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Implementing a protocol to optimize blood use in a cardiac surgery service: results of a pre-post analysis and the impact of high-volume blood users

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Abstract

Background—Blood transfusions are a common and costly intervention for cardiac surgery patients. Evidence suggests a more restrictive transfusion strategy may reduce costs and transfusion-related complications without increasing perioperative morbidity and mortality.

Study design and methods—A transfusion-limiting protocol was developed and implemented in a cardiovascular surgery unit. Over a 5 year period, data were collected on patient characteristics, procedures, utilization of blood products, morbidity and mortality, and these were compared before and after the protocol was implemented.

Results—After the protocol was put in place, fewer patients required transfusions (38.2% vs 45.5%, $p=0.004$), with the greatest reduction observed in post-operative blood use (29.1% vs 37.2%, $p=0.001$). In-hospital morbidity and mortality did not increase. When transfused patients were stratified by procedure, the protocol was most effective in reducing transfusions for patients undergoing isolated coronary artery bypass grafting (4.09 vs 2.51 units, $p=0.009$) and coronary artery bypass grafting plus valve surgery (10.32 vs 4.77 units, $p=0.014$). A small group of patients were disproportionate recipients of transfusions, with approximately 6% of all patients receiving about half of the blood products.

Conclusion—A protocol to limit transfusions decreased the proportion of cardiothoracic surgery patients who received blood products. A very small group of patients received a large number of transfusions, and within that group the observed mortality was significantly higher than in the general patient population. Current protocols cannot possibly account for these patients, and this should be considered when analyzing the performance of protocols designed to reduce unnecessary transfusions.

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Keywords

cardiovascular surgery; blood transfusion; cardiac surgery

Introduction

Cardiac surgery services use a significant proportion of many hospitals' blood supplies, with 40% to 90% of cases receiving blood products.¹⁻³ Blood transfusions provide significant benefits in situations where critically low levels of hemoglobin deplete the oxygen supply.⁴ The discretionary use of blood products may have negative consequences including altered immune function, pulmonary complications, increased infection rates, longer ICU stay, red blood cell alloimmunization, and increased overall mortality, not to mention the potential risks of incompatible transfusions.⁵⁻⁸

In addition to the health risks associated with transfusions, blood products are an increasingly expensive component of cardiac surgery. Hospitals in the United States pay approximately \$225USD per unit of red blood cells,⁹ but the administrative and labor costs associated with receipt, storage, transportation and transfusion of the blood products can more than triple that cost.¹⁰ As such, reducing the unnecessary use of blood products has the potential to control hospital costs associated with blood products and reduce transfusion-related morbidities.

Guidelines have broadly recommended transfusing below 6-7 g/dL Hgb and limiting transfusion in patients with Hgb above 10 g/dL, and that transfusions should be “considered” for patients with <8g/dL for postoperative surgical patients or patients with cardiovascular disease when symptoms such as chest pain or orthostatic hypotension are present.¹¹ These guidelines have not been universally adopted, and there is still some controversy in the literature as to the ideal thresholds for transfusion. Cardiac surgery patients who refuse blood transfusions have similar outcomes to patients who follow standard care.^{13, 14} This combined with increasing evidence of transfusion-related complications in cardiac surgery patients,⁵⁻⁸ has sparked interest in more restrictive strategies.¹² To date the evidence is mixed, with no clear indication of whether reducing blood transfusions significantly improves patient outcomes after cardiac surgery.^{5, 15} As the debate continues in the literature, clinicians must attempt to balance the potential risks and benefits of transfusion on a day-to-day basis, while hospital administrators monitor ever-increasing costs.

