

PROBE

Program to Reduce Orthopedic Blood Exposure

The Development and Evaluation of a Blood Conservation Algorithm in Patients Undergoing Elective Primary Total Hip Joint Arthroplasty (THJA)

Sponsor:

Ontario Ministry of Health and Long-Term Care Blood Conservation and Bloodless Medicine Program

Steering Committee:

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Total Hip Joint Arthroplasty

- Common
 - 9,314 hip operations in Ontario in 2003
- Highly effective, good value to society
- Performed in an elderly population at risk for complications of IHD



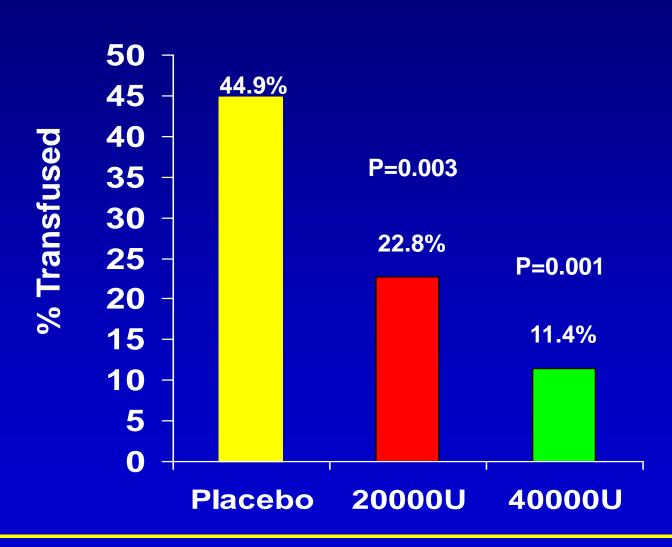
The Problem

- Blood loss is common with THJA
- Consequences:
 - Symptoms fatigue, dizziness, shortness of breath, muscle weakness
 - increased risk of complications of IHD
 - poor mobilization, compliance with physiotherapy
- Transfusion of allogeneic blood is common

Autologous Blood Donation (ABD)

- Most widely used strategy
- Patients predonate 2-3 units of blood before surgery
- Reinfused if needed
- Use restricted Hgb > 110
 - no major CV problems
 - age < 80 years
 - weight > 25 kg
- ~ 60% of population eligible

Perioperative Recombinant Erythropoietin COPES II: Transfusion Rates



Feagan BG et al. Annals of Internal Medicine. 2000;133:845-854

The Krever Commission 1997: Some Key Recommendations



- "The transfusion of one's own blood (autologous transfusion) is safer than the transfusion of blood components made from the donations of other persons (allogeneic transfusion)."
- "The operator of the blood supply system should be fully informed of the risks and benefits of alternative therapies and promote their appropriate use."

Transfusion Practice in Orthopedic Surgery

Chart Review Study 1998-1999

Transfusion Practice in Orthopedic Surgery Chart Review Study 1998-1999

# of hospitals	19
# of patients	4,535
ABD participation	19%
Eligible for ABD*	58%
% of eligible patients that had ABD	33%
Allogeneic transfusion rate for ABD	14%
Allogeneic transfusion for no ABD	30%
Allogeneic transfusion for no ABD (Hemoglobin ≤ 130 g/L)	46%
* Eligibility according to CBS criteria	

