

Liberal Transfusion Causes Higher Infection Rates with No Benefit to Functional Outcomes, Orthopaedic Trauma and Anemia: Conservative versus Liberal Transfusion (ORACL): A Prospective Randomized Study

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Purpose: There is ongoing debate what level of anemia should be used as a transfusion trigger for asymptomatic trauma patients no longer in a resuscitative phase. A previous retrospective case-control study by the lead investigator showed there was a higher risk of complications with a more liberal strategy, and this appeared to be dose-dependent. Multiple previous studies have shown allogeneic blood transfusion is immunosuppressive and may increase infection rates in surgical patients. This study was completed to determine if a more conservative strategy was safe and might decrease the risk of infection.

Methods: The ORACL study randomized 100 patients ages 18-50 years to a conservative transfusion threshold of 5.5 g/dL vs a liberal threshold of 7.0 g/dL in asymptomatic patients no longer being resuscitated for an associated musculoskeletal injury. Enrollment was performed at 3 Level I trauma centers from 2014 to 2021. Musculoskeletal Functional Assessment (MFA) scores were obtained at baseline, 6 months, and 1 year.

Results: 65 patients completed 1-year follow-up. There was a significant association between a liberal transfusion strategy and higher rate of infection (P = 0.01) (Table 1) with no difference in functional outcomes at 6 months or 1 year. The study was adequately powered to detect a difference in superficial infection (7% for liberal group, 0% for conservative; P<0.01) but underpowered to detect a difference for deep infection (14% for liberal group, 6% for conservative group; P = 0.2). Post hoc power analysis showed a total of 414 patients (207 per group) would be needed to achieve power of 80% specifically for deep infection. Multiple secondary outcomes or complications (renal, cardiac, deep vein thrombosis, nonunion, transfusion-related acute lung injury, stroke, MFA, etc.) potentially associated with anemia or transfusion were not different between the 2 groups. MFA overall dysfunction scores at 6 months were 37 (conservative) and 41 (liberal), P = 0.4 and at 1 year were 28 (conservative) and 36 (liberal), P = 0.1.

Conclusion: This study shows a conservative transfusion threshold of 5.5 g/dL in an asymptomatic young trauma patient with associated musculoskeletal injuries leads to a lower infection rate without an increase in adverse outcomes and no difference in functional outcomes at 6 months or 1 year.

Table 1

	Overall (n=99)	Liberal transfusion group (n=49)	Conservative transfusion group (n=50)	p-value
Primary outcome (infection)				
Yes	15 (15.2)	12 (24.5)	3 (6.0)	.0122
No	84 (84.9)	37 (75.5)	47 (94.0)	
Deep or Superficial infection				
Yes	15 (15.2)	12 (24.5)	3 (6.0)	.0122
No	84 (84.9)	37 (75.5)	47 (94.0)	
Deep infection				
Yes	10 (10.1)	7 (14.3)	3 (6.0)	.1997
No	89 (89.9)	42 (85.7)	47 (94.0)	
Superficial infection				
Yes	7 (7.1)	7 (14.3)	0 (0)	.0058
No	92 (92.9)	42 (85.7)	50 (100)	
Secondary outcome				
Yes	13 (13.1)	7 (14.3)	6 (12.0)	.7742
No	86 (86.9)	42 (85.7)	44 (88.0)	
Secondary renal				
Yes	0 (0)	0 (0)	0 (0)	n/a
No	99 (100)	49 (100)	50 (100)	
Secondary cardiac				
Yes	0 (0)	0 (0)	0 (0)	n/a
No	99 (100)	49 (100)	50 (100)	
Secondary MI				
Yes	0 (0)	0 (0)	0 (0)	n/a
No	99 (100)	49 (100)	50 (100)	
Secondary DVT				
Yes	3 (3.0)	2 (4.1)	1 (2.0)	.6173
No	96 (97.0)	47 (95.9)	49 (98.0)	
Secondary TRALI				
Yes	10 (10.1)	5 (10.2)	5 (10.0)	.9731
No	89 (89.9)	44 (89.8)	45 (90.0)	

See the meeting website for complete listing of authors' disclosure information. Schedule and presenters subject to change.