Extracorporeal circuit prime reduces blood transfusion requirements in coronary artery surgery.

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ABSTRACT

Hemodilution resulting from the asanguinous prime of the cardiopulmonary bypass circuit, the volume suppletion at the onset of anaesthesia and the administered crystalloid cardioplegia volume presents a risk factor for blood transfusion in cardiac operations. Several studies related the administration of packed red blood cells (PRBC) to a worsened outcome. On the other side there were studies relating the low hematocrit to the deleterious effect of cardiopulmonary bypass (CPB). These data suggests avoiding the administration of homologous PRBC. Retrograde autologous priming (RAP) is a technique than can be used to decrease PRBC transfusion. In a retrospective study we compared 50 patients using RAP with 50 patients using a standard prime extra corporeal circuit (ECC). Patients were scheduled for elective coronary artery bypass grafting (CABG) surgery. The total volume of standard ECC prime was 1758 ± 676 ml. In the reduced prime group the heart lung machine was primed retrogradely with the patient's own blood, resulting in a priming volume of 784 ± 284 ml. The use of PRBC during the hospital stay was significantly lower in RAP group i.e. 0.8 U versus 2.0 U.

Conclusion: reducing ECC prime using RAP technique reduces blood transfusion requirements in coronary artery surgery.

INTRODUCTION

After initial work of Panico and Neptune in 1959[1] to use a bloodless prime and especially of pioneer in cardiac surgery Denton Cooley and associate[2] in 1962, as well as the introduction into practice of disposable bubble oxygenators, hemodilution technique ultimately received widespread acceptance and became a golden standard of practice. Advances in surgical, anaesthesia and perfusion techniques, as well as improvement in biocompatibility of CPB systems, have resulted in a dramatic decline in mortality rates. However, neurological morbidity remains an important concern and the focus of attention has turned towards the quality of life. Several large observational studies related the low hematocrit to the deleterious effect of CPB. [3-7] On the other side, administration of PRBC to correct this, actually does not lead to improvement. In contrary, several studies related the administration of homologous PRBC to a worsened outcome, expressed by an increased post-operative morbidity and mortality.[8-11] All this data points in the same direction, to avoid the administration of homologous RBC transfusion or at least to minimize it as much as practically possible.

The retrograde autologous priming, first introduced in 1959 by Panico and Neptune[1], was revised and reintroduced in clinical practice in 1990 by Rosengart and associates.[13] Several authors have modified the basic technique of priming the CPB circuit with autologous blood. Balachandran and collegues[14] for an open circuit system, as well as Sobieski and associates[15] for a closed ECC circuit, have reported a simple and practical modification.

MATERIAL AND METHODS

Within the bounds of our hospital Medical Ethics Committee regulations we used a retrospective, non-randomized analysis of 50 consecutive patients undergoing coronary artery bypass using standard CPB compared to 50 patients using reduced prime (mean volume withdrawal: 800 ± 150 ml). Patients with an ejection fraction of less than 30%, recent myocardial infarction, inotropic or intra aortic balloon pump support, or with severe co-morbidities were excluded from the study. Patients were premedicated with midazolam. In the operating room, after preoxygenation a precurarization dose of pancuronium 20 $\mu g.kg^{-1}$ was administered to the patient, followed bij a loading dose of 50 $\mu g.kg^{-1}$ alfentanil (Rapifen, Janssen Pharmaceutica, Beerse, Belgium), 0,3 $mg.kg^{-1}$ etomidate and pancuronium 80$\mu g.kg^{-1}$. Maintenance of anaesthesia was achieved with alfentanil 2$\mu g.kg.min^{-1}$ and propofol 2 $mg.kg.min^{-1}$. For monitoring, an arterial line, pulmonary artery catheter with cardiac output measurement and continuous mixed venous oxygen saturation measurement was used in all patients. Anticoagulation was achieved by a loading dose of heparin (300 IU/kg) with a target value of activating clothing time (ACT) of 480 sec.

