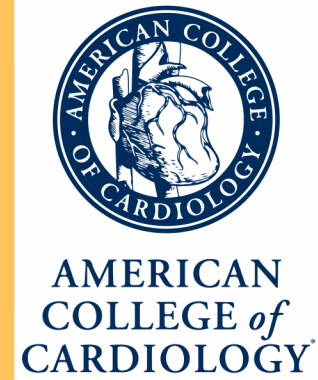


2020

REALITY TRIAL

Transfusion Strategies in Patients With
Myocardial Infarction and Anemia



Randomized, multicenter, controlled trial



Objective: To assess the safety and efficacy of a restrictive versus liberal red blood cell (RBC) transfusion strategy among patients with acute myocardial infarction (AMI) and anemia.

REALITY: A Trial of Transfusion Strategies for Myocardial Infarction and Anemia

Purpose: The study assessed cost-effectiveness and clinical outcomes of liberal vs restrictive red blood cell transfusion strategies in patients with acute MI and anemia.

Trial Design: N= 668, joint French/Spanish trial across 35 hospitals, Open label Randomized trial, All patients were with acute MI and $7 < \text{Hb} \leq 10 \text{g/dL}$ at any time during admission. In the restrictive strategy, transfusion was withheld unless hemoglobin dropped to 8 g/dL. In the liberal strategy, transfusion was given when hemoglobin was 10 g/dL or below

Primary Endpoints:

Clinical end point: Composite of major adverse cardiac events (MACE) at 30 days. MACE included death reinfarction, stroke, and emergency revascularization prompted by ischemia.

Cost-effectiveness endpoint: Incremental Cost-effectiveness ratio (ICER) at 30 days

Secondary: MACE at 1 year, cost-utility at 30-days and 1 year

	Restrictive RBC Transfusion Strategy (N=327 for protocol population and 342 for ITT)	Liberal RBC Transfusion Strategy (N=321 for protocol population and 324 for ITT)	Difference (95% CI)	Relative Risk (Restrictive vs Liberal)
MACE at 30 days per protocol population	n=36 (11.0%)	n=45 (14.0%)	-3.0% (-8.4%, 2.4%)	0.79
MACE at 30 days in ITT population	n=38 (11.1%)	n=46 (14.2%)	-3.1% (-8.4%, 2.3%)	0.78
Total 30 days cost (in Euros)	11,051	12,572	-1,521 (-3359, 318)	0.10

Results: This was the largest randomized trial comparing a restrictive versus liberal blood transfusion strategy in MI patients with anemia. The restrictive transfusion strategy was non-inferior (upper bound of confidence interval was 1.18 for protocol population) to a liberal strategy in preventing 30-day MACE, saves blood and is safe, thus supporting the use of restrictive strategy. Restrictive strategy had an 84% probability of being cost-saving while improving clinical outcomes.





REALITY: a joint French/Spanish trial

630 Pts with acute MI and $7 < \text{Hb} \leq 10 \text{ g/dL}$
at any time during admission



randomization



Liberal RBC transfusion strategy

triggered by $\text{Hb} \leq 10 \text{ g/dL}$
target $\text{Hb}: > 11 \text{ g/dL}$

Restrictive RBC transfusion strategy

triggered by $\text{Hb} \leq 8 \text{ g/dL}$
target $\text{Hb}: 8 \text{ to } 10 \text{ g/dL}$



Patient selection

Inclusion criteria

(all of the below)

1. **MI** (STEMI or NSTEMI)
 - Last ischemic symptoms < 48h before admission
 - Troponin elevation
2. **Anemia** : Hb \leq 10g / dL but > 7 g/dL, at any time of index hospitalisation for MI
3. **Written informed consent**
4. **Healthcare insurance**

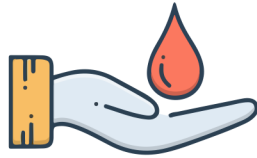
Exclusion criteria

(Any of the below)

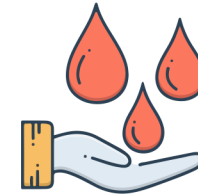
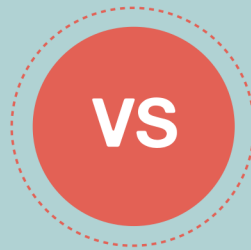
- Cardiogenic shock** (SBP < 90 mmHg with clinic signs of low output or requiring inotropic support)
- Post-PCI or post-CABG MI**
- Transfusion** in the previous 30 days
- Any known **hematologic disease**
- Massive bleeding** or compromising vital prognosis (according to investigator judgment)

666
patients

Inclusion criteria: MI (STEMI or NSTEMI), last ischemic symptoms <48 hours before admission, troponin elevation, anemia: Hb \leq 10g/dl but >7 g/dl, at any time of index hospitalization for MI.



Restrictive (for Hgb \leq 8 g/dl, target Hgb 8-10 g/dl) (n = 324)



Liberal (for Hgb \leq 10 g/dl, goal Hgb >11 g/dl) (n = 342)

PRIMARY OUTCOME

11

**All-cause death, reinfarction, stroke,
and emergency revascularization %**
HR 0.77, 95% CI 0.50-1.18, $p < 0.05$
for noninferiority, $P = 0.22$ for superiority

14

SECONDARY OUTCOME

9.7

Acute renal failure %
P = 0.24

7.1

0

Infection %
P = 0.03

1.5

Conclusion: a restrictive PRBC transfusion strategy (transfusion for Hgb \leq 8 g/dl, goal 8-10 g/dl) is noninferior to a more liberal strategy (transfusion for Hgb \leq 10 g/dl, goal Hgb $>$ 11 g/dl) in patients with acute myocardial infarction.

Presented by Dr. Philippe Gabriel Steg at the European Society of Cardiology Virtual Congress, September 1, 2020.