

Supplementary Appendix 1

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Abraham E, Laterre P-F, Garg R, et al. Drotrecogin alfa (activated) for adults with severe sepsis and a low risk of death. *N Engl J Med* 2005;353:1232-41.

Appendix 1. Organ Dysfunction Definitions.

Organ Dysfunction	Criteria
Cardiovascular	An arterial systolic blood pressure (SBP) of ≤ 90 mm Hg or a mean arterial pressure (MAP) ≤ 70 mm Hg for at least 1 hour despite adequate fluid resuscitation, adequate intravascular volume status, or the need for vasopressors to maintain SBP ≥ 90 mm Hg or MAP ≥ 70 mm Hg. ^a
Renal	Average urine output < 0.5 mL/kg/h for 1 hour despite adequate fluid resuscitation. ^{a,b}
Respiratory	Evidence of acute pulmonary dysfunction $\text{PaO}_2/\text{FiO}_2 \leq 250$ (adjusted for altitude) and, if measured, a pulmonary capillary wedge pressure not suggestive of central volume overload. ^c
Hematologic	Platelet count $< 80,000/\text{mm}^3$ or a 50% decrease in platelet count from the highest value recorded over the last 3 days
Unexplained metabolic acidosis	Defined by (1) pH ≤ 7.30 or base deficit ≥ 5.0 mEq/L and (2) a plasma lactate level > 1.5 times the upper limit of normal for the reporting laboratory. Measurement of pH or base deficit and lactate level should occur within a clinically relevant time interval such that a causal relationship exists between the measured values.

^a Adequate fluid resuscitation or adequate intravascular volume is defined as one or more of the following:

(1) the administration of an intravenous fluid bolus (≥ 500 mL of crystalloid solution, ≥ 20 g of albumin, or ≥ 200 mL of other colloids administered over 30 minutes or less); (2) pulmonary arterial wedge pressure ≥ 12 mm Hg; or (c) central venous pressure ≥ 8 mm Hg. Vasopressors are defined as the following: (1) dopamine ≥ 5 microgram/kg/min; or (2) norepinephrine, epinephrine, or phenylephrine at any dose. Dobutamine or dopexamine are not considered vasopressors.

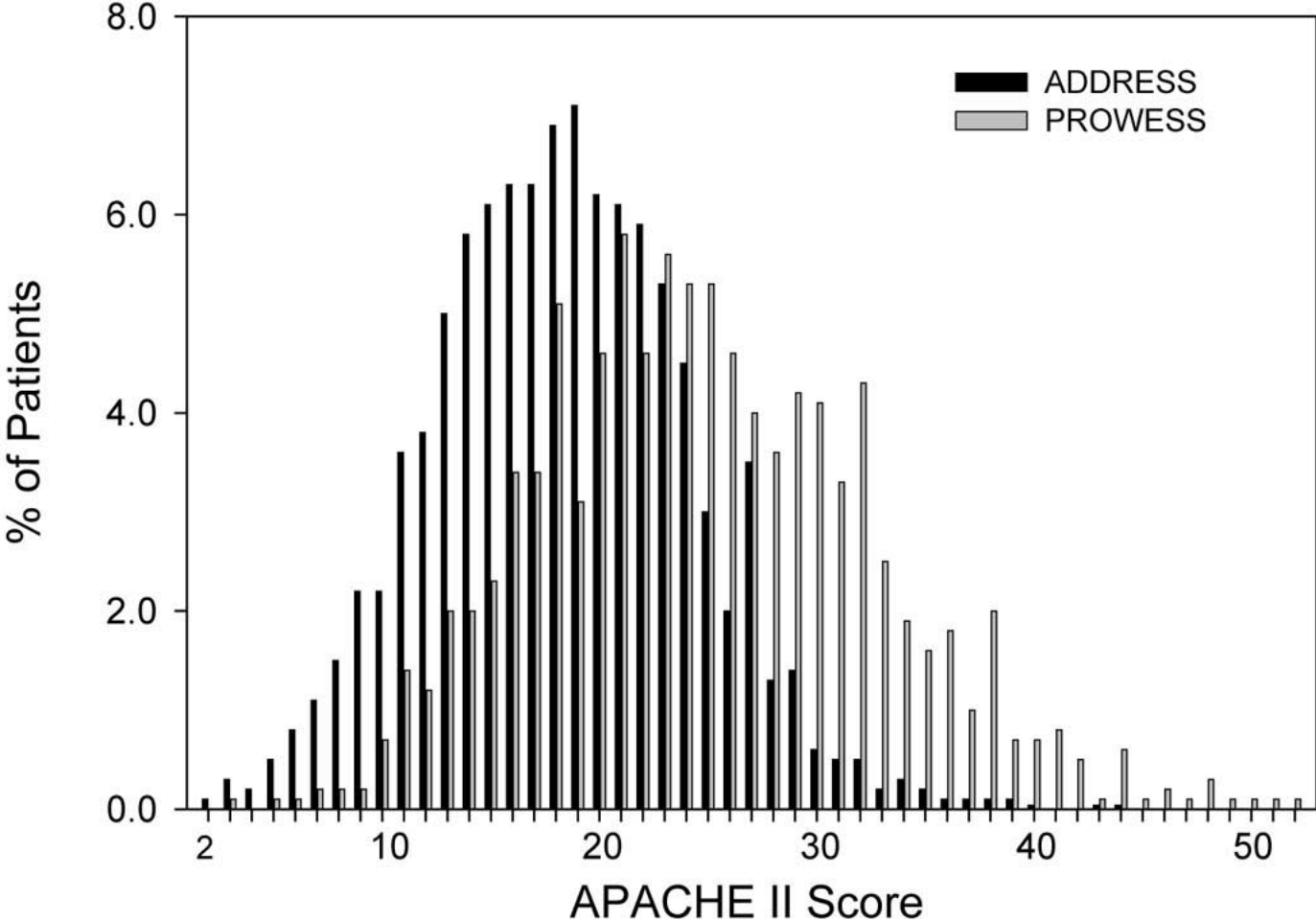
^b In the presence of preexisting impairment of renal function (defined as a serum creatinine concentration > 2 times the upper limit of the normal reference range for the institution prior to the onset of sepsis), the patient must meet one of the other four organ failure criteria.

^c If the lung is also the suspected site of infection, the patient must have a $\text{PaO}_2/\text{FiO}_2 \leq 200$. PaO_2 altitude adjustment: 760 divided by barometric pressure multiplied by PaO_2 .

Appendix Figure 1. Study Design of ADDRESS Trial. * The treatment period was defined as day 0 through day 6 to account for interruptions in the study drug infusion. The study drug infusion started on day 0 and continued until the patient received 96 hours \pm 1 hour of study drug. ** Study drug infusion was started as soon as possible (within a maximum of 6 hours) after obtaining patient treatment assignment.

Appendix Figure 2. Distribution of APACHE II Scores in Patients Enrolled in the ADDRESS Trial compared with the PROWESS Trial. Percentage of enrolled patients with given APACHE II score is indicated by each bar. Black bars represent ADDRESS patients and gray bars represent PROWESS patients.

Appendix Figure 2



Supplementary Appendix 2

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