CARDIOPULMONARY BYPASS

A standard closed bypass circuit was used in all patients. This consisted of a hollow-fibre membrane oxygenator (Capiox SX–18, Terumo Europe N.V. Leuven, Belgium), a soft-shell venous reservoir (JVR 1900, Jostra, Herrlingen, Germany), a hard shell cardiotomy reservoir (Capiox CX–18RX, Terumo Europe N.V. Leuven, Belgium), a 40µm arterial filter (Jostra LG-6 Pall Leucoguard, Jostra, Herrlingen, Germany), Raumedic tubing system (Jostra Bioline, et Cardiopulmonary AG, Herrkingen, Germany) and a roller pump Stöckert Shiley/S-III (Sorin Group S.p.A. Milano, Italy). The Capiox SX oxygenator is X-coated and all other components exposed to blood were pre-treated with heparin-bonded coating (Bioline, Jostra). The standard prime of ECC consisted of 1300 ml of Gelofusine (Braun, Melsungen AG, Germany), 200 ml 20% Mannitol (Baxter B.V. Utrecht, The Netherlands), 100 ml 20% human albumin (Sanquin CLB, Amsterdam The Netherlands), and 50 ml 8.4 % $NaHCO_3$ (Braun, Melsungen AG, Germany), and 6500 IU Heparin Leo (Pfizer bv, Capelle a/d IJssel, Netherlands). The circuit is flushed with CO_2 to facilitate de-airing. After priming the oxygenator is ventilated with air to achieve a normocapnic priming solution. The initial volume of standard ECC prime was 1650 ml. In the RAP-group the clear prime was first taken out of the closed reservoir. After cannulation of the aorta, ECC was retrogradely primed with patient's blood with concomitant discharging of clear prime. The total prime volume was reduced to 784 ± 284 ml at the start of CPB. All patients received 2.0 g of tranexamic acid (cyclokapron).

Normothermic pulsatile perfusion with pulse pressure ≥ 25 mmHg has been applied during perfusion, when the heart was not ejecting. The mean perfusion pressure, which depends on patient's preoperative condition, has been arbitrarily kept between 70 mmHg and 95 mmHg, which is achieved by infusion of phenylephrine, if necessary. The CPB flow rate for both groups was ≥ 2,4 $L.min^{-1}.m^2$. A single dose of modified St.Thomas II solution, at 4 °C, (approximately 900 ml) was administered to arrest and maintain an iso-electrical state of the heart. Additionally, topical cooling with cold saline solution has been applied immediately after cross clamping of the aorta. The arterial pO_2 during CPB was regulated by an automatic PaO_2 regulator and was held at 20 kPa (150 mmHg). In the RAP group, regional cerebral saturation has been routinely monitored in all patients (Invos, Somanetics, Troy, MI, USA) and pH regulated with oxygenator exhaust capnography (Normocap oxy, Datex-Engström, Denmark). Left ventricular venting was accomplished by means of the aortic root cannula. Pericardial blood was aspirated and collected in a cardiotomy reservoir.

RAP TECHNIQUE

The original technique for RAP, as described by Rosengart was modified and adapted as follows for use with a closed

ECC system: A one liter transfer bag was attached to the purge line between oxygenator inlet and the cardiotomy reservoir.

