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Original Article / *Özgün Makale*

The impact of new generation oxygenators with integrated arterial filters on neurological outcome

Arteriyel filtre entegreli yeni nesil oksijenatörlerinin nörolojik sonuçlar üzerindeki etkisi

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ABSTRACT

Background: This study aims to compare the neurocognitive effects of two different oxygenator systems, i.e. membrane oxygenator with or without integrated arterial filters, used during cardiopulmonary bypass in patients undergoing coronary artery bypass grafting.

Methods: This prospective, randomized study included a total of 40 patients (36 males, 4 females; mean age 60.0±8.5 years; range 43 to 75 years) who underwent elective coronary artery bypass grafting between January 2015 and December 2015. The patients were divided into two groups by block randomization using the sealed envelope technique. In group 1, non-integrated arterial filter membrane oxygenators and, in group 2, integrated arterial filter membrane oxygenators were used. Near-infrared spectroscopy was used to assess the cerebral oxygenation intraoperatively in all patients. Cranial diffusion-weighted magnetic resonance imaging was performed 2-4 days before and after the surgical procedure. Cognitive functions were evaluated using the Montreal Cognitive Assessment at the postoperative one month.

Results: Eleven patients in the non-integrated group and seven patients in the integrated group had new lesions in the diffusion-weighted magnetic resonance imaging. The mean pre- and postoperative total Montreal Cognitive Assessment scores were 27.9±3.3 vs 28.1±3.4 and 26.2±3.1 vs 26.8±3, respectively, in the non-integrated and integrated groups. There were no statistically significant differences between the two groups in terms of the number of new lesions, the near-infrared spectroscopy findings, and the Montreal Cognitive Assessment scores.

Conclusion: Membrane oxygenators with integrated arterial filters do not seem to offer a significant advantage over those without integrated arterial filters in terms of neurocognitive outcomes in patients undergoing coronary artery bypass grafting.

Keywords: Cognitive functions; diffusion-weighted magnetic resonance imaging; membrane oxygenators.

ÖZ

Amaç: Bu çalışmada, koroner arter baypas greftleme yapılan hastalarda, kardiyopulmoner baypasta kullanılan iki farklı oksijenatör sistemi olan, membran oksijenatöre entegreli ve entegresiz arteriyel filtrenin nörokognitif etkileri karşılaştırıldı.

Çalışma planı: Bu prospektif, randomize çalışmaya Ocak 2015 - Aralık 2015 tarihleri arasında elektif koroner arter baypas greftleme yapılan toplam 40 hasta (36 erkek, 4 kadın; ort. yaş 60.0±8.5; dağılım 43-75 yıl) alındı. Hastalar kapalı zarf tekniği kullanılarak blok randomizasyon ile iki gruba ayrıldı. Grup 1'de arteriyel filtre entegresiz membran oksijenatörleri ve grup 2'de arteriyel filtre entegreli membran oksijenatörleri kullanıldı. Tüm hastalarda ameliyat sırasında serebral oksijenizasyon yakın kızılötesi spektroskopi ile değerlendirildi. Cerrahi işlemden 2-4 gün önce ve sonra, beyin difüzyon ağırlıklı manyetik rezonans görüntüleme yapıldı. Bilişsel fonksiyonlar ameliyat sonrası birinci ayda Montreal Bilişsel Değerlendirme testi ile değerlendirildi.

Bulgular: Difüzyon ağırlıklı manyetik rezonans görüntülemede entegresiz grupta 11 hastada ve entegreli grupta yedi hastada yeni lezyonlar saptandı. Ameliyat öncesi ve sonrası toplam Montreal Bilişsel Değerlendirme skoru entegresiz ve entegreli grupta sırasıyla ortalama 27.9±3.3'e kıyasla 28.1±3.4 ve 26.2±3.1'e kıyasla 26.8±3 idi. Gruplar arasında yeni lezyon sayısı, yakın kızılötesi spektroskopi bulguları ve Montreal Bilişsel Değerlendirme skorları açısından istatistiksel olarak anlamlı bir fark yoktu.

