Original article

Cost-effectiveness of mini-circuit cardiopulmonary bypass in newborns and infants undergoing open heart surgery

Krzysztof Mozol[1], Ireneusz Haponiuk[2], Andrzej Byszewski[3], Bohdan Maruszewski[2]

[1] The Children's Memorial Health Institute, Warszawa, Poland
[2] Department of Cardiosurgery, The Children's Memorial Health Institute, Warszawa, Poland
[3] Department of Anaesthesiology and Intensive Therapy, The Children's Memorial Health Institute, Warszawa, Poland

Abstract

Background and aim: Miniaturisation of the extracorporeal circuit is a current trend in modern paediatric cardiac surgery. Many investigators stress that reduction of priming volume and artificial surface area of extracorporeal circulation could lead to clinical and economic benefits. The aim of this paper was to evaluate the costs of mini-circuit use in infants undergoing open heart surgery.

Methods: We assessed post-operative course and cost of treatment in 60 infants undergoing open heart surgery. This group was prospectively randomised and divided into 2 equal subgroups: with miniaturised (group M) and conventional cardio pulmonary bypass circuits (group C). The study groups were clinically comparable. Surgical complications, duration of hospitalisation and cost of postoperative treatment were assessed in both groups.

Results: Miniaturisation of the extracorporeal circuit led to a significant reduction of priming volume and artificial surface area (by 46.6% and 68.8% respectively, p=0.0000001). Post-operative cardio-respiratory insufficiency (2 vs. 8, p=0.038), and infection (3 vs. 9, p=0.049) occurred less often in children from group M. Hospital stay was significantly shorter in group M. Total cost of treatment was significantly lower in children from group M (median: 4361.4 vs. 6660.5 €, p=0.037).

Conclusions: Miniaturisation of the extracorporeal circulation significantly improve post-operative outcome in infants undergoing open heart surgery. The mini-circuit significantly reduces cost of treatment in small children undergoing open heart surgery.

Key words: extracorporeal circulation, paediatric cardiopulmonary bypass, cost analysis

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Introduction

Clinical observations supported the necessity of congenital heart disease repair in the youngest children [1]. Medical knowledge development and new technical solutions enabled surgery to be performed using extracorporeal circulation in this age group. Unfortunately, in many hospitals the size of the device used still remains too large relative to the size of the operated child [1, 2]. This disproportion is often associated with significant haemodilution, fluid overload and enhanced inflammatory response [2, 3]. It seems that these effects may be responsible for less favourable postoperative course and in consequence higher treatment costs than in older patients.

The purpose of this study was to compare clinical condition and costs of treatment of infants and neonates undergoing congenital heart disease repair using miniaturised or conventional extracorporeal circulation systems.

Methods

The study involved 60 children up to 1 year old operated on using extracorporeal circulation support. The study group was prospectively randomised to 2 subgroups: subgroup M in which a miniaturised device was used, and subgroup C using a conventional device of standard age-matched area and volume. Reduction of device size was obtained by the use of newly designed oxygenators, elimination of arterial line filter and use of vacuum-assisted venous drainage (VAVD).

There were no significant differences with respect to preoperative clinical evaluation, and technique of surgery and perfusion (Table I). Types of repaired abnormalities are summarised in Figure 1. Anaesthetic technique and postoperative management were carried out according to the same protocols.

Priming volume and inner area of the device were measured. Number and type of clinical complications were assessed. Heart failure was defined as clinical and

Address for correspondence:
Krzysztof Mozol MD, The Children's Memorial Health Institute, ul. Dzieci Polskich 20, 04-730 Warszawa, tel.: +48 22 815 70 00,
e-mail: kmozol@doctors.org.uk
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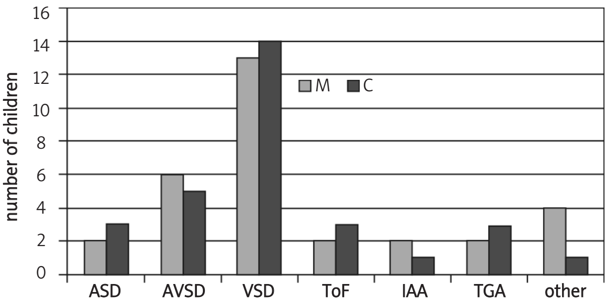
Table I. Preoperative clinical evaluation and extracorporeal circulation parameters in the study group