Venous reservoir drainage.
Prior to aortic cannulation the perfusionist gives the tubing to the surgeon and the heart lung machine (HLM) was positioned close to the patient to make arterial and venous tubing as short as practically possible. This resulted in 200 ml of prime removal. Position A and B (Fig 1) denote the sites where clamps has been placed during this procedure. With clamps A and B in position, the arterial pump is slowly advanced until the venous reservoir volume is transferred to the transfer bag (±200 ml)

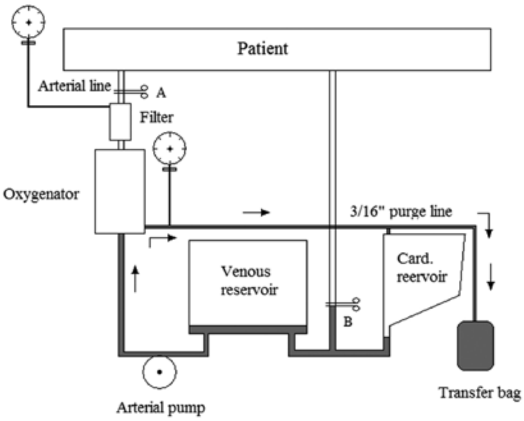

Figure 1. The A and B shows the positions where the clamps are applied or removed from the circuit.

Arterial line and oxygenator drainage. When the aortic cannula (Jostra 24Fr Jostra Bioline, Maquet Cardiopulmonary AG, Herrkingen, Germany) is connected to the arterial line the patient is positioned in Trendelenburg position and the clamp A is removed. (Fig.2)
When both pulsations and aortic pressure are confirmed, blood is allowed to flow from the aorta through the arterial line, the arterial filter and oxygenator via the 3/16 fr purge line to the transfer bag. Once the purge line becomes sanguineous it is closed. In that way up to 600 ml of priming has been replaced to the transfer bag. When the two-stage venous cannula

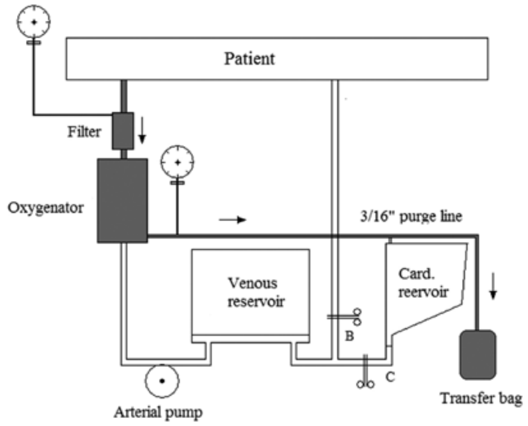

Figure 2.

(32/40 or 36/51fr Edwards Lifesciences, Irvine CA, USA.), is connected to the venous line, the clamp C is placed on the cardiotomy line and clamp B is slowly released allowing the start of bypass. All patients received an infusion of phenylephrine as we started the RAP procedure. Finally, at the end of surgery, patients are positioned first in Trendelenburg position to allow for safe venous de-cannulation. The cardiotomy reservoir was postioned at its lowest. After venous de-cannulation, the surgeon immediately immerses the venous canula in a sterile container filled with 600 ml of heparinized saline solution. Clamp C is than removed to allow venous drainage from the container to the venous reservoir by gravity.
Once the venous line is filled onto the venous reservoir with saline solution, the C-clamp is closed. Fig.3

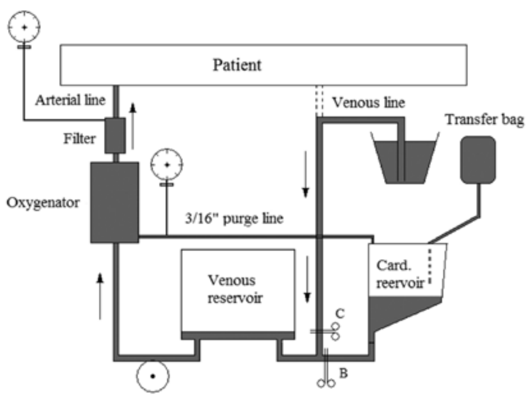

Figure3.