Sonuç: Arteriyel filtre entegreli membran oksijenatörlerin, koroner arter baypas greftleme yapılan hastalarda, nörokognitif sonuçlar açısından, arteriyel filtresi entegre olmayan membran oksijenatörlere kıyasla, anlamlı bir üstünlükleri var gibi görünmemektedir.

Anahtar sözcükler: Bilişsel fonksiyonlar; difüzyon ağırlıklı manyetik rezonans görüntüleme; membran oksijenatörler.

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Cardiopulmonary bypass (CPB) is known to be associated with variable degrees of brain injury after open heart surgery[1] with an incidence of postoperative cerebral events ranging between 1 and 3%.[2] Cognitive dysfunction is by far the most common type of cerebral adverse outcomes following CPB.[3] Gas micro-embolism due to the use of CPB represents a potential mechanism for the development of cognitive deficits, and extracorporeal circulation (ECC), itself, may be an important source of such micro-emboli.[4]

Several strategies have been developed to minimize the entry of micro-bubbles into ECC, and to decrease the surface area as well as the prime volume.[5,6] New generation oxygenators with integrated arterial filters which allow the incorporation of arterial filters into the oxygenators have been reported to decrease cerebral injury through entrapment of the particulate matter and micro-bubbles.[7,8] Integration of arterial-line filters with oxygenators as a novel CPB design was contrived for integrating the concepts of "surface covering", "blood filtration", and "miniature".[9] However, there is a limited number of studies comparing conventional CPB equipment with oxygenators with integrated arterial filters.

In the present study, we aimed to prospectively compare integrated vs non-integrated arterial filters in terms of postoperative neurocognitive functions and neuroradiological changes in patients undergoing coronary artery bypass grafting (CABG).

PATIENTS AND METHODS

Patients and study protocol

This prospective, randomized study protocol was approved by the Institutional Review Board of Medical Faculty of Sakarya University. A written informed consent was obtained from each patient. The study was conducted in accordance with the principles of the Declaration of Helsinki.

A total of 58 patients who underwent elective CABG between January 2015 and December 2015 were included in the study. The patients were divided into two groups by block randomization using the sealed envelope technique. In group 1 (n=28), non-integrated arterial filter membrane oxygenators and, in group 2 (n=30), integrated arterial filter membrane oxygenators were used during CABG surgery. Exclusion criteria included an age less than 18 or older than 90 years, concomitant surgery in addition to CABG, history of cerebrovascular disease, poor educational status, presence of mental or psychiatric disorders, prolonged intensive care unit stay due to any reason, hemodynamic instability, and a carotid stenosis higher than 70% as documented by Doppler ultrasound. Cranial diffusion-weighted magnetic resonance imaging (MRI) was performed two to four days before and after CABG. Preoperative cognitive test was administered within seven days prior to CABG, and postoperative cognitive tests were performed at one month postoperatively.

A total of 58 patients underwent cognitive testing prior to surgery. Five patients were excluded due to emergent chest pain, which required close clinical monitoring before surgery. Two patients did not have surgery. Six patients were unable to attend to postoperative MRI visits due to scheduling problems. Five patients refused the follow-up scan. Therefore, a total of 40 patients were prospectively analyzed.

Anesthesia and surgical procedure

All procedures were performed with a Sorin C5 roller pump (Sorin Group USA, Inc., Arvada, CO, USA) using polyvinyl chloride tubing in both groups. Dideco Evo non-integrated arterial filter membrane oxygenators (Sorin Group Italia S.R.L., Milano, Italy) were used in group 1, while Medtronic Affinity (Medtronic, Inc. Minneapolis, USA) fusion integrated arterial filter membrane oxygenators were used in group 2.