The use of a protocol, rather than standalone thresholds for transfusion, may provide a more nuanced guide for the clinical care providers. Although transfusion thresholds help guide decision-making, studies have shown that thresholds alone are subject to wide variability in provider compliance.⁵ An overall strategy that identifies patients at higher risk of needing transfusion, and adapts an institution's standard of care with the goal of reducing the use of blood products may be more effective. The purpose of this study was to determine whether the initiation of a comprehensive blood transfusion protocol could reduce discretionary transfusions and lead to more appropriate use of blood products in a cardiac surgery unit. Our goals were to determine: 1) whether the transfusion protocol successfully reduced unnecessary transfusion in the perioperative and postoperative periods 2) which operations

benefitted most from this change in protocol and 3) the effects of this change on overall blood product utilization.

Materials and Methods

Patient Population

This study included all consecutive patients who underwent cardiac surgery at the Valley Hospital between the years of 2010 and 2015, with the protocol initiated on November 1st of 2013. A total of 1530 patients were analyzed over a 5 year period, with 736 patients in the pre transfusion protocol initiation (pre-TPI) period and 794 patients in the post transfusion protocol initiation (post-TPI) period. Data were prospectively collected using standard elements and definitions from the Society of Thoracic Surgeons (STS) database. The protocol was reviewed by the institutional review board and the need to obtain informed consent was waived for the study. All patient records included in the study were reviewed individually to ensure the quality and accuracy of perioperative transfusion data.

In-hospital Protocol

The protocol for the management of perioperative blood transfusions in cardiac patients was developed by a multidisciplinary Committee that included cardiothoracic surgeons, intensivists, cardiac anesthesiologists, cardiologists and perfusionists. The goal of the protocol was to reduce the rates of transfusion, particularly unnecessary transfusions, in cardiac surgery patients (See supplement 1). The protocol provides guidelines for the identification of individuals who are more likely to need transfusions; suggestions for their perioperative management; intra- and post-operative blood-sparing strategies; and thresholds at which patients should be transfused. The protocol guided but did not dictate clinical practice, and emphasized the use of clinical judgment whenever appropriate. Preoperative interventions in patients scheduled for surgery were not universally undertaken during this period and therefore are not reported.

The protocol was implemented in consultation with the hospital blood bank, and integrated into the hospital's electronic ordering system to encourage compliance. When orders for blood products were placed via computer, the blood bank would review the orders. If the administration of blood products was not indicated by the protocol, blood bank personnel contacted a member of the transfusion protocol Committee, who would advise on whether the order should be filled. If the Committee suggested the patient should not be transfused, the ordering physician still had the ability to order blood products based on their clinical judgment.

Patient care

Post-operatively, cardiac surgical patients at this center were managed by surgical staff and intensivists in a closed cardiothoracic critical care unit with regular monitoring of hemoglobin (Hgb) and hematocrit (Hct). In the pre-TPI period, the ICU nursing staff could accept physicians' discretionary orders for transfusions. Post-TPI, transfusions ordered contrary to the protocol had to be approved by a member of the protocol committee.

All blood product use, including packed red blood cells (RBCs), platelets, fresh frozen plasma, and cryoprecipitate, was tracked. As specified by the protocol, packed RBCs were given when Hct fell below 21% or Hgb was measured at less than 7 g/dL. For patients with acute coronary syndromes, this was modified so that Hct less than 24% or Hgb less than 8g/dl was used as the threshold. Patients experiencing ongoing blood loss or acute blood loss that did not respond to appropriate volume were managed with the goal of stabilizing the patient hemodynamically by giving blood transfusions as necessary.

Statistical analysis

Categorical variables are displayed as frequencies with proportions in parentheses and were analyzed using the chi square test or Fisher's exact test, as appropriate. Continuous data are displayed as means and were analyzed using the Student unpaired t-test, and ordinal data were analyzed with the Mann-Whitney U test. Statistical analyses were performed using SPSS version 19.0 (IBM/SPSS, Chicago, IL).

