Evidence-based Decision Making for RBC Transfusion Practices

Hematology – Oncology
Department

Objective

- Discuss recent evidence for blood product support scenarios
  - Indications
  - Dosing
  - Product selection

Outline

- Red Cell Transfusion
  - Threshold for transfusion
  - Age of stored blood

Considerations for Transfusing RBCs

- Symptoms
  - Dyspnea
  - Tachycardia
  - Fatigue
- Degree of anemia
- Patient/Family wishes
- Comorbidities
- Clinical status
- Outpatient status

TRICC study

The New England Journal of Medicine

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AMULTICENTER, RANDOMIZED, CONTROLLED CLINICAL TRIAL OF TRANSFUSION REQUIREMENTS IN CRITICAL CARE

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ABSTRACT

Background To determine whether a restrictive strategy of red-cell transfusion and a liberal strategy produced equivalent results in critically ill patients, we compared the rates of death from all causes at 30 days and the severity of organ dysfunction.

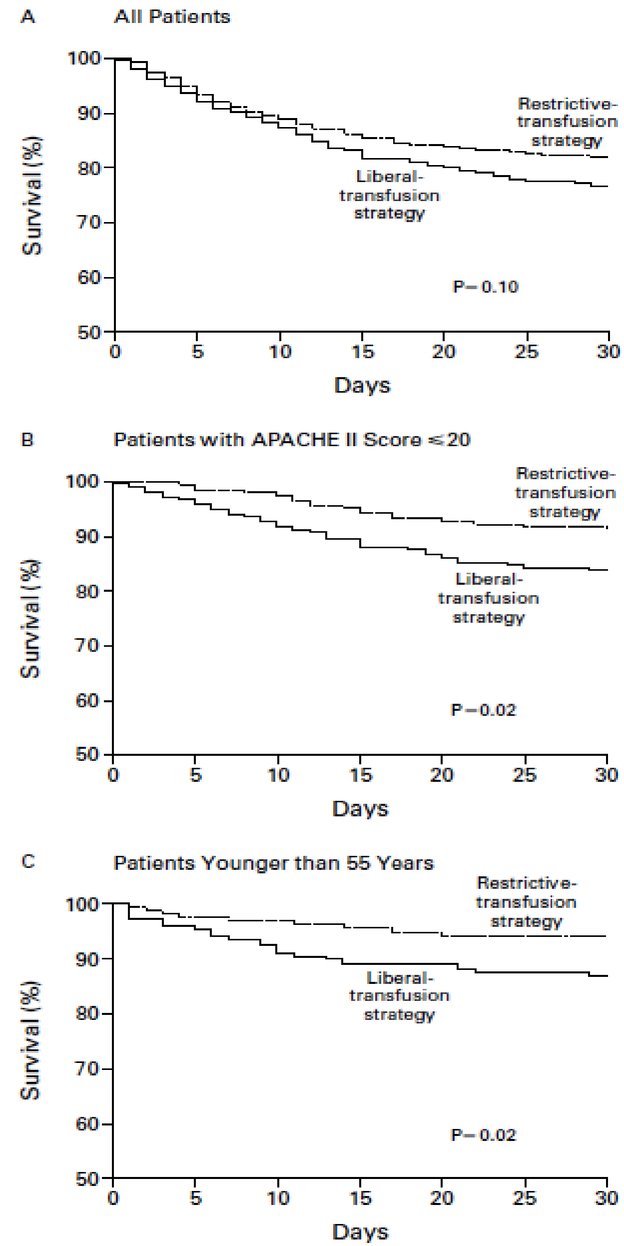
Methods We enrolled 838 critically ill patients with euvolemia after initial treatment who had hemoglobin concentrations of less than 9.0 g per deciliter within 72 hours after admission to the intensive care unit and randomly assigned 418 patients to a restrictive strategy of transfusion, in which red cells were transfused if the hemoglobin concentration dropped below 7.0 g per deciliter and hemoglobin concentrations were maintained at 7.0 to 9.0 g per deciliter, and 420 patients to a liberal strategy, in which transfusions were given when the hemoglobin concentration fell below 10.0 g per deciliter and hemoglobin concentrations were maintained at 10.0 to 12.0 g per deciliter.

Results Overall, 30-day mortality was similar in the two groups (18.7 percent vs. 23.3 percent, P = 0.11). However, the rates were significantly lower with the restrictive transfusion strategy among pa- tients who were less acutely ill — those with an Acute Physiology and Chronic Health Evaluation II score of ≤20 (8.7 percent in the restrictive-strategy group and 16.1 percent in the liberal-strategy group, P=0.03) — and among patients who were less than 55 years of age (5.7 percent and 13.0 percent, respectively; P=0.02), but not among patients with clinical- ly significant cardiac disease (20.5 percent and 22.9 percent, respectively; P=0.69). The mortality rate during hospitalization was significantly lower in the restrictive-strategy group (22.2 percent vs. 28.1 per- cent, P=0.05).

Conclusions A restrictive strategy of red-cell transfusion is at least as effective as and possibly su- perior to a liberal transfusion strategy in critically ill patients, with the possible exception of patients with acute myocardial infarction and unstable angina. (N Engl J Med 1999;340:409-17.)

When to Transfuse: RBCs

- TRICC study (adults)
  - n=838 randomized to restrictive (keep hgb>7) or liberal (keep hgb>10)
  - Outcome: 30d survival
  - Similar in the both groups



TRIPICU study

Transfusion Strategies for Patients in Pediatric Intensive Care Units

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ABSTRACT

BACKGROUND

The optimal hemoglobin threshold for erythrocyte transfusions in critically ill children is unknown. We hypothesized that a restrictive transfusion strategy of using packed red cells that were leukocyte-reduced before storage would be as safe as a liberal transfusion strategy, as judged by the outcome of multiple-organ dysfunction.