All operations were performed through median sternotomy. For all patients, before sternotomy, intraoperative monitoring with transesophageal echocardiography was done to measure the aortic wall thickness and to detect atherosclerotic plaques and calcifications. The aortic wall thickness alterations were recorded according the classification defined by Katz et al.[10] The aortic wall thickness was defined as mild (intimal thickness <3 mm), moderate (intimal thickness 3-5 mm), and severe (intimal thickness >5 mm). Aortic calcifications were evaluated both by intraoperative transesophageal monitoring and manually. Patients who had calcifications and ulceration at the proximal anastomosis and cross-clamp site were excluded from the study.

After the administration of 300 U/kg heparin, CPB was established by aortic and right atrial two-stage single venous cannulation. An aortic root cannula was inserted into the ascending aorta for cardioplegia and venting. Moderate hypothermia (28 °C - 32 °C) was used. When necessary, additional doses of heparin were administered to maintain the activated clotting time over 400 sec. Cold blood cardioplegia (18 °C) was used to achieve cardiac arrest and intermittent antegrade myocardial protection. Partial arterial pressure of carbon dioxide (pCO_2) was maintained at 35-40 mmHg, and the arterial tension of oxygen was maintained at 200-250 mmHg during CPB. Non-pulsatile blood flow during CPB was maintained at 2.4 L/min/m^2 body surface area at normothermia and was adjusted as needed in case of hypothermia. The mean arterial pressure was kept above 55 mmHg throughout the operation using vasoactive agents. Also, packed red cells were administered, when necessary to sustain the hematocrit value above 21% during CPB. Alpha-stat protocol was used to manage the acid-base status.

Cognitive assessments

To assess the alterations in cognitive function, a cognitive test was applied to all participants pre- and postoperatively by an experienced neurologist. The results were evaluated by two blinded observers. Neurological assessments included the evaluation of visual and speech disorders, paralysis in the upper or lower extremities, or mental state disorders. The Montreal Cognitive Assessment (MoCA) test was used to identify cognitive alterations.[11] This tool was originally introduced as a fast screening test for mild cognitive disorder. It assesses the alterations in attention and concentration, coordinating functions, memory, language, visual structuring skills, abstract thought, calculation and orientation. The maximum attainable score is 30. Under these circumstances, a score of ≥26 points indicates normal cognitive functions; 19-25 indicates mild cognitive disorder, and <19 indicates severe cognitive decline.[11,12]

Near-infrared spectroscopy (NIRS)

Cerebral oxygenation of patients was monitored using the near-infrared spectroscopy during surgery. Baseline values were calculated before the induction of anesthesia, and the subsequent regional oxygen saturation (rSO_2) values were recorded after cross-clamping. Decline in saturation was recorded as percentage, and an intervention was performed when a decrease higher than 20% occurred. The NIRS monitoring was performed using the INVOS system (INVOS 5100 C; Somanetics Corp., Troy, MI, USA). This system allows non-invasive and continuous measurement of the changes in the cerebral oxygen saturation. The NIRS probes were placed in the frontotemporal region on the eyebrows of the patients at both sides. The distance between two probes was set as 4 cm. The rSO_2 values were recorded and certain parameters were evaluated while the patients were awake before the induction of anesthesia. After cross-clamps were placed, rSO_2 changes of the patients during CPB were recorded in the Excel format by the perfusionist and were evaluated by two blinded observers. The standard algorithm was used,[13] as suggested for brain oximetry measurements, in case of a >20% decline in the rSO_2 during CPB, compared to baseline.

Diffusion-weighted magnetic resonance imaging

Cranial diffusion-weighted MRI was performed using the GE Signa HDxt MR device (GE Healthcare, Waukesha, WI, USA). The patients were imaged in the supine position using the standard GE 8-channel phased array head-coil. Diffusion tensor imaging (DTI) was measured using an echo planar imaging sequence with TR/TE= 6000 ms/98.7 ms; 12 uniformly distributed gradient directions, b-value of 1000 s/mm^2, number of excitations [NEX]= 2, contiguous axial slices with 5 mm slice thickness, 128×128 matrix, and 27 cm FOV. The slices were positioned to run parallel to the anterior commissural and posterior commissural plane. New diffusion-weighted lesions on postoperative scans were also evaluated. Scans were read by a single experienced neuroradiologist blinded to the clinical and neuropsychological data of the patients until the time of examination (before or after surgery). Preoperative scans and new lesions are shown in Figures 1a-d.