Results

The patient populations in the pre-TPI and post-TPI periods showed generally similar patterns of demographics, comorbidities, and cardiovascular and surgical risk factors (Table 1). The post-TPI period had a higher proportion of patients with peripheral vascular disease and class III/IV heart failure, and a lower rate of renal failure. Patients presenting in both time periods were similar in urgency of surgery, use of intra-aortic balloon support, and had similar STS mortality risk scores and risk for reoperation for bleeding. The proportion of isolated valve surgeries was higher and proportion of surgeries categorized as “other” was lower comparing the post-TPI to the pre-TPI period.

Of the 1530 patients, 638 (47.1%) required a blood transfusion during their hospitalization. Use of the blood transfusion protocol reduced the proportion of patients requiring blood products in the post-TPI compared to the pre-TPI time period (38.2% vs 45.5%, $p=0.004$), with the primary impact of the protocol occurring in the post-operative period (29.1% vs 37.2%, $p=0.001$) (Table 2). There were no statistically significant differences in the use of platelets, plasma, or cryoprecipitate between the pre- and post-TPI periods. The protocol did not have an effect on intra-operative use of blood products between the pre-TPI and post-TPI periods (Table 2). The pattern of blood utilization varied between time periods (Table 3, Figure 1). There was a strong positive skew to the frequency distributions of transfusions. A majority of patients in both pre- and post-TPI periods received no blood transfusions, and a small group of patients received large amounts of blood (Table 3). Patients who received more than 10 units of blood represented 5.0% of patients in the pre-TPI period and 7.2% in the post-TPI period, but represented 39.4% and 58.6%, respectively, of the total blood products transfused during the study period (Table 3).

Analysis by type of procedure demonstrated that the protocol was most effective in reducing the number of transfusions for patients undergoing CABG and CABG plus valve surgeries (Table 4). In the case of CABG plus valve surgeries, the protocol reduced the average number of units of blood patients received by more than 50%.

There was no increase in mortality or other adverse clinical outcomes after the implementation of the blood-sparing protocol (Table 5). In the post-TPI period, there was a significantly lower rate of permanent stroke (0.0% vs. 2.3%; $p<0.0001$) and post-operative atrial fibrillation (19.6% vs. 24.0%; $p=0.037$). Patients who received >10 blood transfusions had significantly higher rates of mortality in both the pre- and post-TPI period (26.2% and 21.7%, respectively).

In a *post hoc* analysis of patients who received ≥ 5 blood transfusions (Table 6), we noted that these patients had a trend towards higher average age and higher STS predicted risk of mortality. They were more likely to undergo operations in the ‘Other’ category, which is a procedure category that included aortic surgeries. With respect to outcomes, almost half of these patients had prolonged ventilation, and almost a fifth had reoperation for bleeding.

Discussion

The implementation of a protocol to limit unnecessary transfusions was associated with an overall decrease in transfusions in cardiac surgery patients, as well as a shift in the overall pattern of blood utilization. Our results are in line with others in the literature, demonstrating that the implementation of a protocol to reduce transfusions can limit the use of blood products and, specifically in our case, increase the percentage of people who are not transfused, without a significant increase in morbidity or mortality. The decreased incidence of post-operative atrial fibrillation observed after TPI implementation is consistent with some published accounts associated blood transfusions and the risk of atrial fibrillation after surgery.¹⁶ We do not, however, have an explanation for the decreased risk of stroke seen after the protocol was put in place.

When analyzed by procedure, there was a significant reduction in the average amount of blood transfused in patients undergoing coronary revascularization, either alone or in conjunction with a valve intervention. The decrease was particularly notable in the CABG plus valve patients, in whom a 50% reduction was observed. There was no significant change in the average volume of transfusions for patients undergoing other types of surgery, including isolated valve surgery or non-CABG, non-valve procedures. This may indicate that revascularization surgeries are particularly amenable to transfusion reduction strategies, but the relatively small number of patients in this single-centre study would suggest that further study in a larger, multi-centre trial is warranted.

