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BLOOD TRANSFUSION REQUIREMENTS IN CARDIAC SURGERY

By

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ABSTRACT

Background: The effect of restrictive blood transfusion in comparison to liberal red cell transfusion strategy on clinical outcome in cardiac surgery remains undetermined.

Objectives: The aim of this work is to evaluate the restrictive blood transfusion strategy versus the liberal strategy in open heart surgery in terms of vital organ functions (heart, brain, lung, and kidney) and mortality.

Patients and Methods: After approval of Institutional ethical committee and obtaining written informed consent from the patient, in this multicenter randomized prospective study, we assigned 100 adult cardiac surgery patients with Euro score I of 6 or more to a restrictive red cell transfusion trigger (transfuse if hemoglobin level was <7.5g/dl starting from the induction of anesthesia) and liberal red cell transfusion trigger (transfuse if hemoglobin level was <9.5g/dl in the operative room or intensive care unit or <8.5g/dl in the ward). The primary outcome was composite of any cause death, myocardial infarction, stroke, or new onset renal failure with dialysis by discharge from hospital or by day28 whichever came first.

Results: There was a significant decrease in RBC transfusion in the restrictive group intraoperative, in the postoperative day (1), and in the ward stay. There was significantly less fresh frozen plasma transfused in the restrictive group during the ward stay only. There were a significant decrease in ventilator time, ICU stay, chest tube drainage, and rapid AF occurrence in the restrictive.

Conclusion: The restrictive transfusion strategy showed efficacy and safety in decreasing transfusion requirements in cardiac surgery, thus decreasing morbidities and mortality associated with blood transfusion. It also showed cost effectiveness.

Key words: Blood transfusion requirements, Cardiac surgery, Cardiopulmonary bypass, Preoperative anemia.

INTRODUCTION

During cardiac surgery, ongoing blood loss and hemodilution as a result of cardiopulmonary bypass (CPB) cause low hemoglobin (HB) levels. Transfusion of red blood cells (RBC) is the current standard practice for perioperative anemia, but RBC transfusion is not without risks *(El-Hilali et al., 2016* and *Vlot et al., 2019).*

The prevalence of patients undergoing cardiac surgery who received blood components is unknown, with values varying from 10-95% *(Ferraris, 2015).*

Such diversity is partly due to different local practices and institutional protocols *(Tagliari et al., 2019)*.

The incidence of perioperative blood transfusion ranges from 40% to as high as 90% and is dependent on the complexity and duration of surgery, prevalence of pre-existing anemia, and age of the patient. However, blood transfusions have risks, including cardiac and respiratory complications, e.g. transfusion-related acute lung injury, transfusion-associated circulatory overload, transfusion-related immunomodulation, transmission of microorganisms causing infections, hemolytic reactions, renal and neurologic complications, and increased hospital length of stay *(Tempe and Khurana, 2018)*. Safely reducing exposure to red blood cell transfusion can prevent transfusion-related adverse effects, conserve the blood supply, and reduce costs *(Carson et al., 2016* and *Delaney et al., 2016)*. Untreated anemia, however, is also associated with adverse effects, particularly in patients having cardiac surgery who are susceptible to anemia-induced tissue hypoxia *(Docherty et al., 2016* and *Garg et al., 2019)*.

This prospective randomized study was designed to investigate the effect of restrictive transfusion strategy on decreasing transfusion requirements in cardiac surgery in comparison to the liberal strategy without adding extra risks on the patient outcome.

PATIENTS AND METHODS

This was a randomized prospective study that included one hundred patients of moderate to high risk of death undergoing cardiac surgery on cardiopulmonary bypass from multiple Egyptian cardiac centers (multicenter study) after obtaining approval of institutional ethical committee and obtaining written informed consent from the patient.