METHODS

In this noninferiority trial, we enrolled 637 stable, critically ill children who had hemoglobin concentrations below 9.5 g per deciliter within 7 days after admission to an intensive care unit. We randomly assigned 320 patients to a hemoglobin threshold of 7 g per deciliter for red-cell transfusion (restrictive-strategy group) and 317 patients to a threshold of 9.5 g per deciliter (liberal-strategy group).

RESULTS

Hemoglobin concentrations were maintained at a mean (±SD) level that was 2.1±0.2 g per deciliter lower in the restrictive-strategy group than in the liberal-strategy group (lowest average levels, 8.7±0.4 and 10.8±0.5 g per deciliter, respectively; P<0.001). Patients in the restrictive-strategy group received 44% fewer transfusions; 174 patients (54%) in that group did not receive any transfusions, as compared with 7 patients (2%) in the liberal-strategy group (P<0.001). New or progressive multiple-organ dysfunction syndrome (the primary outcome) developed in 38 patients in the restrictive-strategy group, as compared with 39 in the liberal-strategy group (12% in both groups) (absolute risk reduction with the restrictive strategy, 0.4%; 95% confidence interval, −4.6 to 5.4). There were 14 deaths in each group within 28 days after randomization. No significant differences were found in other outcomes, including adverse events.

CONCLUSIONS

In stable, critically ill children a hemoglobin threshold of 7 g per deciliter for red-cell transfusion can decrease transfusion requirements without increasing adverse outcomes. (Controlled-trials.com number, ISRCTN37246456.)

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*Investigators and site investigators of the Transfusion Requirements in the Pediatric Intensive Care Unit (TRIPICU) Study are listed in the Appendix.

N Engl J Med 2007;356:1609-19.

TRIPICU study

- N=637 randomized
  - Mean age: 3y
  - Restrictive (keep hgb>7)
  - Liberal (keep hgb>9.5)
- Outcome is new/progressive MODS at 28d
- 12% incidence, both groups
- Mortality: equivalent
- 44% fewer transfusions with restrictive

Lacroix et al. *NEJM.* 2007.

PINT study

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J Pediatr. 2006 Sep;149(3):301-307.

The Premature Infants in Need of Transfusion (PINT) study: a randomized, controlled trial of a restrictive (low) versus liberal (high) transfusion threshold for extremely low birth weight infants.

Kirpalani H[1], Whyte RK, Andersen C, Asztalos EV, Heddle N, Blajchman MA, Peliowski A, Rios A, LaCorte M, Connelly R, Barrington K, Roberts RS.

Author information

Abstract

OBJECTIVE: To determine whether extremely low birth weight infants (ELBW) transfused at lower hemoglobin thresholds versus higher thresholds have different rates of survival or morbidity at discharge.

STUDY DESIGN: Infants weighing <1000 g birth weight were randomly assigned within 48 hours of birth to a transfusion algorithm of either low or high hemoglobin transfusion thresholds. The composite primary outcome was death before home discharge or survival with any of either severe retinopathy, bronchopulmonary dysplasia, or brain injury on cranial ultrasound. Morbidity outcomes were assessed, blinded to allocation.

RESULTS: Four hundred fifty-one infants were randomly assigned to low (n = 223) or high (n = 228) hemoglobin thresholds. Groups were similar, with mean birth weight of 770 g and gestational age of 26 weeks. Fewer infants received one or more transfusions in the low threshold group (89% low versus 95% high, P = .037). Rates of the primary outcome were 74.0% in the low threshold group and 69.7% in the high (P = .25; risk difference, 2.7%; 95% CI -3.7% to 9.2%). There were no statistically significant differences between groups in any secondary outcome.

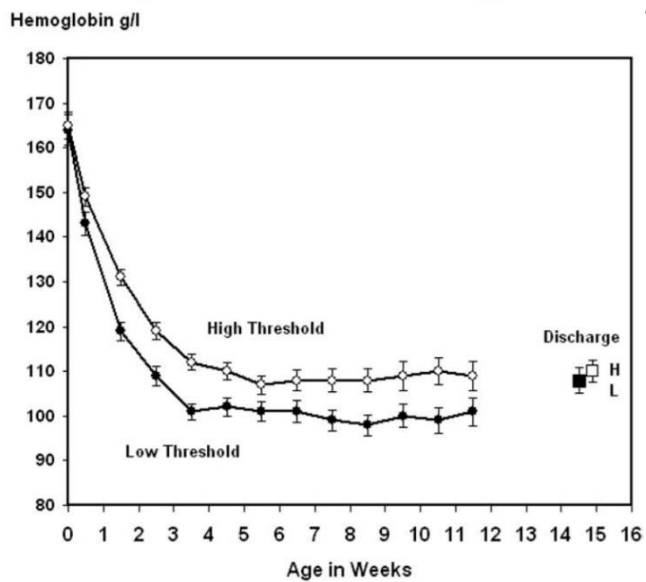
CONCLUSIONS: In extremely low birth weight infants, maintaining a higher hemoglobin level results in more infants receiving transfusions but confers little evidence of benefit.

PINT

- ELBW (<1000g, n=458)

Table I. Hemoglobin threshold levels (g/L) triggering RBC transfusion

		Low threshold		High threshold	
Age in days	**Blood sampling**	**Respiratory support**	**No respiratory support**	**Respiratory support**	**No respiratory support**
1-7	Capillary	≤115	≤100	≤135	≤120
	Central	≤104	≤90	≤122	≤109
8-14	Capillary	≤100	≤85	≤120	≤100
	Central	≤90	≤77	≤109	≤90
≥15	Capillary	≤85	≤75	≤100	≤85
	Central	≤77	≤68	≤90	≤77



Kirpalani et al. *JPeds.* 2006.