This manoeuvre allowed for immediate return of blood from ECC to the patient. In mean time, the cardiotomy reservoir is primed with the volume from transfer bag and an additional 500 ml of Ringer's solution. When the venous reservoir is empty clamp B is removed allowing the rest of volume to be transferred to the patient. At that time the patients are positioned in anti-Trendelenburg position and infusion of nitroglycerine is started to allow all blood from the ECC to be transferred back to the patient or until the central venous and pulmonary artery pressure are optimal. When the aortic cannula becomes assanguinous retransfusion is stopped. The ECC circuit remains primed and ready for a restart of CPB if necessary.

No complications or deaths occurred in either the RAP or standard group. No patients required any form of ventricular assist, such as intra aortic balloon pumping.

There have been no patients in the RAP group in whom the procedure was aborted because of hemodynamic instability. Hemodynamic stability was achieved by Trendelenburg position and small boluses of fenylefrine when necessary. One potential modification of the RAP technique as described in this study might have included the venous line prime withdrawal, which might have increased the volume of RAP withdrawn.

DOCUMENTATION

All data obtained was stored in a computer database. Evaluation is performed with standard protocols and methodology, according to standard clinical practice.

STATISTICS

Statistical analysis was performed using the SPSS software package version 12 (SPSS, Inc. Chicago, Il, USA).

Demographic data were analysed using Student's t-test. For parametric testing independent samples t-test and for non-parametric testing Mann-Whitney test was used.

Differences were considered significant with a P-value <0.005.

RESULTS

A hundred adult patients scheduled for coronary artery bypass grafting procedure were enrolled in this study and randomized to CPB with or without RAP. All patients were included in the data analysis. The RAP and standard groups were closely matched for all preoperative variables, including body weight, body surface area (BSA), New York Heart Association (NYHA) classification and age. There were also no statistically significant differences between the groups in the perfusion time, cross-clamp time, number of grafts and hospital stay (Table 1). However, there were statistically significant differences between the groups in the following variables: Priming volume of the ECC, volume balance after operation, the lowest hematocrit and hematocrit upon arrival in ICU. One perfusionist performed RAP essentially on every patient. In the RAP group a significant fraction of the prime volume was replaced by the patient's circulating blood volume (mean volume withdrawal 800± 150 ml). Intra-operative and haematological data are summarized in table 2. There were no patients requiring reinfusion of RAP volumes during the procedure. Anaesthesia and cardioplegia volume were not significantly different between the two groups.

Variable	control group (n=50)	RAP group (n = 50)	P value
Age (yr)	65.3± 10.8	64.9 ± 9.8	0.679
Weight (kg)	81.4± 12	80.3± 12.7	0.925
High (cm)	170.7±9.5	173.6±8.5	0.864
BSA (dm^2)	194.6±17.2	194.6±17.5	0.781
NYHA classification	2.7±0.8	2.8±0.8	0.555
Perfusion time (min)	72.6± 33.0	72.7± 26.9	0.741
X-clamping time (min)	49.1 ± 24.5	46.3 ± 18	0.103
Number of grafts	3.8 ± 1.1	3.8 ± 1.0	0.448
Hospital stay (days)	7.4 ± 3.4	6.5 ± 2.5	0.392

Table 1. *Patient characteristics and surgical data for standard and RAP groups. Values are expressed as mean ± standard deviation. * The P value< 0.05 is statistically significant.*