These patients were randomly divided into two equal groups: **Group I** (Restrictive transfusion group): Patients received a red cell transfusion if their hemoglobin is <7.5 g/L intraoperative and/or postoperatively, and **Group II** (Liberal transfusion strategy): Patients received a red cell transfusion if their hemoglobin concentration was<9.5 g/L intraoperative, or postoperatively in the intensive care unit; or <8.5 g/L on the ward.

Inclusion Criteria: Age 18 or older, and European System for Cardiac Operative Risk Evaluation (EuroSCORE) of 6 or more.

Exclusion Criteria: Patients who were unable to receive or who refused blood products, patients who were involved in the autologous pre-donation program, and pregnancy or lactation (a negative pregnancy test was obtained prior to randomization for pre-menopausal females).

Both investigational groups were followed during their hospitalization from the induction of anesthesia up to discharge or 28 days postoperatively (whichever came first). There after a contact was continued for 6 months postoperatively.

All Patients in both groups were subjects of the following:

1. **Pre-operative:** Demographics, Medical/Cardiac History, Preoperative laboratory data (within 30 days): HB,

HCT, platelets, INR, PTT, creatinine, CK-MB and/or troponin.

2. **Intra-operative:** Intraoperative laboratory data: HB (pre/during CPB and chest closure), HCT (pre/during CPB and chest closure), lowest arterial and central venous PO2 (pre/during CPB and chest closure), lowest arterial and central venous SO2 saturation (pre/during CPB and chest closure), minimum pump flow (during-CPB), and platelets (within 2 hours of chest closure).
3. **Post-operative:** Postoperative laboratory data: HB, HCT, platelets, creatinine, CK-MB and/or troponinwere assessed on postoperative days 1,2,3,5,7,9 and 11 per protocol (unless discharge occurred earlier) and otherwise as clinically indicated. A 12-lead ECG was performed 24 hours after surgery and at hospital discharge or on day 4-6 postoperatively, whichever comes first.

Statistical analysis of the data:

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp). The Kolmogorov-Smirnov, Shapiro and D'agstino tests were used to verify the normality of distribution of variables, Comparisons between groups for categorical variables were assessed using Chi-square test (Fisher or Monte Carlo). Student t-test was used to compare two groups for normally distributed quantitative variables while Mann Whitney test was used to compare between two groups for not normally distributed quantitative variables.

Data wer presented as mean ± SD, for quantitative data and as frequency and percentage for qualitative data. Significance was considered when ≤ 0.05.

RESULTS

There was a statistically significant difference between the two groups as regards the age **(Table 1)**.

Table (1): Demographic data

Groups / Parameters	Restrictive threshold (n = 50)		Liberal threshold (n = 50)		p
	No.	%	No.	%	
Sex					
Male	15	30.0	18	36.0	0.523
Female	35	70.0	32	64.0	
Age (years)					
Min. – Max.	23.0 – 71.0		28.0 – 79.0		0.001
Mean ± SD.	46.44 ± 12.40		55.12 ± 12.38		
BMI (kg/m^2)					
Min. – Max.	13.97 – 43.75		18.09 – 39.79		0.937
Mean ± SD.	29.27 ± 5.54		29.19 ± 4.29		

Data were represented as Mean ± SD

There was a statistically significant difference between both groups as regards the pre CPB and during chest closure hemoglobin level **(Figure 1)**.