PINT

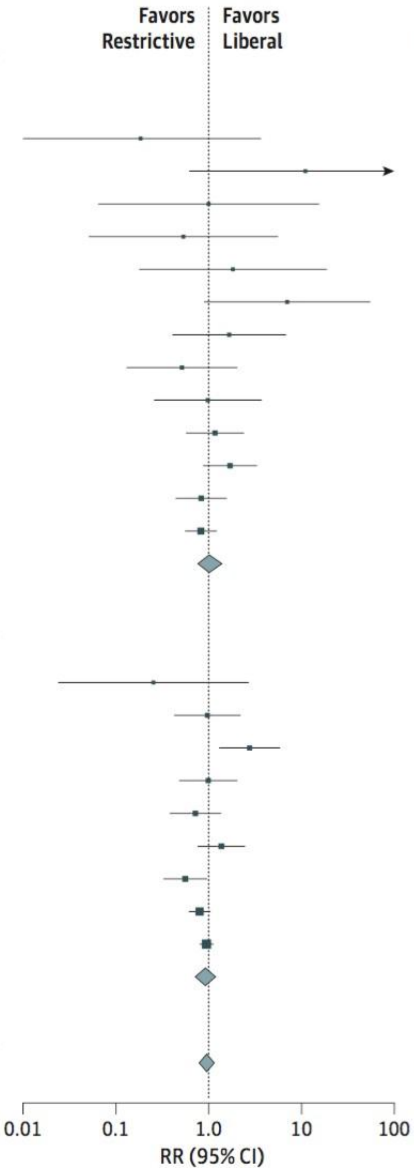
Table V. Primary outcome

Outcome cluster	Low threshold	High threshold	Treatment effect* (95% CI)		P value
Composite primary					
Death, severe ROP, BPD, or head ultrasound brain injury	165/223 (74.0%)	159/228 (69.7%)	OR: 1.30 (0.83, 2.02)	RD: 2.7% (−3.7%, 9.2%)	.25
Individual components					
Death	48/223 (21.5%)	40/228 (17.5%)	OR: 1.38 (0.84, 2.27)	RD: 2.6% (−3.5%, 8.8%)	.21
Survived with severe ROP	33/175 (18.9%)	33/188 (17.6%)	OR: 1.27 (0.71, 2.26)	RD: 1.1% (−4.6%, 6.8%)	.42
Survived with BPD	101/175 (57.7%)	103/188 (54.8%)	OR: 1.18 (0.76, 1.85)	RD: 3.9% (−4.6%, 12.4%)	.46
Survived with head ultrasound brain injury	22/175 (12.6%)	30/188 (16.0%)	OR: 0.86 (0.53, 1.39)	RD: −3.3% (−9.9%, 3.4%)	.53

Kirpalani et al. *JPeds.* 2006.

AABB Systematic Review-Threshold

Source	Restrictive Transfusion Threshold: No. of Deaths	Restrictive Transfusion Threshold: Total No.	Liberal Transfusion Threshold: No. of Deaths	Liberal Transfusion Threshold: Total No.	RR (95% CI)	Weight, %
Restrictive threshold, hemoglobin <8 to 9 g/dL						
Lotke et al,[75] 1999	0	62	0	65	Not estimable	
Blair et al,[53] 1986	0	26	2	24	0.19 (0.01-3.67)	0.4
Foss et al,[63] 2009	5	60	0	60	11.00 (0.62-194.63)	0.4
Carson et al,[58] 1998	1	42	1	42	1.00 (0.06-15.47)	0.4
Webert et al,[86] 2008	1	29	2	31	0.53 (0.05-5.58)	0.6
Cooper et al,[61] 2011	2	23	1	21	1.83 (0.18-18.70)	0.6
Carson et al,[56] 2013	7	55	1	55	7.00 (0.89-55.01)	0.7
Parker,[78] 2013	5	100	3	100	1.67 (0.41-6.79)	1.5
Bracey et al,[54] 1999	3	215	6	222	0.52 (0.13-2.04)	1.6
Bush et al,[55] 1997	4	50	4	49	0.98 (0.26-3.70)	1.7
Hajjar et al,[68] 2010	15	249	13	253	1.17 (0.57-2.41)	4.8
Gregersen et al,[64] 2015	21	144	12	140	1.70 (0.87-3.32)	5.4
Jairath et al,[72] 2015	14	257	25	382	0.83 (0.44-1.57)	5.8
Carson et al,[60] 2011	43	1009	52	1007	0.83 (0.56-1.22)	10.5
Subtotal	121	2321	122	2451	1.05 (0.78-1.40)	34.2
Heterogeneity: $\tau^2=0.02$; $\chi^2_{12}=13.14$; $P=.36$; $I^2=9\%$						
Tests for overall effect: z score $=0.31$; $P=.76$						
Restrictive threshold, hemoglobin <7 g/dL						
DeZern et al,[87] 2016	1	59	2	30	0.25 (0.02-2.69)	0.6
Hébert et al,[70] 1995	8	33	9	36	0.97 (0.42-2.22)	3.8
de Almeida et al,[79] 2015	23	101	8	97	2.76 (1.30-5.87)	4.5
Lacroix et al,[74] 2007	14	320	14	317	0.99 (0.48-2.04)	4.7
Walsh et al,[85] 2013	12	51	16	49	0.72 (0.38-1.36)	5.8
Murphy et al,[76] 2015	26	1000	19	1003	1.37 (0.76-2.46)	6.5
Villanueva et al,[84] 2013	19	416	34	417	0.56 (0.32-0.97)	7.2
Hébert et al,[69] 1999	78	418	98	420	0.80 (0.61-1.04)	14.7
Holst et al,[71] 2014	168	502	175	496	0.95 (0.80-1.13)	18.0
Subtotal	349	2900	375	2865	0.94 (0.74-1.19)	65.8
Heterogeneity: $\tau^2=0.05$; $\chi^2_{8}=16.09$; $P=.04$; $I^2=50\%$						
Tests for overall effect: z score $=0.53$; $P=.59$						
Overall	470	5221	497	5316	0.97 (0.81-1.16)	100
Heterogeneity: $\tau^2=0.04$; $\chi^2_{21}=29.75$; $P=.10$; $I^2=29\%$						
Tests for overall effect: z score $=0.29$; $P=.77$						
Tests for subgroup differences: $\chi^2_{1}=0.34$; $P=.56$; $I^2=0\%$						