Our analysis identified a small group of patients who were disproportionately high users of blood products. These ‘super users’ are patients in whom the sheer number of transfusions is indicative of an anticipated, or in some cases unanticipated, catastrophic peri-operative course. In our study, the super users had a mean STS predicted risk that was significantly higher than the overall patient population, and a higher proportion of these patients were undergoing ‘other’ surgeries, a procedural group that includes higher-risk aortic procedures. This suggests that there was at least some indication prior to surgery that these were higher-risk patients that may be at greater risk for complications, which were observed in the comparatively high rates of reoperation for bleeding and prolonged ventilation. Transfusion restrictions are unlikely to significantly impact these patients, as they are often transfused in

an effort to achieve and maintain some semblance of hemodynamic and clinical stability; these are critically ill patients, and the utility of a transfusion reduction protocol is limited. The phenomenon of super users can be seen clearly in our post-TPI group, where there were more transfusions overall, but also a higher proportion of patients receiving no blood products; there were fewer 1- or 2-unit transfusions, but the super users continued to receive significant amounts of blood products. This was linked to a disproportionately high mortality rate in this subgroup when compared to the rest of the cohort. Super users are likely to have an outsize influence on statistical analyses of blood utilization, and evaluations of transfusion protocols should anticipate and account for these patients in their analyses. This group of individuals also exemplifies the ongoing debate in the literature as to whether blood transfusions are a significant source of morbidity and mortality, or whether patients who receive those blood products are at intrinsically higher risk to develop more complications and achieve worse outcomes. We believe that among super users, it is impossible to assign causality to transfusions.

The clinical experience in treating cardiac surgery patients who refuse blood products, namely Jehovah's Witnesses, is perhaps one of the strongest indicators that a restrictive transfusion strategy can be implemented safely. Studies have shown that outcomes among patients who refuse blood products can be similar to low-risk patients who accept blood products when appropriate peri-operative measures are taken.^{13, 17-19} Some centers treating Jehovah's Witness patients have focused exclusively on intra-operative blood saving techniques such as Cell Saver and meticulous closure techniques^{17, 18}, while others also include measures such as the use of erythropoietin and iron supplements to treat pre-operative anemia, and limiting blood collection for routine labs.¹⁹ These studies are particularly useful indicators of the ability to safely limit transfusions following cardiac surgery as the Jehovah's Witnesses' strict refusal of any and all blood products prevents the cross-over seen in some prospective, randomized trials.

While the protocol described in this manuscript constitutes a significant change in the intra- and post-operative management of cardiac patients, no changes were made to pre-operative care. Studies have demonstrated that optimization prior to surgery is particularly important for cardiac surgery patients that refuse blood transfusions,^{13, 14} which suggests that such management may also improve patient outcomes under a transfusion reduction protocol. Future studies might consider a variety of preoperative measures to address common issues, such as hypervolemia and pre-operative anemia, prior to cardiac surgery. To improve overall efficacy and, more importantly, patient outcomes, protocols for reducing unnecessary blood transfusions should be integrated into an overall perioperative care plan of evidence-based best practices.

Providing feedback to clinicians about their own transfusion practices may increase the efficacy of transfusion reduction protocols. Changing entrenched clinical behaviors is part of an iterative process, and simply implementing a protocol is unlikely to be effective. Beaty and colleagues found that providing feedback improves adherence to blood utilization protocols, particularly when that feedback is provider-specific.²⁰ Studies have reported non-compliance rates as high as 30-45%,⁵ and this could be another important factor when evaluating the efficacy of transfusion reduction protocols. Our protocol did not include a

mechanism for evaluating compliance or providing that information to physicians, which may have improved the overall program effectiveness.