Feagan BG et al. Transfusion Medicine 2001;11:87-95

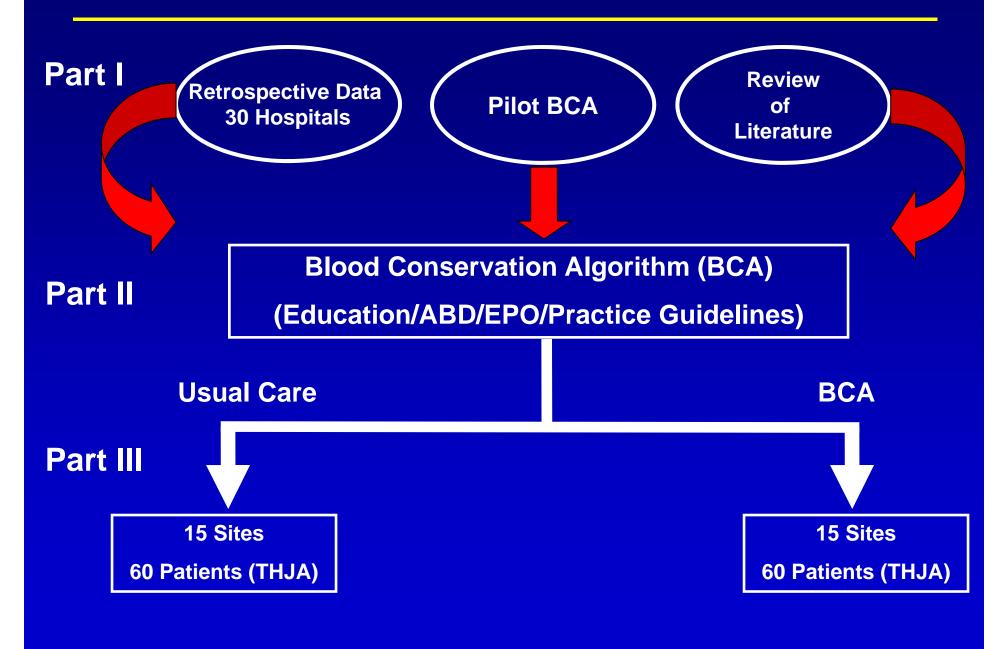
Transfusion Practice in Orthopedic Surgery Chart Review Study 1998-1999 Conclusions

- The proportion of patients ineligible for ABD is high: 42%
- ABD participation remains suboptimal: only 33% eligible for ABD participated in a program
- Allogeneic transfusion rate in 1° THJA is high: 30% overall
- This risk is higher in patients with low baseline [Hgb]: 46% in patients with baseline [Hgb] ≤ 130 g/L
- Use of other blood conservation techniques other than ABD is virtually non-existent
- If allogeneic transfusion rates are to decrease, use of both ABD and other conservation technologies must be enhanced through an integrated approach

PROBE

The objective is to determine whether use of a comprehensive blood conservation algorithm is more effective than usual care for reducing exposure to allogeneic blood in patients undergoing primary THJA at hospitals in Ontario.

Overview

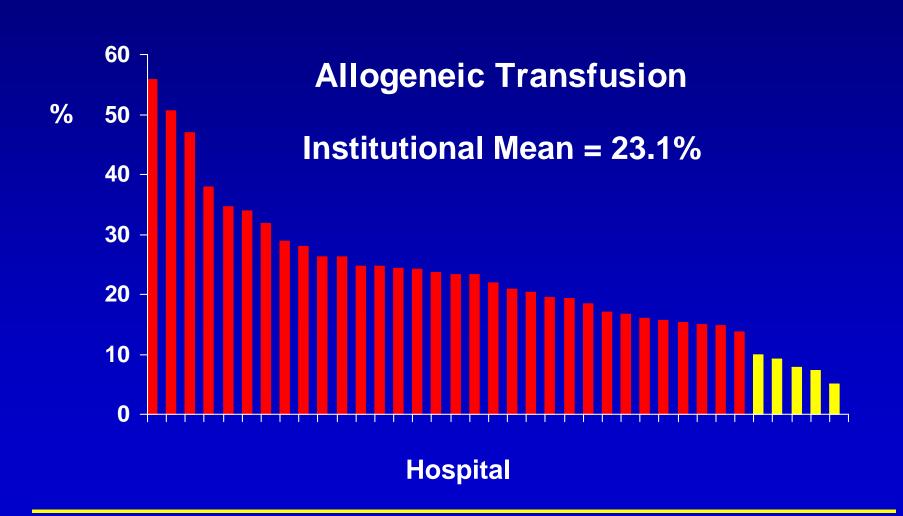


Part I: Collect Background Data

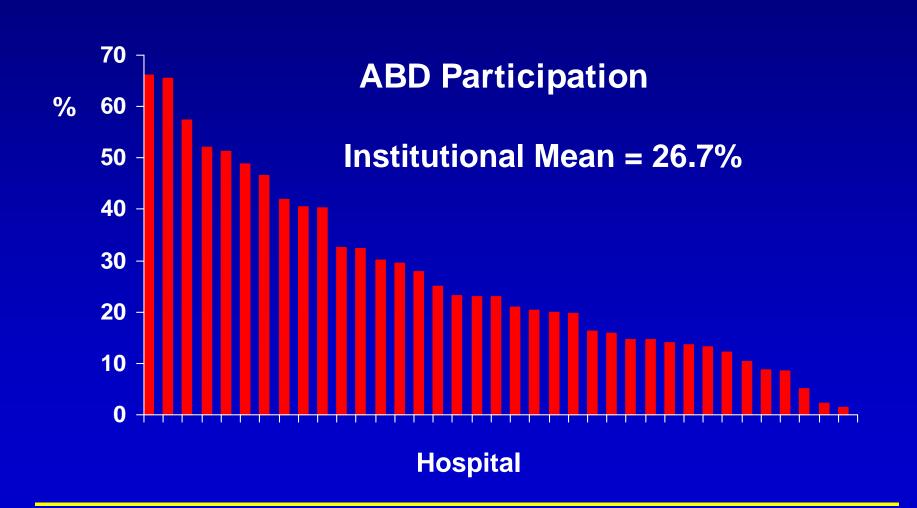
Retrospective review of 37 Ontario hospitals:

