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ARTYKUŁ ORYGINALNY / *ORIGINAL ARTICLE*

Can cardiopulmonary bypass system with blood priming become a new standard in coronary surgery?

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Abstract

Background: Commonly used cardiopulmonary bypass systems with cardiotomy reservoir, oxygenator, and roller pump require preoperative crystalloid filling. Radical reduction of the filling fluid volume and replacing it with the patient's own blood has a fundamental impact on the outcome.

Aim: A comparison of cardiopulmonary bypass filled with the patient's blood, applied in Poland for the first time, and the classical system filled with crystalloids.

Methods: Non-randomised trial in which patients undergoing coronary artery bypass grafting were divided into two groups: first operated on with use of cardiopulmonary bypass system with the patient's own blood priming, and a control group operated on with standard technique. Levels of haemoglobin (HGB), haematocrit (HCT), platelets, leukocytes, creatinine, protein, C-reactive protein, procalcitonin, volume of transfused blood products, postoperative drain output, time to extubation, and consumption of catecholamines were compared.

Results: The results of a study comparing the classical system with the blood-filled system (n = 60) showed a significantly smaller decrease in HGB and HCT levels (p = 0.001), resulting in reduction of blood product transfusions by 75% (p = 0.03). The new type of extracorporeal circulation reduced the total postoperative drain output by approximately 28% (p = 0.003). The systemic inflammatory response syndrome (SIRS) was less pronounced and the tissue perfusion was better due to smaller degree of haemodilution leading to better organ and heart protection. The patients required shorter mechanical ventilation times in the perioperative period.

Conclusions: The use of a new system of cardiopulmonary bypass filled with the patient's blood reduces the postoperative decrease in HGB and HCT, the amount of transfused blood products, and total postoperative drain output. It also shortens the time spent on mechanical ventilatory support.

Key words: mini-cardiopulmonary bypass, mini-ECC, low priming, blood priming, blood protect

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INTRODUCTION

We present our experience in performing coronary artery bypass surgeries with the use of a cardiopulmonary bypass (CPB) system using blood filling instead of the traditional 1000 mL crystalloid filling.

Currently, in the majority of cardiac surgery centres in the world, it is considered safe to use an open system with roller pump and cardiotomy reservoir. The modified oxygenator system with incorporated filter, elimination of cardiotomy reservoir functioning as a blood volume buffer, and the reduc-

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tion of total tubing length results in a considerable reduction in the amount of fluid necessary for priming. Contemporary systems have reduced priming from approximately 1500 mL in the standard system to approximately 650 mL in modern systems. This fluid is indispensable for filling and de-airing but at the same time creates an additional volume, which after termination of CPB increases total circulating blood volume and decreases haematocrit.

METHODS

For the first time in Poland we have begun to use the novel CPB system in which additional fluid filling is almost completely eliminated. We use the ROCSafe (Terumo, USA) CPB set, which is primarily filled with approximately 650 mL of crystalloid and then, after checking the system, retrogradely filled with the patient's blood acquired via aortic cannula (retrograde arterial priming). This is done shortly before starting the CPB without any reduction in blood pressure. Filling with blood leads to flushing back almost all crystalloid, approximately 620 mL. Therefore, it can be assumed that the actual filling volume of about 30 mL is practically negligible. Unfortunately, there are technical limitations to this method. Mini cardiopulmonary bypass (mini-CPB) surgeries have limited possibility of ventricular venting and pump suction usage secondary to the lack of cardiotomy reservoir module with only intermittent but no constant suctioning. For that reason, those surgeries are primarily used for coronary bypass grafting. This method can be applied to valve or aortic aneurysm surgeries as well but only after achieving technical expertise.

Presently there are two systems for the so-called 'mini-CPB'. The first one utilises approximately 650 mL of crystalloid. The second one, used in our institution, is filled only with the patient's blood without crystalloid. This is referred to as a mini extracorporeal circulation system. From the surgical standpoint the use of 'mini-CPB' is relatively simple. In comparison to the classical method, the surgeon needs to connect the CPB to the aortic cannula and fill the cannula retrogradely with the patient's own blood, draining the crystalloid from the system, and then connect the venous cannula. It is essential to ensure that the CPB is connected and initiated without any air bubbles present in either aortic or venous cannula. We have modified the system used at our institution so that pump suction from the field is possible and the blood is returned to the circulation. This eliminates the necessity of cell-saver usage and improves the operator's comfort. This method has no influence on the length of the procedure or CPB time, but requires more skill and experience from the entire team. The role of the anaesthesia and perfusion team is of greater importance here given the absence of a buffer in the form of a cardiotomy reservoir present in the classical CPB. Maintaining mean arterial blood pressure within adequate limits may require use of catecholamines during the CPB. In the case of any problems, of which air lock is the most frequent, there is the possibility to convert to the classical system immediately. The learning curve for both the cardiac surgeon and the anaesthesiologist is very short and limited to three to five cases. For the perfusionist this would require about 10 to 15 extracorporeal circulations performed.