Two large prospective, randomized controlled trials of liberal versus restrictive transfusion protocols reported that a restrictive transfusion strategy is comparable to a liberal strategy, conveying no additional risks but also conferring no significant benefits.^{5, 15} In the TRACS study,¹⁵ the compliance was significantly better, with only 4 patients of 502 receiving a transfusion not indicated by the protocol. The TRACS study showed that the restrictive strategy was not inferior to the liberal strategy for transfusion. In the TITRe trial,⁵ patients randomized to the liberal transfusion group were transfused immediately after randomization, irrespective of their Hgb or Hct, which differs markedly from the standard of care in most major centers. The researchers hypothesized that the restrictive arm would have an event rate of 11% while the liberal strategy would have an event rate of 17%. The actual event rates in the trial were significantly higher, with events occurring at a rate of 35% in the restrictive group and 33% in the liberal group. Clinicians were also able to contravene the assigned threshold provided they documented a rationale, which led to a non-compliance rate of 30.0% in the restrictive group and 45.2% in the liberal group. It is likely that the high rates of both events and non-compliance reflect the discomfort of practitioners with the randomized assignment of their patients, and weakens the usefulness of this study in addressing these two approaches.

Limitations

This study was done in a single center and its generalizability to other centers may be limited. The design of this study was as a pre-post implementation of the blood transfusion protocol, so patients were not randomized to be treated with or without the protocol, and there may have been other unmeasured differences that could have impacted results when comparing the two time periods. As noted, preoperative interventions in patients scheduled for surgery were not universally undertaken during this period and information was not collected for preoperative interventions that could have affected the study results.

Conclusion

Our study demonstrated that a protocol for blood transfusion was effective in decreasing the proportion of cardiothoracic surgery patients who received blood products. The impact of the protocol was primarily on blood use in the post-operative period. At our center, the discussion among practitioners regarding weighing the need for transfusion and patient relative risk of complications is active and ongoing. To this end it is vital to maintain flexibility in blood protocol transfusion algorithms such that patients are transfused appropriately. Our experience implementing a transfusion reduction protocol supported the value of a comprehensive and detailed protocol, which resulted in an increase in patients receiving no blood products in the perioperative period. We also identified a small group of patients who use a disproportionately high number of blood products. Transfusion reduction strategies must also take into account the high-risk patients who experience extraordinarily high rates of morbidity and mortality despite receiving large quantities of blood. We strongly suggest that future protocols should not be judged solely by a decrease in overall blood utilization.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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Figure 1. Distribution of the number of transfusions patients received before (left) and after (right) protocol implementation.

Table 1
Demographics, risk factors and surgical procedures Pre and Post Transfusion Protocol
Initiation (TPI)

	Pre-TPI (N=736)	Post-TPI (N=794)	p-value
Demographics and clinical characteristics			
Female	242 (32.9%)	246 (31.0%)	0.229
Age	69.8	69.2	0.298
BMI	29.7	29.1	0.278
Current smoking	102 (13.9)	121 (15.2)	0.369
Diabetes	236 (32.1)	273 (34.4)	0.182
Renal Failure	36 (4.9)	21 (2.6)	0.014
PVD	63 (8.6)	98 (12.3)	0.034
NYHA III/IV	132 (17.9)	167 (21.1)	0.030
Hematocrit pre-surgery	38.9	39.1	0.487
Hemoglobin pre-surgery	12.95	13.02	0.487
Anticoagulants on admission	144 (19.6%)	170 (21.4)	0.203
Antiplatelets on admission	36 (4.9%)	45 (5.7)	0.287
Type of surgical procedure	n (%)	n (%)	0.001
Isolated CABG	151 (26.1)	206 (25.9)	
Isolated valve	108 (14.7)	154 (19.4)	
CABG + valve	64 (8.7)	95 (12.0)	
CABG + other	192 (26.1)	164 (20.7)	
Valve + other	118 (16.0)	96 (12.1)	
Other (incl. aortic, congenital surgeries)	103 (14.0)	79 (9.9)	
Urgent/Emergent Operation	296 (40.2%)	332 (41.8%)	0.694
Re-do operation	72 (9.8%)	76 (9.6%)	0.814
Off-pump surgery	283 (38.5)	273 (34.4)	0.098
Time on-pump (minutes, mean)	124.77	121.05	
Intra-aortic Balloon Pump Used	46 (6.3%)	68 (8.6%)	0.085
STS Risk Scores	Mean	Mean	
Mortality	3.39%	3.46%	0.839
Reoperation	6.9%	6.8%	0.932
Mortality (Transfused Pts)	5.57%	6.71%	0.172

All demographics are in accordance with the national STS database.