Carson et al. *JAMA*. 2016

RBC Transfusion Threshold

- No clinical trial evidence to support higher threshold for transfusion
- Priority placed on avoiding transfusion, i.e. favor restrictive strategy

Outline

- Red Cell Transfusion
  - Threshold for transfusion
  - Age of stored blood

Storage Lesion

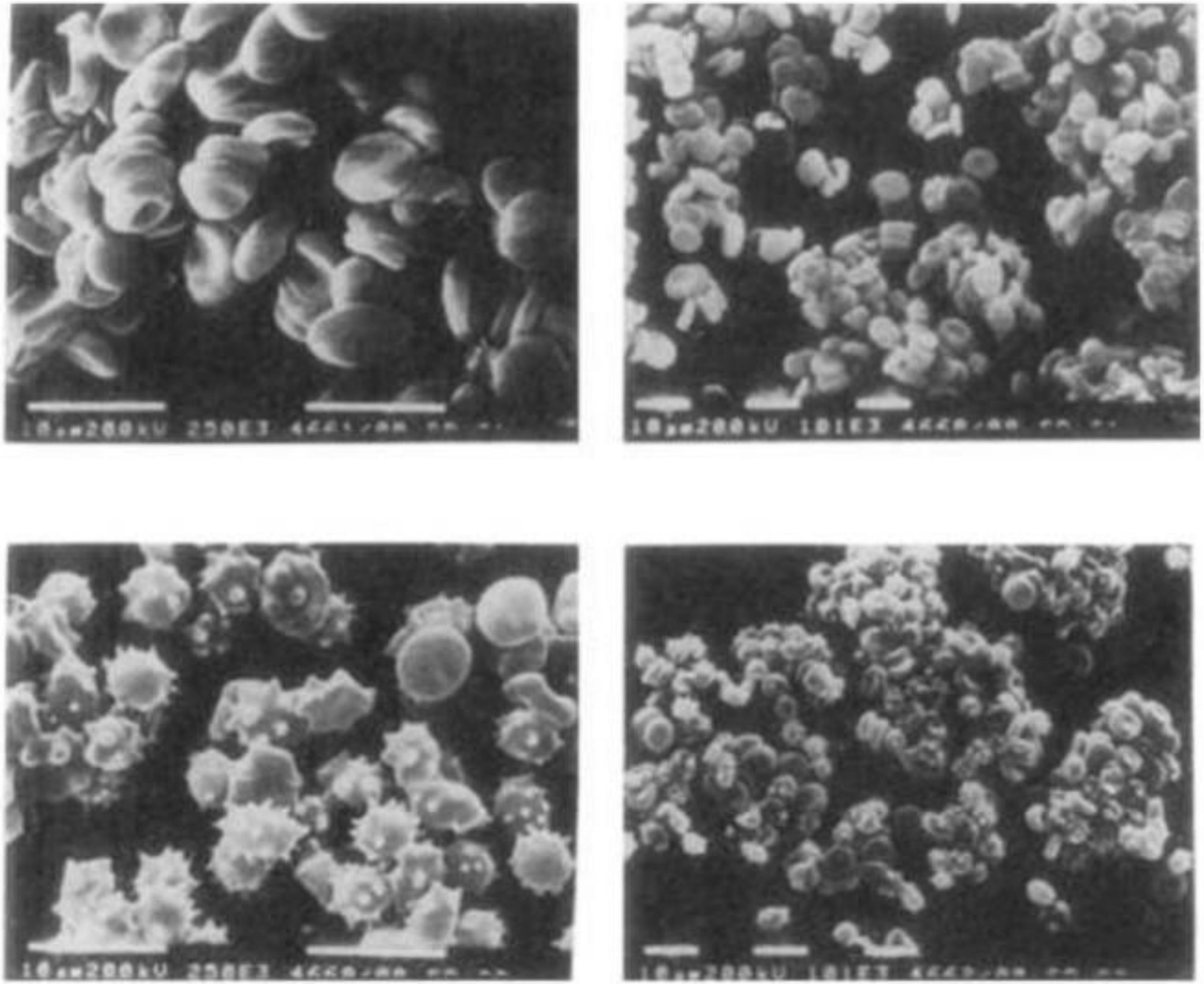
- Myriad biochemical and structural changes
- NO
  - Free hemoglobin (scavenge NO)
  - Asymmetric dimethyl arginine (inhibit NO synth)
- Decrease 2,3 BPG
- Inflammatory cytokine induction
- Promotion of bacterial growth
- Increased thrombin generation

A

Day 1

B

Day 21



Hovav et al. *Transfusion*. 1999.

Duration of Red-Cell Storage and Complications after Cardiac Surgery

Colleen Gorman Koch, M.D., Liang Li, Ph.D., Daniel I. Sessler, M.D., Priscilla Figueroa, M.D., Gerald A. Hoeltge, M.D., Tomislav Mihaljevic, M.D., and Eugene H. Blackstone, M.D.

The Koch Study

Abstract

BACKGROUND

Stored red cells undergo progressive structural and functional changes over time. We tested the hypothesis that serious complications and mortality after cardiac surgery are increased when transfused red cells are stored for more than 2 weeks.