A small, non-randomised, controlled trial linked to a PhD thesis comparing a classical CPB system to the new, blood-primed system is currently being carried out in our centre. The trial was initiated in December 2014 and by the end of February 2015 a group of 30 patients were operated on with this method, with the control group consisting of 30 patients. The participants have been recruited from patients with ischaemic heart disease qualified to isolated coronary artery bypass grafting surgeries. Due to the learning curve, patients with very high operative risks, Euroscore II above 4%, or haematological and neoplastic diseases were excluded (Table 1).

Statistical analysis

Statistical analysis was performed using Statistica 10 (Statsoft) and presented as mean ± standard deviation, numbers, or ratio as required. Data were analysed using the Mann-Whitney U test and Kruskal-Wallis test. P-values < 0.05 were considered significant. There were no statistical differences between the groups in terms of demographics, comorbidities, quantity of grafts performed, ejection fraction, or operative risk. In both groups the surgeries were performed with the same operative techniques and the same intra- and post-operative management methods, and the same indications and strategies for drugs and fluid supply were used. The criteria for packed red blood cells (PRBCs) transfusion were established at a haemoglobin (HGB) level less than 8 g/dL or haematocrit (HCT) less than 25%. For every 2 units of PRBCs transfused 1 unit of fresh frozen plasma was given. Platelets were transfused in patients on antiplatelet therapy directly before the surgery or with a platelet count of less than 80×10^3/dL. In the control group the fluid balance at the end of the surgery was approximately 1000 mL larger than in the 'mini-CPB' group. The study was approved by the Bioethics Committee at the Lower Silesian Chamber of Physicians and Dentists in Wrocław by Resolution No. 1/2014 dated 8 Jan 2014.

RESULTS

The surgical outcome was assessed in the immediate post-operative period and on the follow-up visit in the cardiac surgery outpatients' clinic. In both groups there were no perioperative myocardial infarctions and no cases of renal failure requiring dialysis. Thirty-day mortality was zero in both groups. There was one episode of transient ischaemic attack in each group. These resolved spontaneously and did not necessitate treatment or postoperative rehabilitation. In both groups the same surgical technique was used and the procedures were performed by the same surgical, anaesthetic, and

Table 1. Patients characteristics (n = 60)

Features	Mini-CPB	CPB	P
Mean age [years]	66.52 ± 9.01 (66.0; 60–75)	66.5 ± 5.9 (66.5; 63–71)	NS
Patients number (female:male)	30/23:7	30/23:7	NS
Weight [kg]	83.79 ± 13.1 (80.0; 74–92)	83.63 ± 13.58 (85.5; 75–91)	NS
Height [cm]	169.14 ± 8.3 (170.0; 164–176)	169.1 ± 7.2 (168.0; 164–175)	NS
Logistic 2	1.66 ± 1.39 (1.16; 0.86–1.47)	1.66 ± 0.9 (1.41; 1.02–1.99)	NS
Ejection fraction [%]	52 ± 9.7 (50.0; 45–60)	55 ± 11 (53.0; 45–65)	NS
Canadian Cardiovascular Society	2.8 ± 0.8	2.58 ± 0.82	NS
New York Heart Association	1.17 ± 0.47	1.2 ± 0.41	NS
Atrial fibrillation	3.3%	3.3%	NS
Body surface area [m^2]	1.96 ± 0.18 (1.9; 183–2.07)	1.97 ± 0.19 (2.0; 1.85–2.08)	NS
Due cardiac output [L/min]	4.73 ± 0.44 (4.7; 4.4–4.96)	4.73 ± 0.45 (4.8; 4.45–5)	NS
Chronic obstructive pulmonary disease	3.3%	3.3%	NS
Type II diabetes	46.6%	33.3%	NS
Hypertonia	83.3%	90%	NS
Preoperation dialysis	1	1	NS
History of myocardial infarction	40%	60%	NS
Carotid artery stenosis	2	2	NS
Antiplatelet treatment before procedure	3	3	NS

P — statistical significance; mini-CPB — blood priming; CPB — classical crystalloid priming

perfusionist team. The CPB time was similar (mini-CPB vs. CPB 89.2 ± 20.2 [90.0; 71–103] min vs. 92.6 ± 17.8 [93.5; 82–103] min, p = 0.54) (Tables 2, 3).

