment of severe intra-abdominal hemorrhage: dose finding study.**

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**BACKGROUND:** Noncompressible abdominal bleeding is a significant cause of preventable death on the battlefield and in the civilian trauma environment, with no effective therapies available at point of injury. We previously described the development of a percutaneously administered, self-expanding, poly(urea)urethane foam that improved survival in a lethal Grade V hepatic and portal vein injury model in swine. In this study, we hypothesized that survival with foam treatment is dose dependent.

**METHODS:** A high-grade hepatoportal injury was created in a closed abdominal cavity, resulting in massive noncompressible hemorrhage. After injury, the animals were divided into five groups. The control group (n = 12) was treated only with fluid resuscitation, and four polymer groups received different dose volumes (Group 1, n = 6, 64 mL; Group 2, n = 6, 85 mL; Group 3, n = 18, 100 mL; and Group 4, n = 10, 120 mL) in addition to fluids. Ten minutes after injury, the foam was percutaneously administered, and animals were monitored for 3 hours.

**RESULTS:** Survival with hepatoportal injury was highest in Group 4 (90%) and decreased in a dose-dependent fashion (Group 3, 72%; Group 2, 33%; Group 1, 17%). All polymer groups survived significantly longer than the controls (8.3%). Hemorrhage rate was reduced in all groups but lowest in Group 4 versus the control group (0.34 [0.052] vs. 3.0 [1.3] mL/kg/min,  $p < 0.001$ ). Increasing foam dose volume was associated with increased peak intra-abdominal pressure (88.2 [38.9] in Group 4 vs. 9.5 [3.2] in the controls,  $p < 0.0001$ ) and increased incidence of focal bowel injuries.

**CONCLUSION:** The self-expanding foam significantly improves survival in a dose-dependent fashion in an otherwise lethal injury. Higher doses are associated with better survival but resulted in the need for bowel resection.