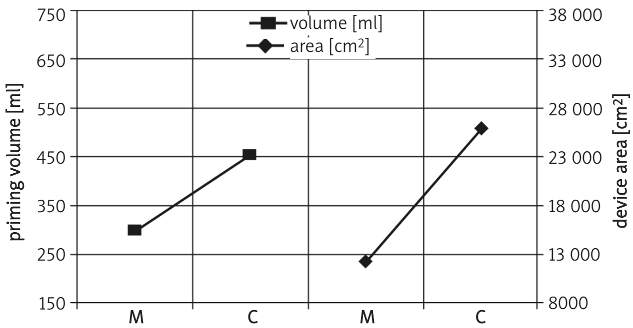
Type of device used	Subgroup M miniaturised	Subgroup C conventional	R
Number	30	30	
Co-morbid congenital defects	8	5	NS
Previous surgery	BPA – 2, CoA angioplasty – 1	BPA – 1, CoA angioplasty – 1	NS
Body weight [kg]	186.4±2.2	5.5±1.6	NS
Body area [m2]	0.31±0.1	0.27±0.13	NS
Age [days]	186.4±175	169.1±114	NS
Duration of extracorporeal circulation [min]	105.8±42.1	90.5±45.3	NS
Duration of aorta clamping [min]	53.2±27.8	45.4±23.6	NS
Duration of circulation cessation [min]	6.4±14.7	3.5±13.6	NS
Hypothermia [°C]	26.2±4.7	27.8±3.5	NS

Abbreviations: BPA – banding of pulmonary artery, CoA – coarctation of the aorta



Abbreviations: ASD – atrial septal defect, AVSD – atrio-ventricular septal defect, VSD – ventricular septal defect, ToF – tetralogy of Fallot, IAA – interrupted aortic arch, TGA – transposition of the great arteries

Figure 1. Type of heart defects undergoing surgery in the study subgroups: M – miniaturised system, and C – conventional devices



	Subgroup M	Subgroup C	P
Priming volume [ml]	297±108.8	453.1±113	0.000001
Device area [cm2]	12153±3388.2	25810±8942.2	0.000001

Figure 2. Comparison of priming volume and device surface area

haemodynamic condition requiring the use of potent vasoactive drugs. Symptoms of respiratory failure were defined as mechanical ventilation duration over 72 hours.

Renal failure was diagnosed if anuria or utmost oliguria was present and required administration of vasoactive drugs, permanent infusion of loop diuretics at doses over 4 mg/kg body weight/day and/or infusion of osmotic agents. Failure of abdominal parenchymal organs was a condition with elevated liver and/or renal damage marker enzymes (LDH, GGTP, AST, ALT, BUN, creatinine) with a prolonged prothrombin time. Infections were referred to as presence of clinical symptoms confirmed with laboratory evidence of microbiological tests.

Multiorgan distress syndrome referred to clinical condition confirmed with laboratory evidence and/or imaging examinations and with abnormal function of at least 3 organs. Duration of hospitalisation at the Intensive Care Units (ICU 1 and 2), Cardiac Surgery Unit and Cardiology Unit as well as total postoperative in-hospital stay were analysed.

Statistical analysis

Results are presented as mean ±standard deviation or numbers and percentages. Fixed, variable and total costs of postoperative treatment were calculated for both groups. Descriptive statistics were used for characteristics of the collected material. Comparison of groups was performed using Student's t-test for continuous variables and chi-square test for qualitative variables. Statistical significance was established as $p < 0.05$.

Results

The use of a miniaturised device allowed the priming volume to be reduced by 46.6% (175.5-491 vs. 272.5-670, p=0.000001) and blood contact area by 68.8% (8468-16459 vs. 11443-35121 cm^2, p=0.0000001) (Figure 2).

No deaths occurred in the study population. Table II presents complications observed in the study groups. Postoperative cardio-pulmonary failure was significantly less frequent in children operated on using a miniaturised system. In two children with intraoperative signs of fluid congestion and subsequent haemodynamic deterioration the sternum was left open (one case in both subgroups). Clinical condition of the subgroup M child allowed us to close the chest wound on the second day post surgery, while in the patient from subgroup C the chest was left open until the third postoperative day. Mechanical ventilation duration was statistically significantly shorter in the M subgroup. Also, multiorgan failure, infection rate and duration of mechanical ventilation were less frequently encountered in children from group M than group C. Patients with infections required modification of antibiotic therapy and administration of immunoglobulins. All had prolonged mechanical ventilation and hospitalisation at the ICU. In one patient from subgroup M and 2 from subgroup C symptoms of heart failure coexisted with signs of respiratory, renal and abdominal soft organ failure. One child from subgroup M and 2 from subgroup C had transient neurological attacks, expressed as seizures with increased muscle tonus. Imaging techniques showed no abnormalities of the central nervous system.