Preliminary results confirm the advantages of the new concept of cardiopulmonary bypass.

There was a much smaller decrease in HGB and HCT levels in the group undergoing the new method of CPB (Figs. 1–3).

Due to the blood and blood products transfusion standards adopted in our centre, the group with standard CPB system had indications for PRBC transfusion much more frequently, which accounted for as much as 77% of the total number of transfusions in both groups (p = 0.001).

For that reason, there is an elevation at the point no. 4 of the graph curve, visible in Figure 2.

A factor that also had a significant impact on the level of complete blood count was the total postoperative drain output, which was approximately 28% lower in the 'mini-CPB' group (p = 0.003) (Fig. 4).

Due to the current small sample size of this ongoing study, no significant statistical differences were found in other parameters of blood cell count, i.e. platelet and white cell count, as well as in serum biochemistry parameters: electrolytes (sodium and potassium) creatinine and glomerular filtration rate, total protein, procalcitonin, C-reactive protein (CRP), or neutrophil gelatinase-associated protein (N-GAL) (Table 4).

All examined patients were discharged from the postoperative department on postoperative day 1 and discharged from the cardiac surgery department on day 5. The intubation time was slightly shorter in the 'mini-CPB' group, mean 15.5 ± 2.7 vs. 18.4 ± 1.4 h (p = 0.26).

DISCUSSION

To our knowledge, there are several trials published in international literature which compare classical extracorporeal circulation with the new closed system, filled with half of the amount of normally used crystalloid. This volume is retained in the patient's body after termination of the CPB. Our concept is based on almost complete elimination of excessive fluids and raises justifiable expectations for better outcome. A substantial feature of all 'mini-CPB' systems is the lack of contact of the blood with the air due to the absence of the cardiotomy reservoir. The presence of barriers separating the blood from the air and decreasing the surface of contact of artificial materials with the blood gives measurable benefits, such as reduction in the incidence of the systemic inflammatory response syndrome (SIRS), although SIRS itself occurs almost always, with a variable degree of severity [1, 2]. 'Mini-CPB' significantly decreases the incidence of early inflammatory response, which was confirmed in a randomised trial by Kiaii et al. [3] and in other studies [1, 4]. In our study we found earlier rise of the CRP and procalcitonin levels as well as leukocyte count in the 'mini-CPB' group than in the control group by approximately 24 h, with a gradual decrease thereafter in both groups. Higher average levels of inflammatory markers in the 'mini-CPB' group

Table 2. Comparison of results

Features	Mini-CPB	CPB	P
Mortality rate	0.0%	0.0%	NS
Duration of CPB [min]	89.2 ± 20.2 (90.0; 71–103)	92.6 ± 17.8 (93.5; 82–103)	NS
Duration of x-clamp [min]	49.93 ± 12.43 (48.0; 40–58)	53.7 ± 11.32 (54.0; 46–58)	NS
No. of distal anastamoses	2.89 ± 0.78 (3.0; 2–3.5)	2.9 ± 0.54 (3.0; 3–3)	NS
Left internal mammary artery	100.0%	100.0%	NS
Postoperative atrial fibrillation	6.6%	23.3%	0.01
Perioperative infarct	0.0%	0.0%	NS
Postoperative renal failure	0.0%	0.0%	NS
Intraoartic balloon pump	0.0%	0.0%	NS
Low output syndrome	0.0%	0.0%	NS
Stroke	3.3% (n = 1)	3.3% (n = 1)	NS
Conversion to CPB	0.0%	–	–
Postoperative respiratory failure	0.0%	0.0%	NS
Delirium	3.3% (n = 1)	3.3% (n = 1)	NS
Reoperation	1	5	0.009
Total drainage [mL]	778 ± 269.16 (815; 630–950)	1084.8 ± 477.12 (950; 130–1440)	0.003
Blood transfusion [U]	0.5 ± 0.86 (0.0; 0–1)	1.76 ± 1.54 (2; 0–2)	0.001
Fresh frozen plasma transfusion [U]	0.13 ± 0.5	0.76 ± 1.4	0.02
Platelets transfusion [U]	9.9%	9.9%	NS