NYHA = New York Heart Association Functional Classification, BMI = Body Mass Index, PVD= Peripheral Vascular Disease

Table 2

Proportion and timing of patients receiving whole blood transfusions.

	Pre-TPI (N=736) n (%)	Post-TPI (N=794) n (%)	p-value
Intraoperative transfusion	178 (24.2)	209 (26.3)	0.337
Postoperative transfusion	274 (37.2)	231 (29.1)	0.001
Overall blood use:	335 (45.5)	303 (38.2)	0.004

Frequency of patients receiving particular blood transfusion, and proportion of overall amount of blood products used by frequency.

Table 3

	Pre TPI (N=736)		Post TPI (N=794)		p-value
	# patients transfused n (%)	% blood utilization	# patients transfused n (%)	% blood utilization	
0 units	401 (54.5)	0	491 (61.8)	0	0.004
1 unit	78 (10.6)	4.9	80 (10.1)	4.1	0.737
2 units	81 (11.0)	10.1	52 (6.5)	5.4	0.002
3 units	36 (4.9)	6.7	25 (3.1)	3.9	0.082
4 units	24 (3.3)	6.0	30 (3.8)	6.2	0.584
5-10 units	79 (10.7)	33.0	59 (7.4)	21.8	0.024
>10 units	37 (5.0)	39.4	57 (7.2)	58.6	0.025

Table 4
Comparison of mean units of blood used by type of surgery for patients receiving blood

	N	Mean # units pre-TPI	N	Mean # units post-TPI	P value
CABG	151	4.09	206	2.51	0.009
Valve	108	6.41	154	5.01	0.233
CABG + valve	64	10.32	95	4.77	0.014
CABG + other	192	2.85	164	3.66	0.238
Valve + other	118	5.22	96	5.82	0.545
Other (incl. aortic surgeries, congenital surgeries)	103	7.37	79	8.85	0.356

Table 5

Morbidity and mortality outcomes in the pre- and post-TPI periods.

	Pre-TPI n (%)	Post-TPI n (%)	p-value
Overall events	304 (41.3)	275(35.0)	0.011
Mortality	18 (2.4)	23 (2.9)	0.585
Prolonged ventilation	55 (7.5)	73 (9.2)	0.224
Reoperation for bleeding	22 (3.0)	27 (3.4)	0.648
Deep sternal wound infection	0 (0.0)	2 (0.3)	0.173
Permanent stroke	17 (2.3)	0 (0.0)	<0.001
Postop renal failure	13 (1.8)	12 (1.5)	0.694
Postop atrial fibrillation	177 (24.0)	156 (19.6)	0.037

Table 6
***Post hoc* description of patients receiving 5 blood transfusions during the entire study period**

	Patients receiving 5 units of blood (N=232)
Demographics, clinical characteristics	
Female (%)	39.7%
Age (mean $\pm$ SD)	71 $\pm$ 12 years
Hemoglobin pre-surgery (mean $\pm$ SD)	11.9 $\pm$ 2
Creatinine pre-surgery (mean $\pm$ SD)	1.5 $\pm$ 1.2
STS predicted risk (mean)	9.1%
Type of surgical procedure (%)	
Isolated CABG	12.9
Isolated valve	21.6
CABG + valve	19.8
CABG + other	6.0
Valve + other	17.2
Other	22.4
Blood transfusions	
Intra-operative	86.2%
Post-operative	96.6%
Outcomes	
Prolonged ventilation	46.6%
Re-operation for bleeding	18.1%