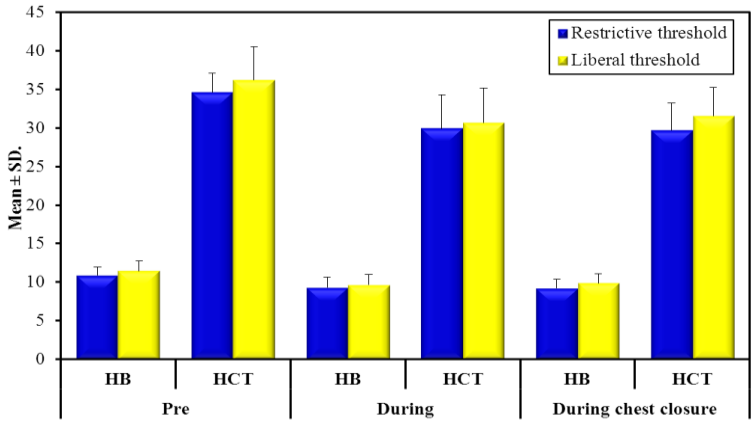

Figure (1): Intra operative HB and HCT

Regarding intraoperative blood and blood products transfusion, blood transfusion occurred in 12 patients (24%) in the restrictive group compared to 26 patients (52%) in the liberal group, with statistically significant difference between both the studied groups. Plasma transfusion occurred in 2 patients in the restrictive group and 4 patients in the liberal group with no significant difference between both groups as regards plasma transfusion. Platelets transfusion occurred in 3 patients in the liberal group. No cryoprecipitate transfusion in both groups. There were no significant differences as regards plasma, platelets transfusion in both of the study groups **(Table 2)**.

Table (2): Intraoperative blood and blood products transfusion parameters

Groups / Intra operative transfusion	Restrictive threshold (n = 50)		Liberal threshold (n = 50)		p
	No.	%	No.	%	
PRBCs or Whole blood transfusion					
No	38	76.0	24	48.0	0.004*
Yes	12	24.0	26	52.0	
Plasma transfusion					
No	48	96.0	46	92.0	MCp= 0.615
1 unit	1	2.0	0	0.0	
2 units	1	2.0	1	2.0	
3 units	0	0.0	2	4.0	
6 units	0	0.0	1	2.0	
Platelets transfusion					
No	50	100.0	47	94.0	FEp= 0.242
Yes (12 unit)	0	0.0	3	6.0	

Data were represented as numbers (No) and percentage (%)

Regarding transfusion parameters postoperatively (day 0), whole fresh blood was transfused in 4 patients (8%) in the liberal group. Packed RBCs was transfused in 3 patients (6%) in the liberal group. Plasma transfusion occurred in 3 patients (6%) in the restrictive group and in 5 patients (10%) in the liberal group. Platelets transfusion occurred in 4 patients (8%) in the restrictive group compared to 7 patients (14%) in the liberal group. Cryoprecipitate was transfused in only 3 patients (6%) in the liberal group.

There were no statistically significant differences between both the study groups as regards blood and blood products transfusion in postoperative day 0 **(Table 3)**.

Table (3): Blood and blood products transfusion parameters (Day 0)

Groups / Blood transfusion parameters (Day 0)	Restrictive threshold (n = 50)		Liberal threshold (n = 50)		p
	No.	%	No.	%	
Whole fresh blood					
Notransfusion	50	100.0	46	92.0	^{FEp}= 0.117
1 unit	0	0.0	4	8.0	
PRBCs					
No transfusion	50	100.0	47	94.0	^{MC}p= 0.248
1 unit	0	0.0	2	4.0	
2 units	0	0.0	1	2.0	
Plasma					
No transfusion	47	94.0	45	90.0	^{MC}p= 0.842
1 unit	0	0.0	1	2.0	
2 units	2	4.0	3	6.0	
3 units	1	2.0	1	2.0	
Platelets					
No transfusion	46	92.0	43	86.0	^{MC}p= 0.461
6 unit s	2	4.0	2	4.0	
12 unit	1	2.0	2	4.0	
15 unit	1	2.0	0	0.0	
24 unit	0	0.0	3	6.0	
Cryoprecipitate					
No transfusion	50	100.0	47	94.0	^{MC}p= 0.235
2 units	0	0.0	1	2.0	
12 units	0	0.0	2	4.0	

Data were represented as numbers (No) and percentage (%)

Regarding transfusion parameters postoperatively (day one), packed RBCs were transfused in 7 patients (14%) in the liberal group. Fresh frozen plasma was transfused in only one patient (2%) in the restrictive group. Platelets transfusion occurred in only one patient in the liberal group. No cryoprecipitate transfusion in any of the two studied groups. There was a statistically significant difference between the two study groups as regards PRBCs transfusion postoperativelyin day one **(Table 4)**.