- Audit of medical records (2000/05/01 2001/04/30) to obtain:
 - number of primary THJA performed
 - patients demographics
 - pre and post [Hgb]
 - use of blood conservation strategies
 - ► ABD eligibility status
 - >transfusion
 - blood loss
 - anemia related complications
 - **>LOS**
- Completed in 9 months
- Total # of unique charts audited = 4,260
- Data were used to plan Part III

Part I Chart Review



Part I Chart Review



Part I Chart Review

Observations:

- 5 of 37 sites with overall allogeneic rate < 10%
 - ⇒ Potential to bring allogeneic rate below 10%?
- Confirmed feasibility of Part III RCT
- Institutions vary greatly
 - ⇒ Consensus-based BCA needs to be adapted to local environment

Part III: Implementation & Evaluation of BCA

Eligibility Criteria:

- Minimum of 60 elective primary THJA performed annually
- No existing comprehensive BCA
- Willing to be randomized

Modified Criteria:

- Overall allogenic rate >= 10%
- Included 3 sites which performed < 60 cases in Part 1

Part III: Implementation & Evaluation of BCA

- Primary outcome: allogeneic transfusion rate
- Secondary outcomes:
 - use of blood conservation strategies
 - autologous transfusion
 - pre- and post operative [Hgb]
 - surgical blood loss
 - **>** LOS
 - anemia-related complications
 - patient/provider satisfaction (survey)
 - cost & effectiveness
- Each hospital to provide data for approximately 60 consecutive cases

Part III: Implementation & Evaluation of BCA

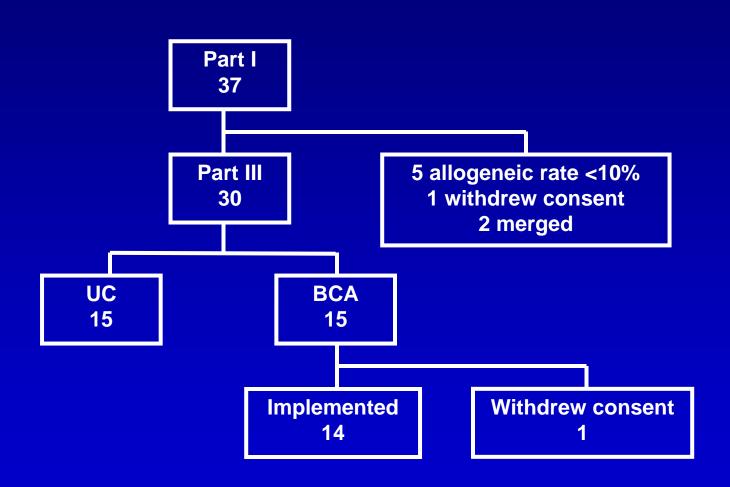
Randomization:

- Cluster randomization
- 1:1 ratio to BCA or usual care
- Minimization procedure to balance:
 - number of 1° THJAs performed
 - > allogeneic transfusion rate
 - > ABD rate

