# A liberal strategy of red blood cell transfusion reduces cardiogenic shock in elderly patients undergoing cardiac surgery

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## ABSTRACT

**Objective:** The aim of this study was to compare outcomes in patients undergoing cardiac surgery who are aged 60 years or more or less than 60 years after implementation of a restrictive or a liberal transfusion strategy.

**Methods:** This is a substudy of the Transfusion Requirements After Cardiac Surgery (TRACS) randomized controlled trial. In this subgroup analysis, we separated patients into those aged 60 years or more (elderly) and those aged less than 60 years randomized to a restrictive or a liberal strategy of red blood cell transfusion. The primary outcome was a composite defined as a combination of 30-day all-cause mortality and severe morbidity.

**Results:** Of the 502 patients included in the Transfusion Requirements After Cardiac Surgery study, 260 (51.8%) were aged 60 years or more and 242 (48.2%) were aged less than 60 years and were included in this study. The primary end point occurred in 11.9% of patients in the liberal strategy group and 16.8% of patients in the restrictive strategy group (P = .254) for those aged 60 years or more and in 6.8% of patients in the liberal strategy group and 5.6% of patients in the restrictive strategy group for those aged less than 60 years (P = .714). However, in the older patients, cardiogenic shock was more frequent in patients in the restrictive transfusion group (12.8% vs 5.2%, P = .031). Thirty-day mortality, acute respiratory distress syndrome, and acute renal injury were similar in the restrictive and liberal transfusion groups in both age groups.

**Conclusions:** Although there was no difference between groups regarding the primary outcome, a restrictive transfusion strategy may result in an increased rate of cardiogenic shock in elderly patients undergoing cardiac surgery compared with a more liberal strategy. Cardiovascular risk of anemia may be more harmful than the risk of blood transfusion in older patients. (J Thorac Cardiovasc Surg 2015;150:1314-20)



Cardiogenic shock occurs in elderly persons after cardiac surgery when exposed to RBC transfusion. This study illustrates that elderly patients undergoing cardiac surgery, in contrast to younger patients, have a greater risk of cardiogenic shock when exposed to a restrictive strategy of RBC transfusion.

#### Central Message

This study aimed to compare clinical outcomes in patients aged 60 years or more or less than 60 years undergoing cardiac surgery and submitted to a restrictive or liberal transfusion strategy. Cardiogenic shock was more frequent in patients in the restrictive transfusion group. There were no differences between groups regarding other severe complications or mortality.

#### Perspective

Anemia and RBC transfusions are associated with worse outcomes after cardiac surgery. Older patients are more exposed to both anemia and transfusion in this setting. Our study is a substudy from the TRACS randomized controlled trial showing that in elderly persons, a restrictive strategy of RBC transfusion is associated with higher rates of cardiogenic shock and its complications. These findings should guide the physician in the decision to administer transfusions to a sick patient at bedside.

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# **Abbreviations and Acronyms**

ICU = intensive care unit

- RBC = red blood cell
- TRACS = Transfusion Requirements After Cardiac Surgery

Life expectancy is increasing worldwide, and growing numbers of elderly patients are undergoing cardiac surgery. Anemia and red blood cell (RBC) transfusions are both associated with increased morbidity and mortality after cardiac surgery, especially in elderly patients.<sup>1,2</sup> Recent studies have shown that a restrictive strategy of RBC transfusion is as safe and effective as a liberal one in critically ill patients.<sup>3</sup> In a recent prospective, randomized clinical trial, Transfusion Requirements After Cardiac Surgery (TRACS), we observed that a restrictive RBC transfusion in a diverse group of patients undergoing cardiac surgery.<sup>4</sup> However, these findings may not apply so readily to elderly patients who have reduced physiologic reserve and more comorbid conditions than younger patients.

