



FOCUS ON RESEARCH: Trial Studies Transfusion in High Cardiac Risk Patients

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Does the anemic – but high cardiac risk – patient need a blood transfusion, or not?

SVS member Dr. Panos Kougias is leading a study on the best transfusion approach when treating patients at high cardiac risk who become anemic postoperatively.

A total of 1,500 participants at 15 Veteran Administration hospitals will be randomly assigned to receive transfusion at one of two postoperative hemoglobin levels: liberal (less than 10 gm/dL) or restrictive (less than 7 gm/dL).

The TOP Trial – "Transfusion Trigger after Operations in High Cardiac Risk Patients" – is expected to last five years. Eight sites will become operational the first year, with seven more open during years two-five.

Recruitment is expected to begin in September 2017.

"Previous trials have shown that a restrictive transfusion strategy is well tolerated in most clinical settings," said Dr. Kougias, principal investigator at Michael E. DeBakey VA Medical Center.

"But patients at high cardiac risk have not been studied," he said, "and vascular and general surgeons face this transfusion issue frequently."

Study participants are those undergoing major general or vascular surgery interventions. Candidates must have a prior history of coronary arterial disease or ischemic stroke, or they should undergo an open intervention for peripheral arterial disease.

With the exception of complex endovascular aneurysm repairs, the study will exclude endovascular-only interventions and same-day interventions associated with minimal likelihood of postoperative anemia.

National guidelines favor a restrictive transfusion strategy that has been shown to be safe in most stable hospitalized patients, said Dr. Kougias, citing transfusion costs and fear of complications as two reasons for the less liberal policy. But practices vary widely among institutions, with surgeons being uncertain as to the best approach to transfusion for high cardiac risk patients.

"Clinicians are often hesitant to allow those patients to become overly anemic, out of concern that reduced oxygen-carrying capacity in the setting of ischemic heart disease may trigger serious complications," he said.

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No matter which approach is determined to be preferable, the trial will have a positive outcome, said Dr. Kougias. "If the liberal transfusion strategy is better – and that's our hypothesis – then we'll truly save lives," he said. "Appropriate revisions in national transfusion guidelines will be made."

And if no approach is proven superior, "then the study will provide the definitive evidence needed for widespread adoption of a restrictive transfusion policy to all patient populations, including those at high cardiac risk. The study will provide critical information to clinicians and policy-makers, regardless of its outcome."

Others on the trial's executive committee include two SVS members, Drs. Hassan Dosluoglu and Peter Nelson; two internists, Drs. Jeff Carson and Frank Lederle; and Dr. George Sarosi, a general surgeon.

The trial is being funded with a \$16.9 million grant from the VA Cooperative Studies Program, which represents the Division of Veterans Affairs Research and Development branch that plans and conducts large multicenter clinical trials and epidemiological studies with the Department of Veteran Affairs.

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