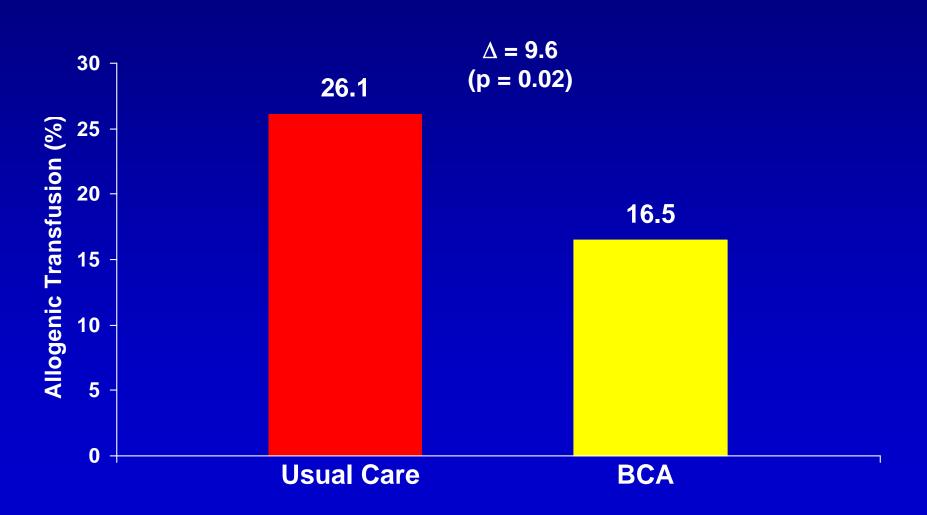
Based on data obtained in Part I

PROBE BLOOD CONSERVATION ALGORITHM FOR ELECTIVE PRIMARY THIA PATIENTS Surgeon's Office **Patient Education Provider Education Materials Patient Education Materials Pre-Admission Clinic** Insufficient time for **Patient Education** pre-op intervention: Select patient likely **Pre-Op Period** with Hgb > 150 Hgb <=100 Hgb >150 Hgb >100-130 Hgb >130-150 **Pre-op Duration Start Niferex Start Niferex** Consider No Blood >4 weeks to OR EPO 40,000u x 4 ABD 2 units Delaying Conservation 3-<4 weeks to OR EPO 40,000u x 3 ABD 2 units Surgery **Strategies** EPO 40.000u x 2 2-<3 weeks to OR ABD 1 unit No EPO therapy <2 weeks to OR No ABD **OR / Post-op Transfusion** - transfusion likely appropriate Hgb < 70 Hgb 70-100 - transfusion likely appropriate **Guidelines:** if patient symptomatic Hgb > 100 - transfusion likely inappropriate

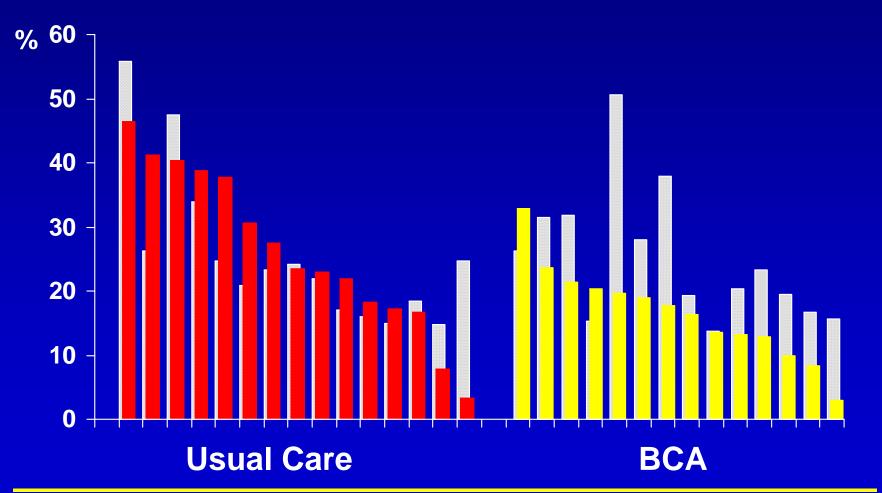
Disposition of Institutions



Allogeneic Transfusion Rate (Institutional Level Summary):