P — statistical significance; CPB — cardiopulmonary bypass; mini-CPB — blood priming; CPB — classical crystalloid priming

Table 3. Blood parameter levels before and 24 hours after procedure

Features	Before mini-CPB	Before CPB	24 h after mini-CPB	24 h after CPB	P
Haemoglobin [g/dL]	14.1 ± 1.10 (14.15; 13.6–14.9)	14.3 ± 1.26 (14.15; 13.3–15.5)	11.74 ± 1.62 (11.85; 10.4–13)	10.25 ± 1.81 (10.65; 8–11.7)	0.001
Haematocrit [%]	42.00 ± 2.89 (42; 40–44)	42.34 ± 3.17 (42.35; 39.7–44.8)	34.97 ± 5.4 (34.65; 30.5–38)	30.21 ± 4.85 (31.65; 25–33.7)	0.001
Leukocytes [G/dL]	7.16 ± 1.57 (7.1; 5.9–8)	7.7 ± 1.93 (7.5; 6.1–9.1)	11.8 ± 4.07 (11.6; 8.8–15.5)	15 ± 20.7 (11.7; 8.6–13.7	0.4
Procalcytonin [μg/L]	0.11 ± 0.165 (0.05; 0.05–0.05)	0.05 ± 0.01 (0.05; 0.05–0.05)	1.78 ± 5.19 (0.795; 0.17–1.44)	0.5 ± 1.19 (0.24; 0.05–0.5)	0.2
CK-MB [μg/L]	0	0	9.55 ± 11.7 (0; 0–17.6)	5.48 ± 9.24 (0; 0–13)	0.14
Creatinine [mg/dL]	0.99 ± 0.45 (0.92; 0.78–1)	0.97 ± 0.33 (0.94; 0.8–1.05)	1.07 ± 0.84 (0.93; 0.75–1.12)	0.94 ± 0.33 (0.85; 0.79–1.01)	0.45

CPB — cardiopulmonary bypass; CK-MB — creatinine kinase-myocardial band

are probably attributable to lack of haemodilution with higher overall concentration of all blood components and slightly different methods of blood suctioning from the field. The rise in inflammatory markers resolved spontaneously and did not seem to have clinical significance.

Our findings support the results of all available randomised trials comparing standard vs. 'mini-CPB' in coronary artery bypass grafting surgery, showing decreased need for blood and blood products.

This is related to higher HGB and HCT levels after the 'mini-CPB' procedure is conducted [4, 5]. This significantly smaller decrease in HCT level is caused by minimal haemodilution. In addition, there is a reduction of factors causing damage to blood cells, such as lack of contact of the blood with the air and reduced area of contact with artificial materials. The 'mini-CPB' system is more physiological and closer to off-pump surgeries without the use of extracorporeal circulation. The higher HGB concentration during the procedure

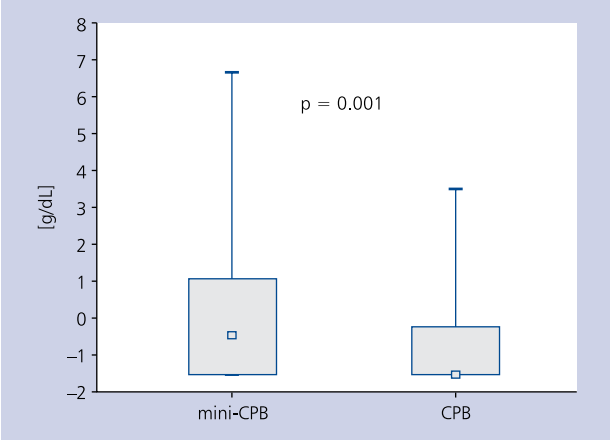

Figure 1. Mean decrease in haemoglobin level in the first 24 h from the beginning of the operation; CPB — cardiopulmonary bypass

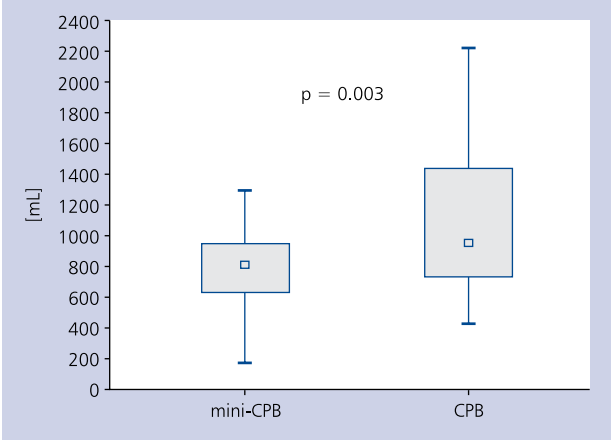

Figure 4. Comparison of mean total postoperative drainage in both groups; CPB — cardiopulmonary bypass