A few studies have evaluated clinical outcomes in the elderly according to different strategies of RBC transfusion.<sup>5</sup> The FOCUS study was a multicenter trial to determine whether a higher threshold for blood transfusion would improve recovery in elderly patients who had undergone surgery for hip fracture.<sup>6</sup> The inclusion criteria were history of or risk factors for cardiovascular disease. A liberal transfusion strategy (hemoglobin treshold of 10 g/dL), as compared with a restrictive strategy (hemoglobin treshold of 8 g/dL), did not reduce rates of death or inability to walk independently on 60-day follow-up.6 In contrast, a recent pilot trial in 110 patients (mean age of 71 years) with acute coronary syndrome or stable angina undergoing cardiac catheterization and with a hemoglobin less than 10 g/dL showed a trend for fewer major cardiac events and deaths with a liberal than with a more restrictive RBC transfusion strategy.<sup>7</sup> Thus, the risk-benefit profile of RBC transfusions remains uncertain, and more evidence is needed to guide practice in older patients with cardiorespiratory disease,<sup>8</sup> such as those undergoing cardiac surgery.

Therefore, the aim of this study was to compare outcomes in patients aged 60 years or more or less than 60 years undergoing cardiac surgery after implementation of a restrictive or a liberal transfusion strategy.

## MATERIALS AND METHODS

The TRACS study (ClinicalTrials.gov number NCT01021631) was designed as a prospective, randomized, controlled, noninferiority trial to study blood transfusion thresholds during elective cardiac surgery.<sup>4</sup> Consecutive adult patients who were scheduled for elective cardiac surgery

with cardiopulmonary bypass between February 9, 2009, and February 1, 2010, were enrolled. We excluded patients requiring surgery in an urgency situation; undergoing ascending or descending thoracic aortic procedures; with left ventricular aneurysm resection; unable to receive blood products; who were pregnant; who had cancer, congenital heart defect, hepatic dysfunction, or end-stage renal disease; or who refused consent. The study was approved by the Heart Institute Ethics Committee of the Clinics Hospital, University of Sao Paulo, and written informed consent was obtained from all patients before enrollment. Patients were randomly assigned to be managed according to a liberal (hematocrit values maintained at  $\geq$ 30%) or restrictive (hematocrit values maintained at  $\geq$ 24%) transfusion strategy from the start of the operation until discharge from the intensive care unit (ICU).

The primary outcome was a composite end point of 30-day all-cause mortality and severe morbidity (cardiogenic shock, acute respiratory distress syndrome, or acute renal injury requiring dialysis or hemofiltration). Cardiogenic shock was defined as the presence of tachycardia, hypotension, and poor perfusion associated with a central venous oxygen saturation less than 65%, a cardiac index 2.2 L/min/m<sup>2</sup> or less, or the presence of metabolic acidosis (base deficit >4 mmol/L) or an increase in lactate level (>18.02 mg/dL) in the absence of a cause other than heart failure.<sup>9</sup> Renal injury was defined according to the Risk, Injury, Failure, Loss of kidney function, and End-stage kidney disease criteria.<sup>10</sup> Acute respiratory distress syndrome was diagnosed if patients had an acute onset of an inflammatory lung injury characterized by hypoxemia (arterial oxygen tension/inspired oxygen fraction), bilateral infiltrates on chest radiograph, and no clinical evidence of left atrial hypertension.<sup>11</sup>

#### **Statistical Analysis**

In this subgroup analysis, we separated patients into those aged 60 years or more (elderly) and those aged less than 60 years (younger). We compared baseline characteristics, follow-up measures, and clinical outcomes in the 2 age groups on an intention-to-treat basis according to the randomized study group assignment. Continuous variables were compared using a t test or Mann–Whitney U test, and categoric variables were compared using the Pearson chi-square, Fisher exact, or likelihood ratio test. We compared hemoglobin levels between groups using a mixed-design analysis of variance model. We evaluated exposure to



FIGURE 1. Flowchart of the study.

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