Duration of postoperative treatment at the Intensive Care Units (median: 5.13 vs. 11 days, p=0.045) and Intensive Cardiac Care Units (median: 1.26 vs. 9.07 days, p=0.002) was significantly shorter in children from group M (Figure 3). However, duration of treatment at the Cardiac Surgery Unit was similar in both study subgroups (median: 10.8 vs. 11.03 days, NS). Total in-hospital treatment duration was significantly reduced in children from subgroup M (median: 20.8 vs. 25.48 days, p=0.042).

Fewer blood products (median: 635 vs. 800 ml, p=0.0007) and infusion fluids (median: 592 vs. 689 ml, p=NS) were given in subgroup M (Table III). Children treated with a miniaturised system required shorter parenteral nutrition (4.28 vs. 9.35 days, p=0.038).

Costs of treatment with inotropic agents, spasmolytic anaesthetics, sedatives and antibiotics were lower in subgroup M (p=0.05, p=0.045, p=0.05, respectively). Similarly, costs of performed laboratory tests and microbiological tests were significantly lower in subgroup M (p=0.04). Costs of imaging examinations showed no significant differences between the study subgroups (Figure 4). The total cost of other surgical procedures performed revealed no significant differences between the study groups (pleural drainage, delayed closure of the chest, insertion and removal of peritoneal dialysis catheter).

The fixed and variable treatment costs of subgroup M children were significantly lower. The median fixed treatment costs at the individual wards were as follows: ICU – median: 2916.41 (1165.7-37 330.08) vs. 4666.26 PLN

Table II. Comparison of the frequency of post--operative complications between studied groups

	Subgroup M	Subgroup C	p
Heart failure	6	11	0.048
Respiratory failure	2	8	0.038
Renal failure	1	2	NS
Multiorgan distress syndrome	2	7	0.042
Neurological disorders	1	2	NS
Opened sternum	1	1	NS
Duration of mechanical ventilation [hours]	12	21	0.049
Dialysis	0	1	NS
Infection	3	9	0.049
Postoperative pleural drainage	3	5	NS
Delayed closure of the chest	1	1	NS
Insertion and removal of peritoneal dialysis catheter	0	1	NS

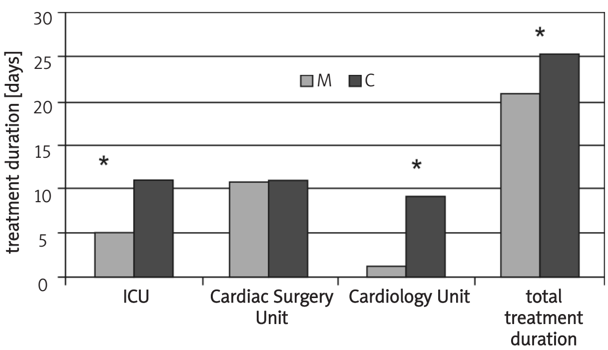


Figure 3. Median duration of postoperative treatment duration in the study groups: M – miniaturised system, and C – conventional

**p <0.05*

Table III. Blood products and crystalloid volumes transfused in the study groups

	Subgroup M	Subgroup C	p
Perioperatively packed red blood cells [ml]	318±128	415±97	0.001
Plasma [ml]	192±140	285±129	0.01
Albumins [ml]	113±83	139±109	NS
Packed red blood cells [ml]	14±31	32±47	NS
Intraoperative crystalloids [ml]	313±243.9	266±262.9	NS
Postoperative crystalloids [ml]	601±199.1	662.9±159	NS