Table (4): Blood and blood products transfusion parameters (Day 1)

Groups / Blood transfusion parameters (Day 1)	Restrictive threshold (n = 50)		Liberal threshold (n = 50)		p
	No.	%	No.	%	
PRBCs					
No	50	100.0	43	86.0	$^{MC}p=0.013$
1 unit	0	0.0	4	8.0	
2 units	0	0.0	3	6.0	
FFP					
No	49	98.0	50	100.0	$^{FE}p=1.000$
2 units	1	2.0	0	0.0	
Platelets					
No	50	100.0	49	98.0	$^{FE}p=1.000$
12 units	0	0.0	1	2.0	

Data were represented as numbers (No) and percentage (%)

Regarding transfusion parameters in the ward stay, packed RBCs was transfused in 6 patients (12%) in the liberal group. FFP was transfused in only 1 patient (2%) in the liberal group. Regarding transfusion parameters in the ward stay, there were statistically significant differences between the two studied groups as regards PRBCs transfusion and FFP transfusion **(Table 5)**.

Table (5): Blood and blood products transfusion parameters (ward stay)

Groups / Blood transfusion parameters (ward)	Restrictive threshold (n = 50)		Liberal threshold (n = 50)		p
	No.	%	No.	%	
PRBCs					
No	50	100.0	44	88.0	$^{MC}p=0.025^{*}$
1 unit	0	0.0	3	6.0	
2 units	0	0.0	3	6.0	
FFP					
No	50	100.0	49	98.0	$^{MC}p=1.000$
3 units	0	0.0	1	2.0	

Data were represented as numbers (No) and percentage (%)

Regarding the postoperative outcomes, ICU stay in the restrictive group was ranging from 1 to 6 days with a mean of 2.21 ± 0.81, while in the liberal group was ranging from 2 to 28 days with a mean of 3.4 ± 3.85 with a statistically significant difference between the two studied groups. Total chest tube drainage in the restrictive group was ranging from 250 to 1000 cc with a mean of 499 ± 171.8 while in the liberal group was ranging from 250 to 1500 with a mean of 730.0 ± 303.8, with a statistically significant difference between the two studied groups. Ventilator time in the restrictive group was ranging from 3 to 24 hours with a mean of 8.96 ± 4.15, while in the liberal group was ranging from 4 to 240 hours with a mean of 18.70 ± 35.89, with a statistically significant difference between the two studied groups. Total hospital stay in the restrictive group was ranging from

5 to 11 days with a mean of 6.88 ± 1.44, while in the liberal group was ranging from 5 to 30 days with a mean of 9.0 ± 5.19, with no significant difference. Rapid AF occurred in 3 patients (6%) in the restrictive group compared to 11 patients (22%) in the liberal group, with a statistically significant difference between the two studied groups regarding the occurrence of rapid AF.

There was no significant difference between the study groups as regards the neurological events. Regarding the renal problems, there were no cases with acute kidney injury in the restrictive group compared to 4 patients (8%) in the liberal group, with no significant difference. Regarding death from any cause, there were 4 patients (8%) died in the liberal group, one of them died from renal failure, other one from suture line endocarditis, and two cases with sudden cardiac arrest. No significant difference between the two studied groups as regards death due any cause **(Table 6)**.