New-generation oxygenators with integrated arterial filters

The main difference between oxygenators with integrated arterial filters and conventional

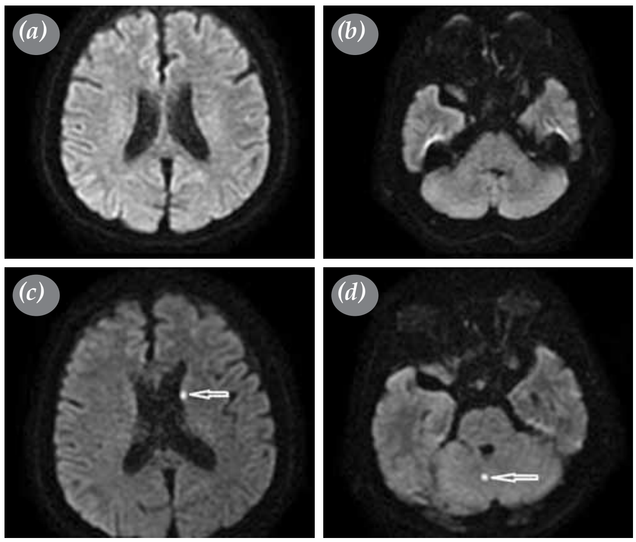

Figure 1. Diffusion-weighted magnetic resonance imaging one week before **(a, b)** and 2-4 days after **(c, d)** coronary artery bypass grafting. While there is no acute ischemic lesion preoperatively, there are multiple hyperintense foci at different cerebral anatomic locations postoperatively. Small new lesions (arrows) appear in the left caudate nucleus head and right temporal lobe white matter postoperatively.

oxygenators is represented by an embedded 30 micron arterial filtering capability of the former technology which avoids an increase in the total prime volume. The maximum prime volume of the oxygenator is 260 mL including the hollow fiber membrane, heat exchanger, and the arterial filter. The mid-upper part of the oxygenator includes a bubble-trap, together with a separate shunt line conveying the potentially formed bubbles to the reservoir as well as a single-direction valve at the oxygenator end of this line which prevents backward flow. The pore size of the venous/cardiotomy filter within the reservoir is less than 26 microns. In addition, a 25-micron film is incorporated into the cardiotomy reservoir to prevent foaming.

Statistical analysis

Statistical analysis was performed using the IBM SPSS version 23.0 software (IBM Corp., Armonk, NY, USA). Descriptive analyses were performed to provide data on overall characteristics of the study population. The Kolmogorov-Smirnov test was used to test the normality of the data. The independent sample t-test was used to compare the patient characteristics of the two groups (membrane oxygenators with or without integrated arterial filters). The paired sample t-test was used to compare pre- and postoperative MoCA scores. Two-way analysis of variance (ANOVA) for repeated measurements was used to analyze the NIRS values between two groups according to values of cerebral saturation evaluated during surgery. The continuous data were presented in mean ± standard deviation. Categorical variables were compared using the chi-square test and were presented in number and percentage. A p value of <0.05 was considered statistically significant.

RESULTS

Demographic and preoperative characteristics are listed in Table 1. There was no statistically significant difference in the demographic and baseline characteristics of the patient groups. However, the number of diabetic patients was higher in group 1 than in group 2, although the difference was not statistically significant (9 (45%) vs 3 (15%), p=0.084). On the other hand, intraoperative glucose levels were comparable between the two groups (Table 2).

New MRI lesions were detected in 18 of 40 patients (45%), 11 in group 1 and seven in group 2 (p=0.34).