Variable	Stand. Group (n = 50)	RAP group (n = 50)	P value
Priming ECC (ml)	1758 ± 676	780 ± 85	0.010*
Anaesthesia volume (ml)	784 ± 284	891 ± 407	0.163
Cardioplegia volume (ml)	913 ± 450	919 ± 321	0.152
Total clear volume given during operation (ml)	3526 ± 944	2640 ± 617	0.177
Ultrafiltration (ml)	606 ± 973	32 ± 226	0.001*
Volume balance (ml)	758 ± 893	429 ± 656	0.045*
Pre CPB Hct (%)	41.0 ± 4.4	42.2 ± 3.4	0.133
Lowest Hct (%)	22.2 ± 3.3	26.8 ± 3.0	0.001*
Hct at arrival in ICU (%)	26.7 ± 3.4	28.5 ± 4.0	0.019*
Hct after 24 h (%)	29.3 ± 3.2	29.8 ± 3.0	0.421
Hct at discharge (%)	33.7 ± 4.1	34.5 ± 4.3	0.384
Blood loss during surgery (ml)	484 ± 534	370 ± 256	0.029*
Blood loss after 24h (ml)	857 ± 439	741 ± 455	0.621
Total blood loss (ml)	1331 ± 738	1106 ± 567	0.135
PRBC during operation (U)	0.58 ± 1.28	0.08 ± 0.34	0.000*
PRBC in ICU (U)	1.34 ± 2.16	0.72 ± 1.3	0.081
Total PRBC during hospitalisation (U)	2.0 ± 2.5	0.8 ± 0.98	0.025*

Table 2. *Intraoperative and haematological data. Values are expressed as mean ± standard deviation.*
** The P value< 0.05 is statistically significant.*

The residual volume from the ECC was collected in blood transfusion bags and retransfused gradually, with tendency to avoid transfusion bags in RAP group. Patients in standard group received significantly more volume from the ECC. Whenever the hematocrit (Hct) was below 20% during bypass in-line hemofiltration was started, or PRBC was given. Significantly more ultrafiltration volume has been taken out from circulation in standard group than in RAP group. Both the lowest Hct and Hct at arrival in the ICU were significantly higher in RAP group of patients (22 versus 27 and 27 versus 29). Requirements of homologous blood were registered during and after the operation. The intraoperative blood loss was calculated in each patient by the weighing the wet swabs plus the amount of shed blood collected intraoperatively by suction. After surgery, mediastinal and pleural drainage tubes have been connected to the Pleurevac system (Deknatel GmbH, Neustadt, Germany) and blood loss was measured hourly. The total blood loss is calculated adding the blood loss during surgery to the blood loss after removal of the chest tubes. Shed blood was not reinfused to the patient. Total intraoperative blood loss was significantly different between the two groups (standard group 484 ± 533 versus RAP 370 ± 256 ml, P=0.029), but it has to be pointed out that with higher Hct in RAP group, the blood loss was actually similar in both groups. However, blood loss after 24 h and total blood loss during hospital stay was similar between standard and RAP group. Forty-seven (94%) of 50 patients subjected to RAP had no intraoperative transfusion, and 37 (74%) of 50 in standard prime group. (P = 0.001) The number of patients without any homologous PRBC transfusion within the two groups during the entire hospitalisation was 32 of 50 (64%-RAP) versus 18 of 50 (36%-standard), P = 0.001.

Packed red cells given during CPB, as well as total PRBC during hospital stay was significantly different between the two groups (standard group 0.58 ± 1.28 and 2.0 ± 2.5, RAP group 0.08 ± 0.34 and 0.8 ± 0.98 respectively). Further, to exclude the influence of surgical bleeding, we excluded all patients with blood loss during surgery >500 ml. The t-test performed shows that 34 patients in standard group and 37 patients in RAP group had less bleeding than 500 ml during operation. In this subgroup the PRBC given during operation was as follows: Standard 0.35 ± 0.88 and RAP 0.008 ± 0.36 (P=0.001). In the ICU 1.41 ± 1.39 versus 0.54 ± 1.09 (P = 0.023) and finally total PRBC during hospital stay in this subgroup was 1.0 ± 1.35 versus 0.43 ± 0.95 (P= 0.034). Because of the fact that the blood loss during surgery was statistically significant higher in standard group, the chest tube drainage in the ICU was similar in both groups, and hematocrit during bypass was higher in the RAP group, the reduction in allogeneic blood transfusions appears to be related to a decrease in prime-induced hemodilution.