METHODS

We examined data from patients given red-cell transfusions during coronary-artery bypass grafting, heart-valve surgery, or both between June 30, 1998, and January 30, 2006. A total of 2872 patients received 8802 units of blood that had been stored for 14 days or less ("newer blood"), and 3130 patients received 10,782 units of blood that had been stored for more than 14 days ("older blood"). Multivariable logistic regression with propensity-score methods was used to examine the effect of the duration of storage on outcomes. Survival was estimated by the Kaplan–Meier method and Blackstone's decomposition method.

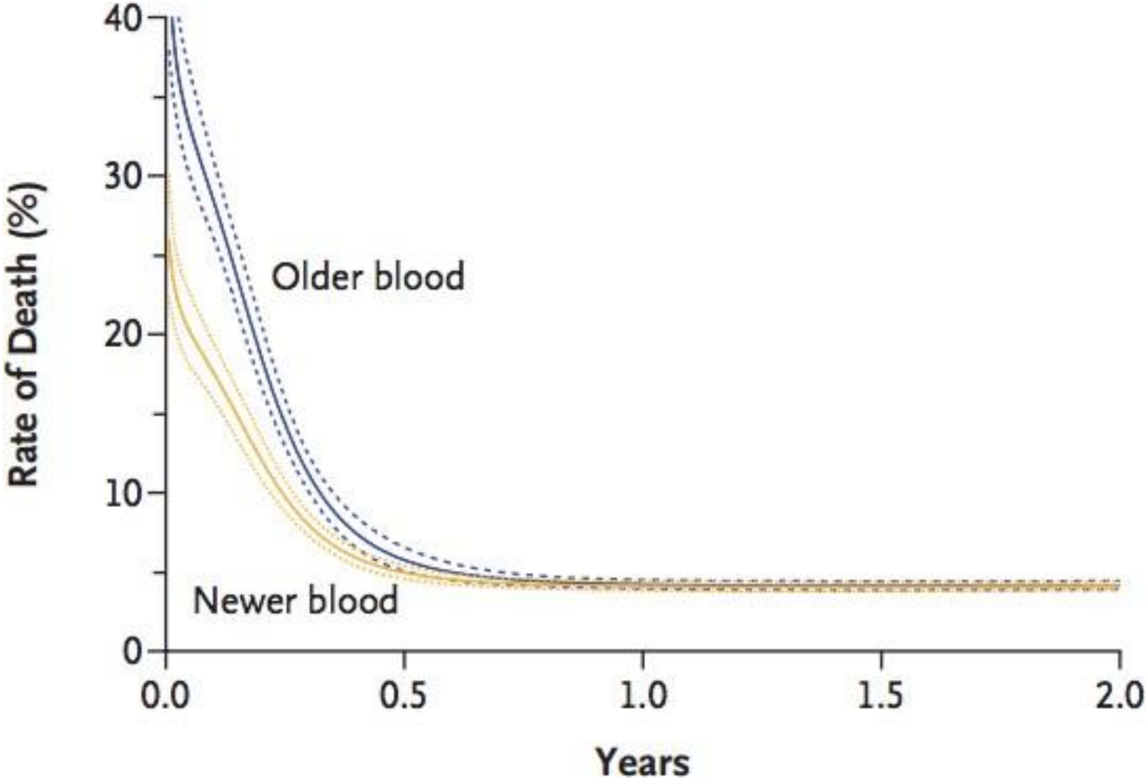
RESULTS

The median duration of storage was 11 days for newer blood and 20 days for older blood. Patients who were given older units had higher rates of in-hospital mortality (2.8% vs. 1.7%, $P=0.004$), intubation beyond 72 hours (9.7% vs. 5.6%, $P<0.001$), renal failure (2.7% vs. 1.6%, $P=0.003$), and sepsis or septicemia (4.0% vs. 2.8%, $P=0.01$). A composite of complications was more common in patients given older blood (25.9% vs. 22.4%, $P=0.001$). Similarly, older blood was associated with an increase in the risk-adjusted rate of the composite outcome ($P=0.03$). At 1 year, mortality was significantly less in patients given newer blood (7.4% vs. 11.0%, $P<0.001$).

CONCLUSIONS

In patients undergoing cardiac surgery, transfusion of red cells that had been stored for more than 2 weeks was associated with a significantly increased risk of postoperative complications as well as reduced short-term and long-term survival.

The Koch Study



Cardiac surgery, 1998-2006
Exclusively +/-14d storage
Propensity score adjusted

ABO imbalanced
Not adjusted for time (practice change)

Koch, CG et al. *NEJM* 2008.

ARIPI Trial

Effect of Fresh Red Blood Cell Transfusions on Clinical Outcomes in Premature, Very Low-Birth-Weight Infants

The ARIPI Randomized Trial

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Stan Shapiro, PhD

Context Even though red blood cells (RBCs) are lifesaving in neonatal intensive care, transfusing older RBCs may result in higher rates of organ dysfunction, nosocomial infection, and length of hospital stay.

Objective To determine if RBCs stored for 7 days or less compared with usual standards decreased rates of major nosocomial infection and organ dysfunction in neonatal intensive care unit patients requiring at least 1 RBC transfusion.

Design, Setting, and Participants Double-blind, randomized controlled trial in 377 premature infants with birth weights less than 1250 g admitted to 6 Canadian tertiary neonatal intensive care units between May 2006 and June 2011.

Intervention Patients were randomly assigned to receive transfusion of RBCs stored 7 days or less (n=188) vs standard-issue RBCs in accordance with standard blood bank practice (n=189).