Table 1. Demographic and clinical characteristics of patient groups

	Non-integrated group (n=20)			Integrated group (n=20)			
	n	%	Mean±SD	n	%	Mean±SD	*p*
Age (year)			61.2±8.4			58.9±8.7	0.41
Gender							1.00
Female	2	10		2	10		
Male	18	90		18	90		
Hypertension	12	60		7	35		0.21
Diabetes mellitus	9	45		3	15		0.08
Chronic obstructive pulmonary disease	0	0		1	5		1.00
Chronic renal insufficiency	1	5		0	0		1.00
Tobacco use	10	50		7	35		0.52
Alcohol use	3	15		0	0		0.23
History of cerebrovascular disease	4	20		8	40		0.30
Hyperlipidemia	7	35		9	45		0.75
Atrial fibrillation	1	5		0	0		1.00
Ejection fraction							0.84
Good (>50%)	14	70		16	80		
Moderate (30-50%)	5	25		3	15		
Poor (<30%)	1	5		1	5		
Aorta thickness							0.56
<3 mm	2	10		3	15		
3-5 mm	17	85		14	70		
>5 mm	1	5		3	15		
Peripheral arterial disease	0	0		1	5		1.00

SD: Standard deviation.

Table 2. Perioperative data, clinical outcomes and findings on brain magnetic resonance imaging

	Non-integrated group (n=20)			Integrated group (n=20)			
	n	%	Mean±SD	n	%	Mean±SD	*p*
Intraoperative data							
Number of proximal anastomosis							0.43
0	2	10		2	10		
1	1	5		5	25		
2	15	75		12	60		
3	2	10		1	5		
Cardiopulmonary bypass time (min)			84.6±24.2			86.8±32.5	0.81
Aortic cross-clamp time (min)			48.4±19.1			51.1±23.5	0.66
Temperature (°C)			29.7±1.1			29.5±0.8	0.64
Mean arterial pressure (0-30 min) (mmHg)			79.1±9.1			74.6±9.7	0.14
Mean arterial pressure (30-60 min) (mmHg)			67.3±8.8			64.5±5.4	0.23
Mean arterial pressure (60-90 min) (mmHg)			66.6±6.5			67.1±5.3	0.81
Mean arterial pressure (post ACC) (mmHg)			81.5±8.6			78.9±8.3	0.34
Hematocrit (cardiopulmonary bypass) (%)			41.4±3.8			40.3±5.8	0.49
Hematocrit (ACC) (%)			24.3±5.4			25.9±3.4	0.25
Glucose (cardiopulmonary bypass) (mg/dL)			134.1±40.5			124.9±33.8	0.44
Glucose (ACC, 0-60 min) (mg/dL)			130.3±25.7			127.2±19.7	0.67
Glucose (ACC, >60 min) (mg/dL)			163.8±21.3			163.6±30.9	0.98
Glucose (post ACC, 0-60 min) (mg/dL)			176.2±30.4			185.4±38.6	0.41
Glucose (post ACC, >60 min) (mg/dL)			195.8±24.2			183.5±42.2	0.63
Clinical outcomes							
Transient psychotic syndrome	3	15		2	10		1.00
Arrhythmia	8	40		7	35		1.00
Stroke	0	0		0	0		1.00
Bleeding	1	5		0	0		1.00
Myocardial infarction	0	0		0	0		1.00
Intensive care unit length of stay (days)			2.3±0.9			2.1±0.7	0.44
Hospital length of stay (days)			8.1±2.1			8.4±1.2	0.71
Findings on brain DW-MRI							
New lesions	11	55		7	35		0.34
Anatomic locations and number of lesion							
Left hemisphere							
Parietal	7			9			
Frontal	3			1			
Occipital	5			1			
Temporal	2			2			
Cerebellum	1			8			
Thalamus	0			0			
Putamen	0			1			
Caudate nucleus	0			1			
Nucleus ruber	1			0			
Right hemisphere							
Parietal	4			19			
Frontal	6			3			
Occipital	3			5			
Temporal	1			1			
Cerebellum	4			6			
Thalamus	0			2			
Putamen	0			0			
Caudate nucleus	0			0			
Nucleus ruber	1			0			

SD: Standard deviation; ACC: Aortic cross-clamp; DW: Diffusion-weighted; MRI: Magnetic resonance imaging.