Table (6): Postoperative outcomes

Groups / Postoperative outcomes	Restrictive threshold (n = 50)	Liberal threshold (n = 50)	p
Chest tube drainage			
Min. – Max.	250 – 1000	250 – 1500	<0.001 *
Mean ± SD.	499 ± 171.8	730.0 ± 303.8	
Ventilator time			
Min. – Max.	3.0 – 24.0	4.0 – 240.0	0.001*
Mean ± SD.	8.96 ± 4.15	18.70 ± 35.89	
ICU stay (days)			
Min. – Max.	1.0 – 6.0	2.0 – 28.0	<0.001 *
Mean ± SD.	2.21 ± 0.81	3.4 ± 3.85	
Total hospital stay			
Min. – Max.	n5.0 – 11.0	5.0 – 30.0	0.053
Mean ± SD.	6.88 ± 1.44	9.0 ± 5.19	

Data were represented as Mean ± SD

DISCUSSION

Restrictive and liberal transfusion strategies are both effective and safe techniques for blood transfusion in patients with an elevated perioperative risk of death who were undergoing cardiac surgery with cardiopulmonary bypass according to this study. In the restrictive threshold group, there were fewer patients receiving red cell transfusion than in the liberal threshold group. Also, fewer units of allogeneic red cells were transfused in the restrictive threshold group than in the liberal group.

Our findings were consistent with those found in *Mazer et al. (2018)* who found that a restrictive transfusion threshold (hemoglobin<7.5 g/dl) was non inferior to a liberal transfusion strategy (hemoglobin<9.5 d/dl in the operating room or ICU, and <8.5 g/dl on the ward) as regarding death and major disabilities (myocardial infarction, stroke, and new onset renal failure with dialysis) in patients undergoing cardiac surgery with

moderate to high risk of death. These results were achieved with fewer units of RBCs being transfused.

Van Boven et al. (2015) stated that there was no difference between restrictive and liberal transfusion during cardiac surgery regarding either mortality rate or perioperative complications which run in lines with our results.

Garg et al. (2019) found in their study that there was no difference between restrictive and liberal groups regarding mortality rate which was in agreement with our results.

Docherty et al. (2016) revealed in their study that the use of liberal transfusion improves outcome in cases of surgery for acute coronary syndrome which conflicting with our results.

Murphy et al. (2015) documented in their study that, in the restrictive strategy of transfusion, there was increased mortality within three months postoperatively which conflicted with our results without significant difference between both of the transfusion strategies (restrictive or liberal), but regarding post-operative morbidity was in agreement with our results.

The current study did not involve low risk patients. Also, it did not answer the question of whether even lower transfusion triggers might also be as safe and effective as the thresholds used in this study.

CONCLUSION

The restrictive transfusion strategy showed efficacy and safety in decreasing transfusion requirements in cardiac surgery, thus decreasing morbidities and mortality associated with blood transfusion. It also showed cost effectiveness.

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متطلبات نقل الدم فى عمليات جراحة القلب

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خلفيـــة البحـــث: تـــأثير اســـتراتيجية نقـــل الـــدم التحفظيـــة مقارنـــة باســـتراتيجية نقـــل الـــدم السخائية على النتائج الإكلينيكية فى مرضى جراحة القلب لا يزال غير محدد.

الهـــدف مـــن البحـــث: بعـــد موافقـــة اللجنـــة الأخلاقيـــة المؤسســـية والحصـــول علـــى موافقـــة خطيـــة مـــن المرضـــى, تـــم تضـــمين مائـــة مريضـــاً بالغـــاً عشـــوائياً, لإجـــراء عمليـــات قلـــب مفتـــوح بنســـبة خطـــورة متوســـطة إلـــى شـــديدة، وذلـــك طبقـــاً للنظـــام الأوروبـــى لتقيـــيم خطـــورة عمليـــات جراحـــة القلـــب (بتقيـــيم 6 فمـــا فـــوق) وتـــم تقســـيمهم إلـــى مجمـــوعتين متســـاويتين:مجموعة تـــم نقـــل الـــدم لهـــا باســـتراتيجية نقـــل الـــدم التحفظيـــة (نقـــل الـــدم إذا كانـــت نســـبة الهيموجلـــوبين>7.5 جم/ديســـيليتر بـــدءاً مـــن بدايـــة التخـــدير). مجموعـــة تـــم نقـــل الـــدم لهـــا باســـتراتيجية نقـــل الـــدم الســـخائية (نقـــل الـــدم إذا كانـــت نســـبة الهيموجلـــوبين>9.5جم/ديســـيليتر فـــى غرفـــة العمليـــات والعنايـــة المركـــزة أو نســـبة الهيموجلوبين>8.5 جم/ديسيليتر فى عنبر القسم الداخلى).