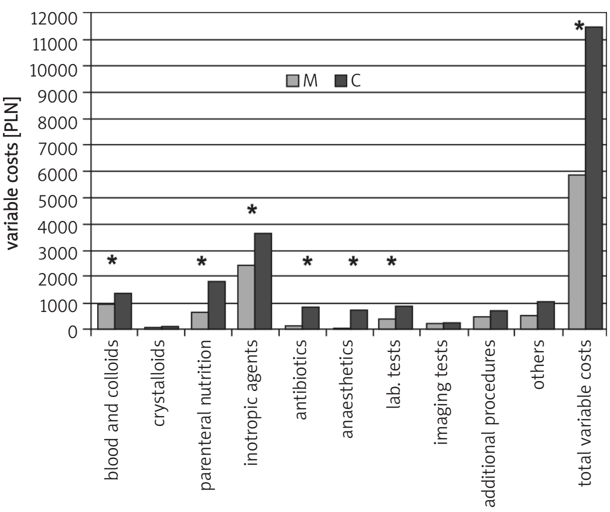


Figure 4. Median variable costs (in Polish currency – PLN) in subgroup with miniaturized (M) and conventional (C) system use

**p <0.05*

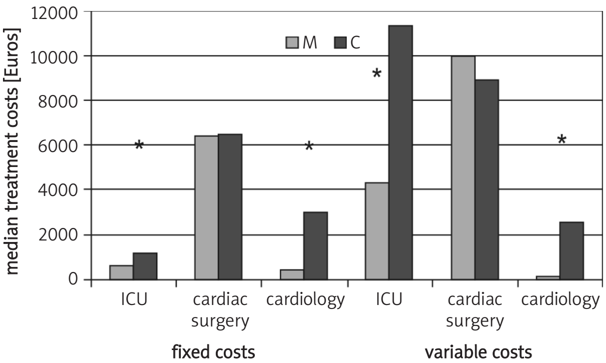


Figure 5. Median costs of postoperative treatment in the study group: M – miniaturised system, and C – conventional devices

**p <0.05*

(1166.57-67 660.77) (NS); Cardiac Surgery – median: 5006.84 (2945.2-17 671.2) vs. 5301.36 PLN (1178.08-19 438.32) (NS); Cardiology – median: 1654.4 (0-2630.48) vs. 11 927.7 PLN (0-12 494.78 PLN) (p=0.001). The median variable costs of therapy at the individual wards were as follows: ICU – median: 2149.94 (859.98-27 519.36) vs. 45 227 PLN (1199.98-69 598.84) (NS); Cardiac Surgery – median: 3729.04 (2193.55-171 096.9) vs. 7278.39 PLN (1617.42-26 687.43) (NS); Cardiology – median: 602.6 (0-957.84) vs. 10 147.2 PLN (0-10 629.74) (p=0.0005).

Total postoperative treatment cost was significantly lower in subgroup M median: 17 375.67 (7420.1-84 308.45) vs. 26 535.38 PLN (16 484.7-86 944.7) (p=0.037) (Figure 5 – values in euros are presented).

Discussion

Growing social expectations associated with constant technological advancement increase the requirements for state-of-the-art medical facilities. On the other hand, in the light of restricted expenditures on medical services, reasonable financial policies have become the leading problem of medical facilities globally. This apparent discrepancy forces the use of techniques and technologies of maximum benefit in clinical and economic aspects.

Determination of perioperative factors threatening increased therapy costs following cardiosurgical procedures is now one of the leading medical problems [4-10]. It should be highlighted that medical risk factors of increased costs were similar in both subgroups in the study. There were no significant differences between study groups with respect to patients' age, preoperative clinical condition, duration of preoperative treatment, type of repaired defect, surgical technique or postoperative management.

Significantly milder postoperative course was a discriminating factor of the miniaturised circuit subgroup. The available literature underlines the significant influence of postoperative complications, such as infections, cardio-pulmonary failure or renal failure, on in-hospital costs of treatment of patients undergoing cardiac surgery [5, 11-13]. More severe postoperative condition, including complications, increases costs of administered drugs and additional procedures, as well as prolongs the duration of the postoperative period itself. It may possibly translate into higher costs of therapy in children treated with larger cardiopulmonary bypass devices, in whom the postoperative period was more often complicated and postoperative course was more severe. The above statement is supported by the variable cost analysis in our study group. Variable costs depend on the nature of the dressing materials, drugs, and diagnostic and other procedures carried out. As such they closely correlate with the patient's condition and method of treatment.

It seems important that while fixed ICU costs showed no significant differences between the study subgroups, the variable costs were significantly lower in children treated with a miniaturised device. Considerably lower variable costs resulted from pharmacological treatment used, shorter duration of mechanical ventilation, and lower rate as well as milder complications in this group of patients.