The lesions identified in the postoperative diffusion-weighted MRI were similarly distributed across the study groups (p=0.66). Of 18 patients with new lesions, four had a single lesion, four had two lesions, four had three lesions, and six had ≥3 lesions. The mean number of lesions was 2.8±7.4 and 1.9±3.8 in group 1 and group 2, respectively (p=0.631).

The mean preoperative total MoCA scores were 27.9±3.3 and 28.1±3.4 in group 1 and group 2, respectively (p=0.85). The mean postoperative total MoCA scores one month after surgery were 26.2±3.1 and 26.8±3.8 in group 1 and group 2, respectively (p=0.58). There was no statistically significant difference in the pre- and postoperative MoCA scores between the study groups (p=0.09 and p=0.26, respectively). In addition, a comparison of the change in MoCA test scores over time between the two groups did not show significant differences (p=0.11). The further analysis of MoCA scores are shown in Table 3.

In addition, the decline in saturation as assessed by the NIRS was similar between the two groups (p>0.05) and values are shown in Table 4.

Table 3. Mean Montreal Cognitive Assessment Scores according to the groups

	Non-integrated group (n=20)	Integrated group (n=20)	
	Mean±SD	Mean±SD	*p**
Visuospatial executive			
Preoperative	3.7±1.7	3.5±1.9	0.86
Postoperative	3.6±1.6	3.4±1.8	0.84
Naming			
Preoperative	3.2±0.5	3.4±0.4	0.47
Postoperative	3.1±0.2	3.0±0.2	1.00
Attention			
Preoperative	2.4±0.4	2.2±0.4	0.68
Postoperative	2.1±0.4	2.1±0.3	0.38
Vigilance			
Preoperative	1±0	1±0	1.00
Postoperative	1±0	1.0±0.2	0.32
Serial7s			
Preoperative	3.3±1.0	3.2±0.6	0.55
Postoperative	2.8±0.6	2.8±0.4	0.81
Repetition			
Preoperative	1.8±0.6	2.0±0.6	0.16
Postoperative	1.5±0.6	1.8±0.7	0.47
Fluency			
Preoperative	1±0	2.0±0.2	0.32
Postoperative	1±0	1±0	1.00
Abstraction			
Preoperative	2.5±0.3	2.6±0.3	1.00
Postoperative	2.0±0.2	2.2±0.3	0.55
Delayed recall			
Preoperative	3.3±1.2	3.8±1.2	0.34
Postoperative	3.4±1.6	3.7±1.9	0.13
Orientation			
Preoperative	6±0	6.0±0.2	0.32
Postoperative	6.0±0.2	6.0±0.2	1.00
Total MoCA scores			
Preoperative	27.9±3.3	28.1±3.4	0.85
Postoperative	26.2±3.1	26.8±3.8	0.58
p-values**	0.09	0.26	
p-values***	0.11		

SD: Standard deviation; MoCA: Montreal Cognitive Assessment test; * Comparison results between two groups; ** Comparison results between two periods; *** Comparison results between two groups according to the alteration between two periods.

Table 4. Mean near-infrared spectroscopy values according to the groups, time periods, and sides