DISCUSSION

In the beginning of heart surgery the ECC circuit, consisting mainly of disk oxygenators with a large surface area, have ultimately been primed with homologous blood. Later on, when disposable, low prime, bubble oxygenators became available, and especially after elegant work of Cooley and associates[2], assanguinous prime technique ultimately received widespread acceptance, and became a gold standard of practice all over the world. Numerous articles had been written, showing the benefit of hemodilution. However, when most investigators in last decades had been focused on the quality of life of patients after cardiac surgery, it has become obvious that a lot of work in that field has yet to be done. Postoperative complications associated with CABG surgery involving CPB are still a major clinical issue[18-20]. Since the 1960s much work has been done to improve efficacy of the larger part of ECC- the gas exchange device, resulting in the development of high-performance micro porous hollow-fibre oxygenators. Improvements in the hemocompatibility of ECC circuits[20-24], use of arterial line filters, alpha-stat acid-base management during hypothermia, and pulsatile flow diminished various post pump syndromes. But overall, CPB is still far from perfect. At last, the two of known causes of higher morbidity and mortality after CPB has been recognized as excessive hemodilution[3-7] and transfusion during operation[10-12]. DeFoe and associates[3] reported results from a multicenter study of 6980 patients undergoing CABG surgery. They showed that a hematocrit <25% in women and <23% in men was associated with increased mortality, intra-aortic balloon pump use, and need to return to CPB. Additionally, patients with hematocrit of 19% or less during CPB had more than twice the mortality as patients with lowest hematocrit value of 25%. The lowest hematocrit was also associated with increased morbidity. Habib and associates[4] in a retrospective analysis of 5000 CABG patients found that stroke, myocardial infarction, low cardiac output, renal failure, multiorgan failure, prolonged ventilation times, pulmonary oedema and sepsis were all significantly increased as the lowest hematocrit decreased to less than 22%. Karkouti and associates[5] analyzed a series of 10,949 CABG patients and found that the risk of a perioperative stroke increased 10% with each percentage decrease in lowest hematocrit with best results when the lowest hematocrit was between 27 and 29%. Ranucci and collegues[6] performed a retrospective analysis of 1766 CABG patients in a multicenter study and found that hemodilutional anaemia on CPB increases morbidity and mortality after coronary surgery. The hematocrit cut-off values were similar for renal failure (23%) and low-output syndrome (24%). Additionally they found that blood transfusions were significantly associated with both renal failure and low-output syndrome. However it has to be pointed out that in all this studies ECC prime consisted of crystalloid fluids and pressure was relatively low that could have influence on morbidity. Engoren and associates[8] studied 1,915 CABG patients and found that blood transfusions during or after coronary artery bypass operations were associated with increased long-term mortality. Koch and associates[9] performed a retrospective study of 10,289 CABG patients to examine the influence of PRBC transfusion on patient's outcome. They found that each unit of PRBC transfusion was associated with a dose-dependent decrease in survival. Surgenor and collegues[10] in a study of 8,004 isolated CABG patients found that exposure to PRBC transfusion was a significant, independent predictor of low output heart failure, defined as placement of an intraoperative or postoperative intra-aortic balloon pump, return to CPB after initial separation, or treatment with > or = 2 inotropes at 48 hours postoperatively, after CABG, (adjusted odds ratio, 1.27; 95% CI, 1.00 to 1.61; P=0.047). Finally, Utley and collegues[11] performed a retrospective analysis of 2,569 patients having coronary bypass from a database of grafting and determined factors that contribute to poorer outcomes in women compared with men. Women were found to have greater mortality, postoperative bleeding, and postoperative pulmonary failure than men ($p < 0.05$). The risk of anaemia and the risk associated with transfusion warrant a reduction of the priming volume that could lead to bloodless cardiac surgery and concomitant decrease of both morbidity and mortality. Our data shows that RAP technique is safe, effective and simple in avoiding the use of banked blood. It therefore should be considered for patients undergoing operations using CPB. Further studies are needed to understand the relationship between low Hct during CPB and adverse outcome.

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