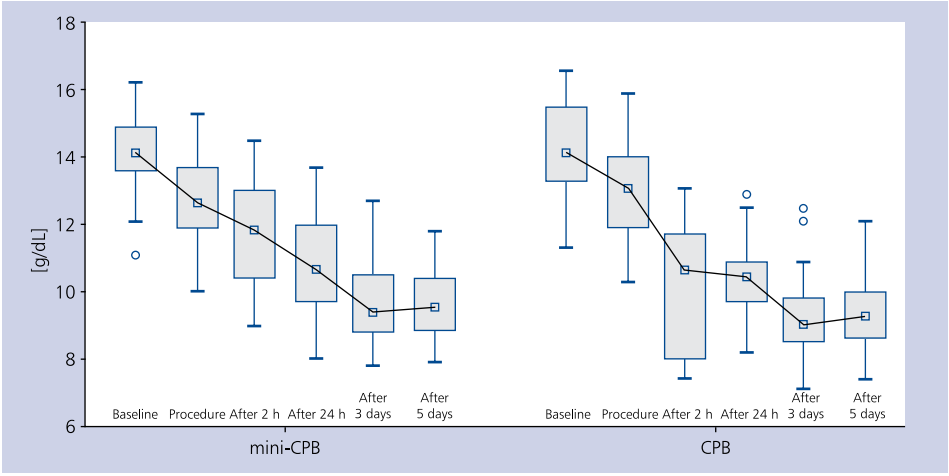

Figure 2. Mean decrease in haemoglobin levels in both types of cardiopulmonary bypass (CPB)

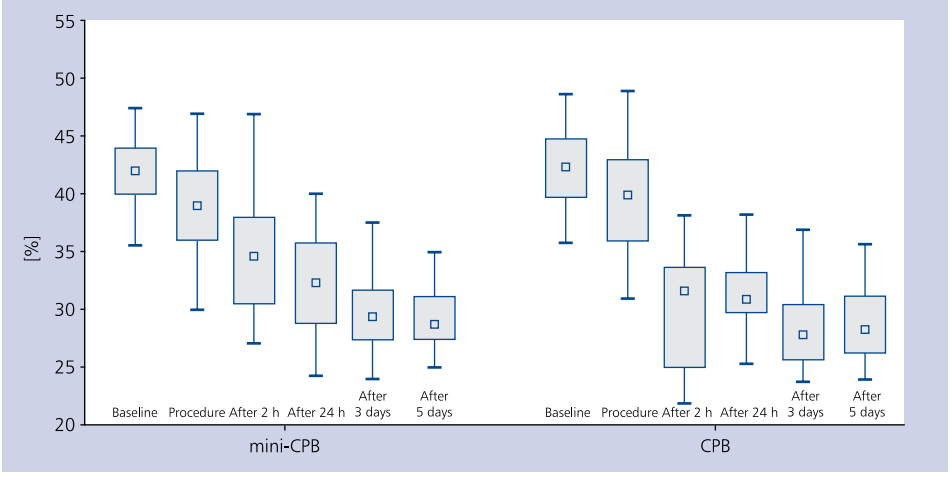

Figure 3. Mean decrease in haematocrit levels in both types of cardiopulmonary bypass (CPB)

Table 4. Test results of C-reactive protein [mg/L] (mean ± standard deviation)

	Time point			Kruskal-Wallis test
	Before	After 24 h	After 48 h	
Mini-CPB	5.9 ± 20.0	120.7 ± 40.2	43.2 ± 26.5	$p < 0.001$
CPB	2.6 ± 4.7	28.8 ± 56.7	105.6 ± 38.5	$p < 0.001$
Mann-Whitney U test	$p = 0.385$	$p < 0.001$	$p < 0.001$	–

CPB — cardiopulmonary bypass

provides better tissue perfusion. This theory is supported by previous studies revealing decreased troponin and creatinine kinase myocardial band (CK-MB) levels, as well as kidney and liver parameters after 'mini-CPB' surgeries [6, 7]. To the best of our knowledge, studies that used retrograde autologous priming did not reveal statistically significant differences in the levels of myocardial ischaemia. In our study, the CK-MB level in the 'mini-CPB' group was almost twofold higher when compared to the control group. However, it did not reach levels signifying peri-operative infarction. Furthermore, the CK-MB levels difference did not reach statistical significance. Higher myocardial injury markers in the 'mini-CPB' are related to lack of haemodilution.