Main Outcome Measures The primary outcome was a composite measure of major neonatal morbidities, including necrotizing enterocolitis, retinopathy of prematurity, bronchopulmonary dysplasia, and intraventricular hemorrhage, as well as death. The primary outcome was measured within the entire period of neonatal intensive care unit stay up to 90 days after randomization. The rate of nosocomial infection was a secondary outcome.

Results The mean age of transfused blood was 5.1 (SD, 2.0) days in the fresh RBC group and 14.6 (SD, 8.3) days in the standard group. Among neonates in the fresh RBC group, 99 (52.7%) had the primary outcome compared with 100 (52.9%) in the standard RBC group (relative risk, 1.00; 95% CI, 0.82-1.21). The rate of clinically suspected infection in the fresh RBC group was 77.7% (n=146) compared with 77.2% (n=146) in the standard RBC group (relative risk, 1.01; 95% CI, 0.90-1.12), and the rate of positive cultures was 67.5% (n=127) in the fresh RBC group compared with 64.0% (n=121) in the standard RBC group (relative risk, 1.06; 95% CI, 0.91-1.22).

Conclusion In this trial, the use of fresh RBCs compared with standard blood bank practice did not improve outcomes in premature, very low-birth-weight infants requiring a transfusion.

Trial Registration clinicaltrials.gov Identifier: NCT00326924; Current Controlled Trials Identifier: ISRCTN65939658

JAMA. 2012;308(14):1443-1451
Published online October 8, 2012. doi:10.1001/2012.jama.11953 www.jama.com

ALTHOUGH RED BLOOD CELL (RBC) transfusions are used routinely in acutely ill patients, including those in neonatal intensive care units, the clinical consequences of the prolonged stor-

ARIPI Trial- Neonates

Figure 2. Distribution of Age of Red Blood Cell Transfusion Episodes in Fresh and Standard Groups

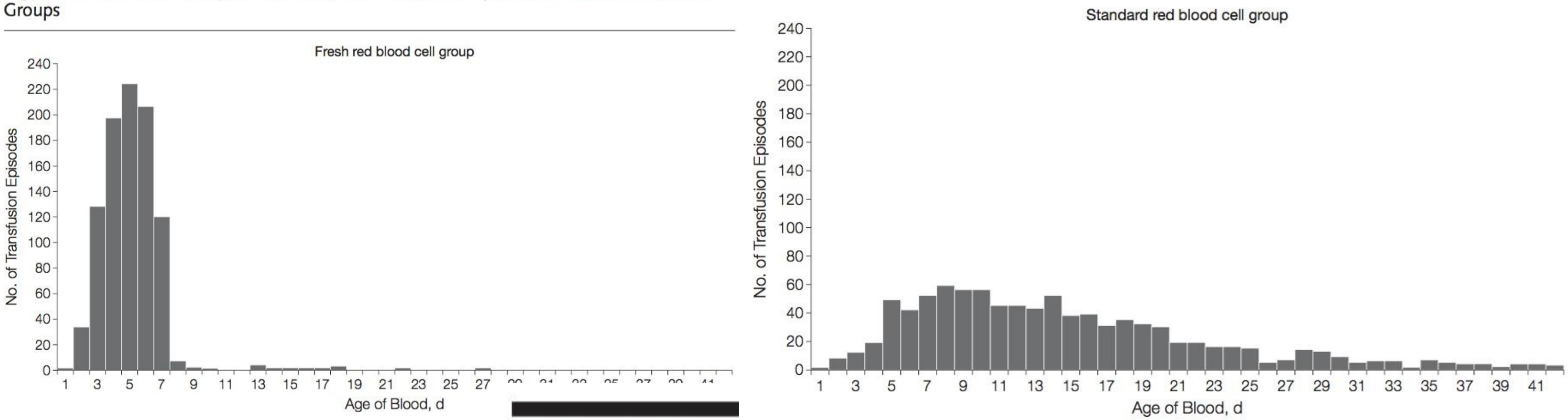


Table 4. Primary Outcomes

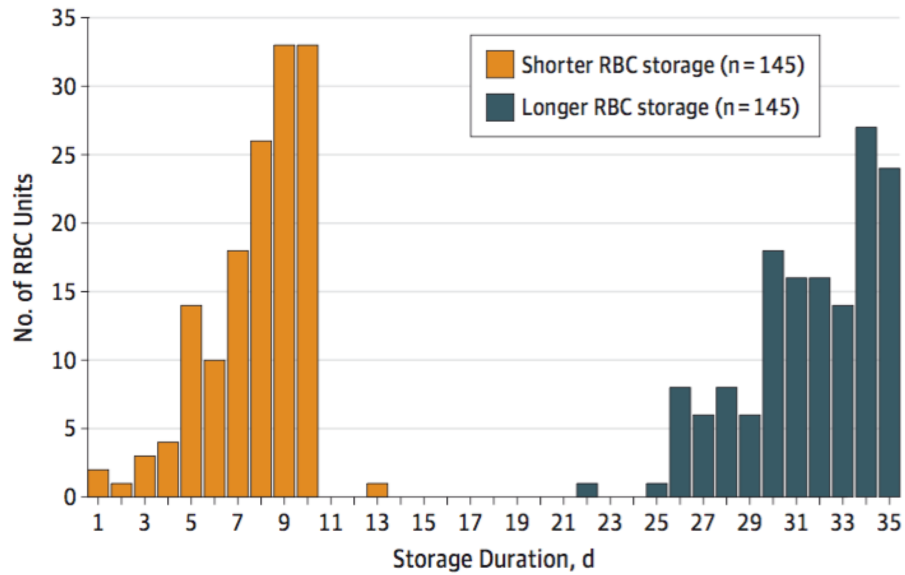
Primary Outcomes	No. (%) Standard Red Blood Cell Group (n = 189)	No. (%) Fresh Red Blood Cell Group (n = 188)	Relative Risk (95% CI)
Necrotizing enterocolitis (Bell criteria stage ≥2)	15 (7.9)	15 (8.0)	1.00 (0.48-2.12)
Intraventricular hemorrhage (Papile criteria grade ≥3)	11 (5.8)	18 (9.6)	1.65 (0.80-3.39)
Retinopathy of prematurity (stage ≥3)	26 (13.8)	23 (12.2)	0.89 (0.53-1.50)
Bronchopulmonary dysplasia	63 (33.3)	60 (31.9)	0.96 (0.72-1.28)
Death	31 (16.4)	30 (16.0)	0.97 (0.61-1.54)
Composite primary outcome: any of above	100 (52.9)	99 (52.7)	1.00 (0.82-1.21)