Longer mechanical ventilation forced prolongation of hospitalisation at the ICU. Hekmat et al. reported that total in-hospital treatment costs are directly related to duration of treatment at the intensive care unit [14]. This was supported by other investigators [9, 15].

One of the key factors that may influence severity of postoperative course in the youngest children operated on using extracorporeal circulation is the size of the device itself [2]. This unfavourable relation applies to both priming volume and device inner area contacting patients' blood. Large priming volume causes significant volume overload of the immature young body of the child. Incompletely developed secretory mechanisms including neurohormonal regulation [16] act in favour of fluid retention, which subsequently intensifies adverse consequences of surgery [17]. Perioperative fluid retention increases cardio-pulmonary failure symptoms [18], and favours infections and multiorgan distress syndrome [19], requiring use of larger amounts of drugs, additional procedures and examinations. In this light, it significantly increases treatment costs.

Large priming volume and haemodilution in consequence increase perioperative haematological disorders [20]. Significant decrease in haemoglobin level results in the necessity for transfusion of blood products [21]. Additionally, haemodilution escalates coagulation changes, which are a significant risk factor of increased postoperative bleeding requiring blood products transfusion [22, 23]. It also seems that large priming volume enforces perioperative immune disturbances due to haemodilution itself [24] or increased blood transfusion [3].

Definitely more controversial is the role of device inner area size. It adds to blood cell and endothelial activation [25]. It seems that large device inner area is responsible for increased postoperative unspecific inflammatory response [2, 3], activation of coagulation and fibrinolysis [26]. The above phenomena lead to enhancement of the observed unfavourable consequences of the extracorporeal circulation itself and increased therapeutic costs. Taking this into account, system miniaturisation seems to be a reasonable solution reducing treatment costs and improving outcomes.

The necessity of prolonged treatment at the cardiology unit in the conventional device group results from the postoperative stabilisation period required due to more severe disease course. It significantly added to increased postoperative treatment costs in this group of patients.

It should be highlighted that standard deviation of total treatment costs in the conventional subgroup was significantly higher. Larger variability of total therapeutic costs in subgroup C may indicate a barely foreseeable postoperative period course of variable severity. It may also predict increased risk of higher postoperative treatment costs in this group of patients.

In the light of the above facts it seems that the use of mini-circuit cardiopulmonary bypass reduces the risk as well as the costs of surgical treatment of the youngest patients.

Conclusions

1. Miniaturisation of the cardiopulmonary bypass device significantly improves postoperative clinical condition and shortens duration of postoperative therapy.
2. Miniaturisation of the cardiopulmonary bypass device significantly decreases in-hospital costs of treatment of neonates and infants undergoing surgery for congenital heart disease.

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Komentarz redakcyjny

dr hab. n. med. Małgorzata Pawelec-Wojtalik

Zakład Radiologii Pediatrycznej, Pracownia Angiografii i Hemodynamiki, Samodzielny Publiczny Szpital Kliniczny Nr 5, Poznań

Znaczny postęp w kardiochirurgii umożliwił całkowitą korekcję złożonych wad serca u noworodków i niemowląt w krążeniu pozaustrojowym. Dzięki lepszemu rozpoznawaniu wad serca, poprawie technik operacyjnych oraz udoskonalaniu metod krążenia pozaustrojowego, w ostatnich latach znacznie zmniejszyła się śmiertelność okołooperacyjna.

Krążenie pozaustrojowe całkowicie zastępuje funkcję płuc i serca w czasie operacji kardiochirurgicznej na otwartym sercu. Klinicznie po raz pierwszy zostało ono zastosowane u osób dorosłych w 1953 r., a u dzieci dopiero w 1970 r. W przypadku pełnej reperfuzji cała krew gromadzona jest w pozaustrojowym układzie krążenia, gdzie się ją natlenia, a następnie pompą mechaniczną kierowana do aorty. W ostatnim czasie w wielu publikacjach podkreśla się korzystne znaczenie miniaturyzacji urządzeń do krążenia pozaustrojowego u dorosłych, a autorzy opisali ciekawą metodę minimalizacji krążenia pozaustrojowego u dzieci. Przedstawili oni wyniki leczenia z zastosowaniem zminiaturyzowanego aparatu do krążenia pozaustrojowego i wykazali, że stosowanie tej metody powoduje łagodniejszy przebieg pooperacyjny, mniej powikłań infekcyjnych i skrócenie czasu leczenia. Wykazali także, że leczenie z zastosowaniem zminiaturyzowanego urządzenia do krążenia pozaustrojowego ma znaczenie ekonomiczne, porównując jego koszty z kosztami leczenia metodą konwencjonalną.