Furthermore, higher HCT and HGB following the procedure with the new CPB system allow a reduction of the need for blood product transfusions or even eliminate the need for transfusions altogether. During 'mini-CPB' procedures only 15% of patients required PRBC administration, and the total transfusion count was 30–50% less in comparison with classic CPB in different studies. This is of much importance in surgeries performed in Jehova's Witnesses [8]. Several studies have shown that any amount greater than 1 unit of PRBC transfused, regardless of the procedure performed, results in decreased life expectancy of the patient [9–11]. In contrast to our study, other publications compared standard CPB with the system in which low crystalloid filling was used, and the postoperative day 1 drain output was comparable in both groups [12]. However, in our study the 'mini-CPB' group had a total drain output decrease of 30%.

The 'mini-CPB' system allows safe and complete myocardial revascularisation on either an arrested or a beating heart [7]. It has also been reported that the administration of catecholamines is lower in this group of patients, similarly to observations in our centre [12, 13].

Another vital matter that must be taken into consideration more and more often is the cost of treatment. The reduction in the number of transfusions leads to cost reduction. Other factors like the presence and severity of complications, the length of stay in the intensive care unit, and hospitalisation time are as important. Finally, the time before return to normal life and work by the patient is crucial as well. In our department the time of hospitalisation has not yet been modified. Due to the small number of patients who underwent 'mini-CPB' procedures at our institution, hospitalisation time has not been adjusted so far. Studies analysing the quality of life after such procedures are also in progress at our centre. In accordance with the recommendations of the Society of Thoracic Surgeons (STS) and the Society of Cardiovascular Anaesthesiologists (SCA), 'mini-CPB' should be used for surgeries requiring blood protection, including those performed in children and Jehova's Witnesses in particular (class IA recommendation).

CONCLUSIONS

The new technique of 'mini-CPB', along with its compact build and retrograde autologous priming, is safe when compared to traditional CPB and at present has the best protective properties for patient's blood. We observed smaller decreases in HGB and HCT levels in the postoperative period, along with decreased need for blood product transfusions and total drain output. This could potentially improve long-term survival and warrants further study.

Conflict of interest: *none declared*

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Czy nowatorski system krążenia pozaustrojowego z wypełnieniem krwią pacjenta może się stać nowym standardem w chirurgii wieńcowej?

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Streszczenie

Wstęp i cel: Powszechnie stosowane układy do krążenia pozaustrojowego ze zbiornikiem kardiotomijnym, oksygenatorem i pompą perystaltyczną wymagają przed rozpoczęciem pracy zalania krystaloidami. Radykalne zredukowanie objętości wymaganego do zalania płynu i pomysłowe zastąpienie tego wypełnienia krwią własną pacjenta ma istotny wpływ na wyniki leczenia.

Materiał i wyniki: Wyniki wstępne badania porównującego system klasyczny z systemem wypełnionym krwią (n = 44) pokazują znacznie mniejsze spadki stężenia hemoglobiny i hematokrytu (p = 0,05), co pozwala na redukcję ilości przetoczeń preparatów krwiopochodnych o 75% (p = 0,03). Nowy rodzaj krążenia pozaustrojowego zmniejsza całkowity drenaż pooperacyjny o ok. 28% (p = 0,01). Występuje istotnie mniejsza uogólniona reakcja zapalna, a lepsza perfuzja tkankowa dzięki zmniejszeniu hemodilucji zapewnia lepszą protekcję narządów wewnętrznych i serca. Chorzy wymagają w okresie okołooperacyjnym znacznie mniejszych dawek amin katecholowych i krótszego czasu intubacji dotchawiczej.

Wnioski: Metoda ta, zastosowana po raz pierwszy w Polsce, jest bezpieczna, mimo że jest bardziej wymagająca dla zespołu uczestniczącego w zabiegu. Jest szczególnie przydatna u świadków Jehowy lub chorych z niskim stężeniem hemoglobiny ze względu na mechanizm protekcyjny krwi.

Słowa kluczowe: mini-CPB, mini-ECC, wypełnienie krwią, protekcja krwi

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