وكـــان النتـــاج الأولـــى لهـــذه الدراســـة مركبـــاً مـــن حـــدوث وفـــاة مـــن أى ســـبب, وحـــدوث جلطـــة بالقلـــب, وحـــدوث جلطـــة بـــالخ, أو حـــدوث فشـــل كلـــوى جديـــد يتطلـــب غســـيل كلـــوى, وذلـــك فـــى الفتـــرة مـــن إجـــراء الجراحـــة وحتـــى الخـــروج مـــن المستشـــفى, أو مـــرور 28 يومـــاً بعـــد الجراحـــة, أيهمـــا يحـــدث أولاً. أمـــا النتـــائج الثانويـــة لهـــذه الدراســـة فقد كانت عبارة عن حدوث نقل دم أو أيمن المضاعفات الأخرى لجراحة القلب.

نتـــائج البحـــث: تـــم مقارنـــة المجمـــوعتين إحصـــائياً مـــن حيـــث الأساســـيات الديموجرافيـــة والخصـــائص الجراحيـــة. فيمـــا يتعلـــق بمتطلبـــات نقـــل الـــدم كانـــت هنـــاك فـــروق ذات دلالـــة إحصـــائية بـــين المجمـــوعتين, كونهـــا أقـــل فـــى المجموعـــة ذات الاســـتراتيجية التحفظيـــة

فـــى الفتـــرات أثنـــاء إجـــراء الجراحـــة, خـــلال اليـــوم الأول بعـــد الجراحـــة, وفـــى فتـــرة الإقامـــة فـــى القســـم الـــداخلى. وأيضـــاً كـــان هنـــاك فـــرق لـــه دلالـــة إحصـــائية فـــى نقـــل البلازمـــا الطازجـــة, حيـــث كـــان أقـــل فـــى المجموعـــة ذات الاســـتراتيجية التحفظيـــة مـــن مـــا كـــان عليـــه فـــى المجموعـــة ذات الاســـتراتيجية الســـخائية وذلـــك أثنـــاء فتـــرة الإقامـــة فـــى القسم الداخلى فقط.

وكانـــت هنـــاك فـــروق ذات دلالـــة إحصـــائية بـــين المجمـــوعتين كونهـــا أقـــل فـــى المجموعـــة ذات الاســـتراتيجية التحفظيـــة عمـــا كانـــت عليـــه فـــى المجموعـــة ذات الاســـتراتيجية الســـخائية, وذلـــك بالنســـبة إلـــى مـــدة البقـــاء علـــى جهـــاز التـــنفس الصـــناعى, ومـــدة البقـــاء بالعنايـــة المركـــزة, وحاصـــل إنتـــاج أنابيـــب الصـــدر, وحـــدوث رفرفـــة أذينيـــة بالقلـــب.ولا يوجـــد فـــروق ذات دلالـــة إحصـــائية بـــين المجمـــوعتين بالنســـبة لحـــدوث النتـــاج الأولى لهذه الدراسة.

الاســـتنتاج: اســـتراتيجية نقـــل الـــدم التحفظيـــة ذات فعاليـــة وأمـــان فـــي تقليـــل متطلبـــات نقـــل الـــدم فـــى جراحـــة القلـــب, وبالتـــالى تقلـــل المضـــاعفات والوفيـــات المرتبطـــة بنقـــل الـــدم, وكذلك فعالية التكلفة.