Fergusson et al.
JAMA. 2012

TOTAL: Ugandan PICU

- ≤10 vs 25-35 day
- N=290, Age 0.5-5y
- Mean Hgb 3.7
- Outcome: Lactate <3 mmol/L @8h
- Dx: 81% malaria; 13% SCD
- No:
  - Pressors
  - Intubation
  - Dialysis

Figure 2. Duration of Red Blood Cell Storage by Study Group



Dhabangi et al. *Lancet*. 2015

TOTAL: Ugandan Children

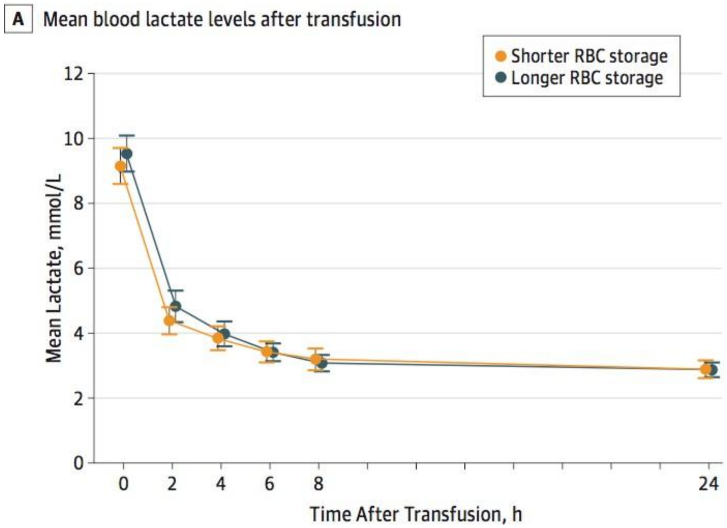
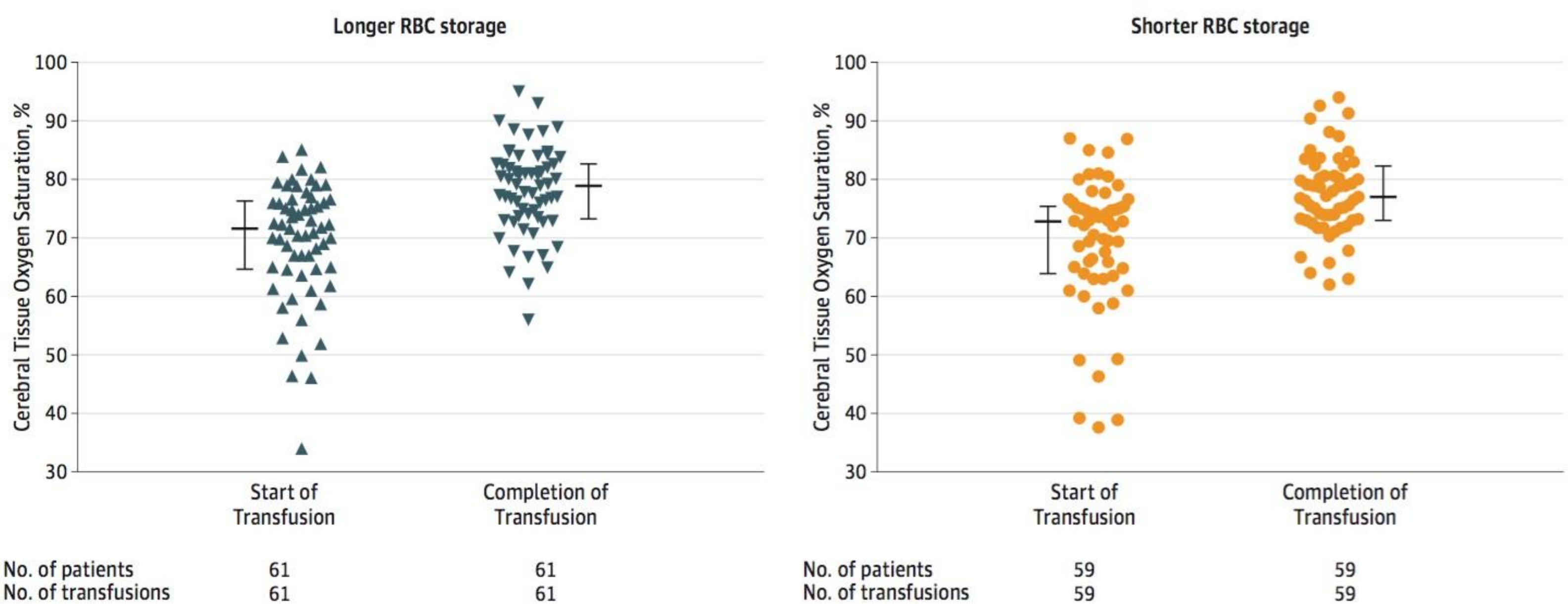


