Prehospital Plasma during Air Medical Transport in Trauma Patients at Risk for Hemorrhagic Shock.


Abstract

BACKGROUND: After a person has been injured, prehospital administration of plasma in addition to the initiation of standard resuscitation procedures in the prehospital environment may reduce the risk of downstream complications from hemorrhage and shock. Data from large clinical trials are lacking to show either the efficacy or the risks associated with plasma transfusion in the prehospital setting.

METHODS: To determine the efficacy and safety of prehospital administration of thawed plasma in injured patients who are at risk for hemorrhagic shock, we conducted a pragmatic, multicenter, cluster-randomized, phase 3 superiority trial that compared the administration of thawed plasma with standard-care resuscitation during air medical transport. The primary outcome was mortality at 30 days.

RESULTS: A total of 501 patients were evaluated: 230 patients received plasma (plasma group) and 271 received standard-care resuscitation (standard-care group). Mortality at 30 days was significantly lower in the plasma group than in the standard-care group (23.2% vs. 33.0%; difference, -9.8 percentage points; 95% confidence interval, -18.6 to -1.0%; P=0.03). A similar treatment effect was observed across nine prespecified subgroups (heterogeneity chi-square test, 12.21; P=0.79). Kaplan-Meier curves showed an early separation of the two treatment groups that began 3 hours after randomization and persisted until 30 days after randomization (log-rank chi-square test, 5.70; P=0.02). The median prothrombin-time ratio was lower in the plasma group than in the standard-care group (1.2 [interquartile range, 1.1 to 1.4] vs. 1.3 [interquartile range, 1.1 to 1.6], P<0.001) after the patients' arrival at the trauma center. No significant differences between the two groups were noted with respect to multiorgan failure, acute lung injury-acute respiratory distress syndrome, nosocomial infections, or allergic or transfusion-related reactions.
CONCLUSIONS: In injured patients at risk for hemorrhagic shock, the prehospital administration of thawed plasma was safe and resulted in lower 30-day mortality and a lower median prothrombin-time ratio than standard-care resuscitation. (Funded by the U.S. Army Medical Research and Materiel Command; PAMPer ClinicalTrials.gov number, NCT01818427).


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