

Restrictions on female plasma may not be warranted

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Three years after the U.S. blood banking industry issued recommendations that discourage transfusing plasma from female donors because of a potential antibody reaction, Duke University Medical Center researchers discovered that female plasma actually may have advantages.

The Duke team conducted a retrospective study of Red Cross donor and hospital data from a period when female plasma wasn't restricted. They examined heart [surgery](#) outcomes for lung problems, and prolonged length of hospital stay or death. [Cardiac surgery](#) patients use about one-fifth of all transfused blood products.

They found that patients receiving female-donor plasma did significantly better than similar patients receiving male-donor plasma.

"Our findings raise the possibility of unanticipated effects of restricting female donor plasma use," said Mark Stafford-Smith, M.D., a Duke professor of anesthesiology and senior author of a study appearing in the *Journal of Thoracic and Cardiovascular Surgery* on Feb. 11.

Blood products, such as red cells and plasma, are manufactured from blood collected from volunteer donors, and both male and female donors are still encouraged to donate whole blood, which is then separated into different components.

The recommendations to restrict plasma transfusions were based on

evidence tying female-donor plasma to a serious lung injury called transfusion-related [acute lung injury](#) (TRALI). Antibodies that may cause TRALI are more common in women who have been pregnant, and the antibodies may form as a reaction to their fetus. The more pregnancies a woman has had, the greater the chance that she has these antibodies.

The AABB (formerly the American Association of Blood Banks) recommended in late 2006 that blood banks adopt measures to reduce the risk of TRALI, such as avoiding use of female donor plasma for transfusion due to the higher risk antibodies associated with TRALI.

"We were very surprised by the results, because when we began the study, we expected to see data that supported the idea that female-donor plasma would be riskier," said Mark Stafford-Smith. "In fact, we found just the opposite. At first, we thought we might have switched our data somehow, but careful re-examination confirmed that recipients of male-donor plasma had worse outcomes."

The study identified 1,069 patients who had received plasma exclusively from female donors or male donors, and put them into pairs for comparison that were matched for the number of units transfused and surgery date.

Recipients of female-donor plasma had a lower incidence of pulmonary dysfunction (5.9 percent vs. 10.8 percent) and death within 30 days of surgery or hospitalization longer than 10 days (9 percent vs. 16.4 percent). The two groups had similar long-term survival rates.

Co-author Nicholas Bandarenko, M.D., medical director of Duke Transfusion Services and associate professor of pathology, said the blood banking community has been focused locally and nationally on reducing the significant morbidity and mortality from TRALI. However,

TRALI is a relatively rare event that happens in roughly every 1 in 3,000 transfusions.

"This study suggests more subtle but still clinically significant outcomes and morbidity may be occurring," Bandarenko said. "As required, regulatory policies are now in place to minimize the risk of severe TRALI, but there appears to be a spectrum of pulmonary (lung) injuries that may be associated with blood transfusion and these may not all be impacted by the policies that restrict plasma collection to male donors exclusively."

The study did not specifically address the catastrophic lung problem. "It may be true that with enough patients we would have observed fewer TRALI incidents in the male-donor plasma recipients, but our data suggests that any gain from avoiding a small number of catastrophic occurrences may require subjecting patients to other potentially worrisome effects of male-donor plasma," Stafford-Smith said.

He stressed that the Duke study findings need to be re-evaluated in prospective studies. There isn't enough data yet to support or refute the policy to exclude female-donor plasma as a way to avoid catastrophic TRALI.

The finding cannot be generalized across all types of patients getting [plasma](#) transfusions either, he said. "We studied cardiac surgery patients, because this is the subset of patients that we care for. This study provides one more tool to aid in policy decisions, and more studies, including prospective studies, will be needed to improve our understanding of the male- versus female-donor question."

Provided by Duke University Medical Center

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