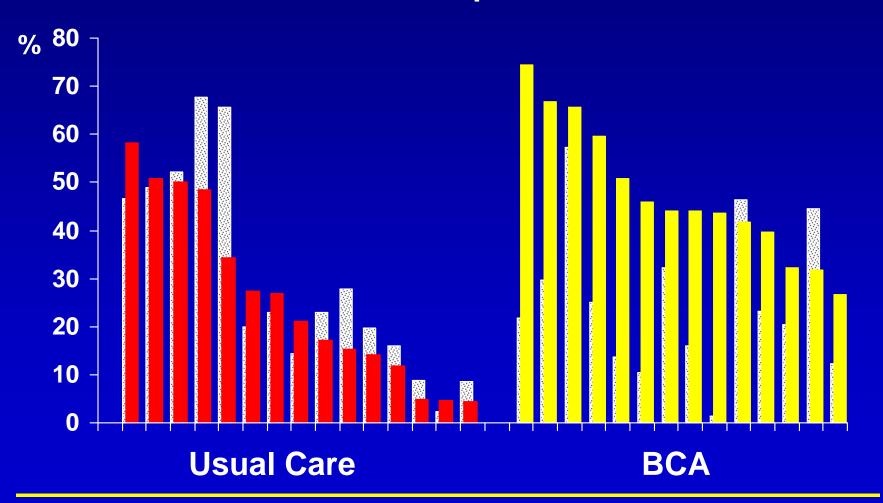




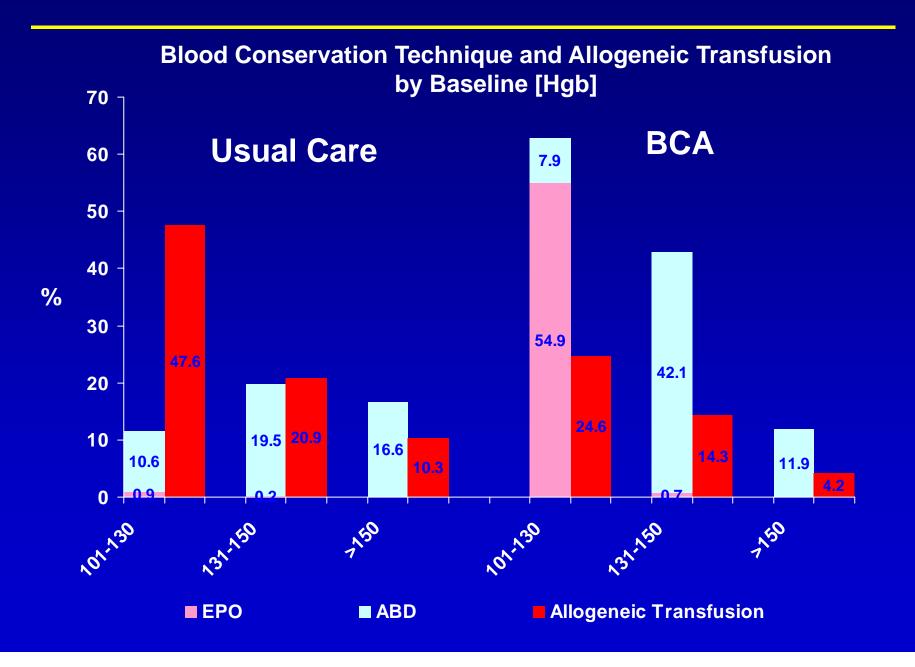


^{*} Part I allogeneic transfusion rates are displayed in the background.

EPO / ABD Participation Rate *



^{*} Part I EPO / ABD participation rates are displayed in the background.



Length of Hospital Stay*:

Institutional Summary

	Usual Care (N = 15) Mean (Range)	BCA (N = 14) Mean (Range)
Adm to D/C	6.4 (4.1 – 9.2)	5.8 (2.4 – 8.6)
Sx to D/C	6.3 (4.0 - 9.2)	5.8 (2.4 – 8.1)

^{*} Number of nights in hospital

Major Complications:

	Usual Care	BCA
	# Pts (% overall) Institutional Range	# Pts (% overall) Institutional Range
In Hospital Death	3 (0.3%)	1 (0.1%)
	0 – 1.7%	0 – 1.7%
Stroke	2 (0.2%)	1 (0.1%)
	0 – 1.7%	0 – 1.6%
MI	7 (0.8%)	9 (0.8%)
	0 – 1.7%	0 – 3.6%
Death/Stroke/MI	11 (1.2%)	10 (0.9%)
	0 – 3.3%	0 – 3.6%

PROBE: Conclusions

- Blood conservation algorithm is effective (~10% ARR)
- Evidence exists that individual key components (ABD, EPO, practice guidelines) were effective
- Largest impact is in patients at highest risk of requiring allogeneic transfusion (i.e. patients with [Hgb] 101 - 130 g/L)
- Some institutions are "non-responders" Why?
- Most efficient in institutions with high baseline allogeneic rates

PROBE Benefits to Ontario

- Expect decrease in use of allogeneic transfusion& more rational use of autologous blood
- Comprehensive analysis from a controlled study will estimate the cost-effectiveness of an integrated blood conservation program
- Heighten awareness of blood conservation among members of the public and providers
- MOH has provided strong leadership in attempt to resolving discrepancy between Krever recommendation and current practice in Ontario