



Danbury Hospital
Department of Pathology & Laboratory Medicine
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Safety of Albumin Administration in Critically Ill Patients

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May 16, 2005

The Food and Drug Administration (FDA) is issuing this notice in order to update an earlier correspondence and revise our previous advice regarding the safety of albumin administration in critically ill patients. This action is being taken following FDA's review of recent studies on the safety of albumin, and is consistent with recommendations made on March 17, 2005 by members of the Blood Products Advisory Committee (BPAC).

In a Letter to Healthcare Providers issued on August 19, 1998

<<http://www.fda.gov/cber/ltr/albumin.htm>>, FDA expressed serious concern over the safety of albumin administration in the critically ill population and urged treating physicians to exercise discretion in its use. This advice was based on a meta-analysis published in the July 25, 1998 issue of the British Medical Journal conducted by the Cochrane Injuries Group, which found that compared to normal saline, albumin administration was associated with a six percent increased risk of

dying (relative risk: 1.68; 95% confidence interval: 1.26, 2.23); similar findings were noted for patients with hypovolemia, hypoproteinemia, and burns. In May 2004, the New England Journal of Medicine published the SAFE study, the largest randomized controlled trial to date to have addressed the safety of albumin (*N Engl J Med* 2004;350:2247-56). In this trial, 6997 critically ill subjects were randomized to receive either 4% albumin or normal saline for the treatment of hypovolemia. The results presented by the Principal Investigator at the BPAC meeting on March 17, 2005 indicate that for patients in the general ICU population requiring fluid resuscitation, the mortality rate of those who receive albumin is the same as for those who receive saline (relative risk of mortality 0.99; 95% confidence interval: 0.91, 1.09). Secondary analyses of pre-specified subgroups of patients with ARDS, severe sepsis, and trauma were consistent overall with this finding. Two additional findings deserve mention. First, results of an exploratory analysis of trauma patients with concomitant traumatic brain injury showed increased mortality in the albumin treatment arm (relative risk of mortality 1.36; 95% confidence interval 0.99, 1.86). Second, a higher survival rate was observed in the albumin treated patients with severe sepsis, but since this finding was not statistically significant (p=0.09), its clinical significance remains uncertain.

Based on these data, the BPAC voted unanimously that the SAFE study had resolved the prior safety concerns raised by the Cochrane Injuries Group in 1998. However, the relative safety of albumin for use in patients with burns cannot be determined at this time as this group was excluded from the SAFE study. Additionally, further evaluation of albumin in patients with traumatic brain injury and septic shock will have to be performed to ascertain the safety of albumin administration in these patient populations.

Updated May 16, 2005

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