Figure 5. Cerebral Tissue Oxygen Saturation in Response to Transfusion



Dhabangi et al. *Lancet*. 2015

AABB Systematic Review-Storage Age

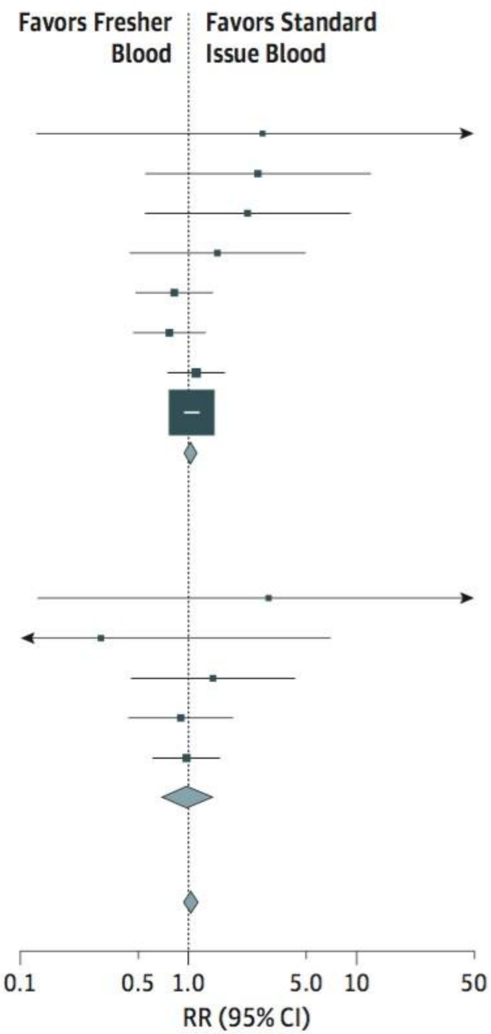
Figure 2. Association Between Fresher vs Standard-Issue Blood and Mortality in Adults, Neonates, Infants, and Children in Randomized Clinical Trials

Source	Fresher Blood: No. of Deaths	Fresher Blood: Total No.	Standard Issue Blood: No. of Deaths	Standard Issue Blood: Total No.	RR (95% CI)	Weight, %
Adults						
Bennett-Guerrero et al,[33] 2009	1	12	0	11	2.77 (0.12-61.65)	0.1
Aubron et al,[34] 2012	5	25	2	26	2.60 (0.55-12.19)	0.4
Schulman et al,[30] 2002	4	8	2	9	2.25 (0.55-9.17)	0.4
Hébert et al,[32] 2005	5	26	4	31	1.49 (0.45-4.98)	0.6
Steiner et al,[41] 2015	23	538	29	560	0.83 (0.48-1.41)	3.1
Kor et al,[37] 2012	17	50	22	50	0.77 (0.47-1.27)	3.6
Heddle et al,[36] 2012	35	309	61	601	1.12 (0.75-1.65)	5.8
Lacroix et al,[40] 2015	448	1211	430	1219	1.05 (0.94-1.17)	79.2
Subtotal	538	2179	550	2507	1.04 (0.95-1.15)	93.2
Neonates, Infants, and Children						
Dhabangi et al,[38] 2013	1	37	0	37	3.00 (0.13-71.34)	0.1
Strauss et al,[29] 1996	0	21	1	19	0.30 (0.01-7.02)	0.1
Dhabangi et al,[39] 2015	7	143	5	143	1.40 (0.45-4.31)	0.7
Fernandes da Cunha et al,[31] 2005	9	26	10	26	0.90 (0.44-1.85)	1.7
Fergusson et al,[35] 2012	30	188	31	189	0.97 (0.61-1.54)	4.2
Subtotal	47	415	47	414	0.99 (0.69-1.42)	6.8
Overall	585	2594	597	2921	1.04 (0.95-1.14)	100

Adults — Heterogeneity: $\tau^2 = 0$; $\chi^2_7 = 5.47$; $P = .60$; $I^2 = 0\%$
Tests for overall effect: z score $= 0.85$; $P = .40$

Neonates, Infants, and Children — Heterogeneity: $\tau^2 = 0$; $\chi^2_4 = 1.46$; $P = .83$; $I^2 = 0\%$
Tests for overall effect: z score $= 0.06$; $P = .96$

Overall — Heterogeneity: $\tau^2 = 0$; $\chi^2_{12} = 7.00$; $P = .86$; $I^2 = 0\%$
Tests for overall effect: z score $= 0.81$; $P = .42$
Tests for subgroup differences: $\chi^2_1 = 0.08$; $P = .78$; $I^2 = 0\%$



Carson et al. *JAMA*. 2016

Age of RBC

- No clinical trial evidence to support using fresher blood

Summary:

- Threshold for RBCtx: no difference
- Age of stored blood: no difference

Red blood cell transfusion: 2016 clinical practice guidelines from AABB

- **Recommendation 1:** AABB recommends a restrictive RBC transfusion threshold of 7 g/dL in hospitalized hemodynamically stable adult patients, including critical care patients, rather than 10 g/dL (strong recommendation, moderate quality evidence). For patients undergoing orthopedic surgery and cardiac surgery and those with existing cardiovascular disease, AABB recommends a restrictive RBC transfusion threshold of 8 g/dL (strong recommendation, moderate quality evidence). The restrictive transfusion threshold of 7 g/dL is likely comparable to 8 g/dL, but randomized trial evidence is not available for all patient categories. These recommendations apply to all but the following conditions, where the evidence is judged to be insufficient for any recommendation: acute coronary syndrome, severe thrombocytopenia in hematology/oncology patients at risk of bleeding, and chronic transfusion-dependent anemia.
- **Recommendation 2:** AABB recommends that patients, including neonates, should receive RBC units selected at any point within their licensed dating period (standard issue) rather than limiting patients to transfusion of only fresh (storage length: <10 days) RBC units (strong recommendation, moderate quality evidence).

THANK YOU