Materiał przedstawiony w pracy jest ciekawy. Bardzo dobre wyniki operacji i mała śmiertelność świadczą o dużym doświadczeniu ośrodka kardiochirurgicznego.

Ekonomiczna ocena miniaturyzacji urządzenia do krążenia zewnątrzustrojowego stosowanego u noworodków i niemowląt poddanych operacjom wrodzonych wad serca

Krzysztof Mozol[1], Ireneusz Haponiuk[2], Andrzej Byszewski[3], Bohdan Maruszewski[2]

[1] Instytut „Pomnik – Centrum Zdrowia Dziecka”, Warszawa
[2] Klinika Kardiochirurgii, Instytut „Pomnik – Centrum Zdrowia Dziecka”, Warszawa
[3] Klinika Anestezjologii i Intensywnej Terapii, Instytut „Pomnik – Centrum Zdrowia Dziecka”, Warszawa

Streszczenie

Wstęp: We współczesnej kardiochirurgii wrodzonych wad serca istnieje tendencja do miniaturyzacji urządzenia do krążenia zewnątrzutrojowego. Rosnące oczekiwania społeczeństwa przy stałym rozwoju technologii wyznaczają zadania, którym powinny sprostać współczesne ośrodki medyczne. Z drugiej strony, wobec ograniczonych nakładów na służbę zdrowia, jednym z głównych problemów placówek medycznych na całym świecie stała się racjonalna polityka finansowa. Ta pozorna sprzeczność wymusza konieczność stosowania technik i technologii przynoszących maksymalne korzyści zarówno kliniczne, jak i ekonomiczne. Wielu badaczy podkreśla, że mniejsza objętość wypełnienia wstępnego i powierzchni sztucznej urządzenia może przynieść wymierne korzyści zarówno ekonomiczne, jak i kliniczne.

Cel: Celem pracy było porównanie kosztów leczenia u dzieci z zastosowaniem zminiaturyzowanego i konwencjonalnego urządzenia.

Materiał i metody: Grupę 60 dzieci do 1. roku życia podzielono w sposób prospektywny, randomizowany na 2 podgrupy: podgrupę M, w której zastosowano układ zminiaturyzowany, i podgrupę K, w której zastosowano układ konwencjonalny. Obie podgrupy nie różniły się istotnie pod względem wieku, masy ciała, typu operowanej wady oraz zastosowanej techniki perfuzji. Operacje zostały wykonane w jednym ośrodku, przez ten sam zespół chirurgiczny i anestezjologiczny. Oceniono powikłania pooperacyjne, czas leczenia szpitalnego oraz koszty leczenia. Ocenę statystyczną przeprowadzono metodą statystyki opisowej.

Wyniki: Miniaturyzacja urządzenia umożliwiła zmniejszenie objętości wypełnienia wstępnego o 46,6% (p=0,000001) i powierzchni kontaktującej się z krwią chorego o 68,8% (p=0,0000001). W grupie, w której zastosowano układ zminiaturyzowany, rzadziej wystąpiła niewydolność krążeniowo-oddechowa (2 *vs* 8, p=0,038) oraz powikłania infekcyjne (3 *vs* 9, p=0,049). Czas leczenia pooperacyjnego był istotnie krótszy u dzieci z podgrupy M (mediana: 20,8 *vs* 25,48 dnia, p=0,042). W grupie M koszty leczenia pooperacyjnego były istotnie niższe (mediana: 17 375,67 *vs* 26 535,38 zł, p=0,037).

Wnioski: Miniaturyzacja urządzenia do krążenia zewnątrzustrojowego w istotny sposób poprawia pooperacyjny stan kliniczny noworodków i niemowląt. Zastosowanie zminiaturyzowanego urządzenia znacząco zmniejsza koszty leczenia dzieci poddanych operacjom wad serca.

Słowa kluczowe: krążenie zewnątrzustrojowe, perfuzja pediatryczna, analiza kosztów leczenia

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Adres do korespondencji:
dr n. med. Krzysztof Mozol, Instytut „Pomnik – Centrum Zdrowia Dziecka”, ul. Dzieci Polskich 20, 04-730 Warszawa, tel.: +48 22 815 70 00,
e-mail: kmozol@doctors.org.uk

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