	Non-integrated group (n=20)	Integrated group (n=20)	
	Mean±SD	Mean±SD	*p*
rSO_2 (%)			
Baseline			
Right	63.2±7.3	65.9±6.3	
Left	64.1±6.9	65.5±5.4	
Cardiopulmonary bypass on			
Right	58.5±5.9	61.4±5.6	
Left	60.5±5.6	59.9±6.5	
Clamp on			
Right	56.3±5.1	59.2±4.7	
Left	58.2±5.8	58.7±5.8	
Cardioplegia			
Right	54.2±4.7	58.9±6.3	
Left	55.5±6.2	58±4.9	
Clamp off			
Right	54.8±4.9	58.4±7.5	
Left	57.3±5.4	57.3±6.3	
Cardiopulmonary bypass off			
Right	59.9±5.1	62.9±6.6	
Left	61.4±4.8	63±5.4	
Δ rSO_2 (%)*			
Cardiopulmonary bypass on			
Right	-7.2±7.8	-6.5±6.9	0.77
Left	-5.1±9.8	-8.2±5.9	0.23
Clamp on			
Right	-9.4±9.3	-9.9±7.4	0.84
Left	-8.5±10.2	-9.6±6.3	0.68
Cardioplegia			
Right	-13.2±11.1	-10.4±7.9	0.37
Left	-12.4±12.8	-10.6±6.1	0.57
Clamp off			
Right	-12.3±8.6	-11.1±7.7	0.63
Left	-10.1±10.2	-11.8±7.3	0.55
Cardiopulmonary bypass off			
Right	-4.3±8.1	-4.1±8.4	0.94
Left	-2.5±8.6	-3.3±6.2	0.72

SD: Standard deviation; rSO_2: regional cerebral oxygenation saturation; Δ rSO2: Change in rSO_2; * rSO_2 changes according to baseline values on near-infrared spectroscopy.

DISCUSSION

In the present study, we found no significant differences in cognitive functions in patients undergoing CABG with membrane oxygenators with or without integrated arterial filters. Postoperative diffusion-weighted MRI scans showed new small lesions which were comparable in terms of incidence, median number, and distribution between the two groups. Furthermore, the NIRS-identified decline in cerebral saturation did not differ significantly between the groups.

Major cerebral injury represents a major cause of morbidity after cardiac surgery, occurring in up to 6% of patients undergoing CABG, as reported by recent studies.[13,14] Cognitive decline is a significant clinical marker of brain injury after cardiac surgery. Micro-embolism during CPB may also contribute to the postoperative cognitive decline (POCD) in these patients.[15] Recent evidence suggests that POCD may actually represent a multi-factorial condition.[15] However, regardless of the extent of the role of CPB in the development of POCD, it is recommended that every effort should be made to protect the patients from micro-embolism.[16] Newer generation oxygenators with integrated arterial filters have been introduced for the dual purpose of effective embolism filtration and improving CPB safety through reduced prime volume. The design of the newer oxygenators also allows incorporation of the arterial filter within the oxygenator chamber.[9,17] On the other hand, studies comparing conventional oxygenators without integrated arterial filters to those newer oxygenators with integrated arterial filters aiming at minimizing the risk of micro-embolism and POCD by forming less micro-bubbles and by entrapping more micro-bubbles are relatively low in number. To the best of our knowledge, the present study is the first prospective, randomized study to compare these two CPB oxygenator systems in terms of their effects on neurocognitive functions and neuroradiological outcomes. In the current study, the MoCA test was used to evaluate neurocognitive functions and cranial MRI was used to evaluate neuroradiological outcomes. To ensure the homogeneity of the cerebral oxygenation of patients in either group, the NIRS was also used for cerebral oxygenation monitoring. When needed, necessary interventions were performed to optimize the factors related to the cerebral brain oxygenation.

The NIRS is a tool, which is used to detect cerebral perfusion abnormalities, and cerebral MRI is used to detect cerebral lesions. In open heart surgery, the NIRS can offer invaluable information concerning the intraoperative cerebral perfusion alterations, which may be due to major bleeding and hemodynamic instability, during the aortic cross-clamping. Therefore, all patients in both groups were monitored by the NIRS through the operation in our study.

In a previous study by Gursu et al.,[9] Sorin Synthesis integrated arterial filtration system was compared with Sorin Dideco Compactflo (Dideco Compactflo Evo, Sorin group, Mirandola Modena, Italy) non-integrated arterial filtration system in patients undergoing CABG with respect to certain clinical variables, inflammatory responses, and need for transfusion. The authors did not report data on the incidence of embolism. However, they concluded that systems with integrated arterial filters were associated with higher intraoperative hematocrit levels and reduced need for red blood cell transfusions. In another study, oxygenators both with or without integrated arterial filters were found to convey micro-bubbles during the bolus entry of air into ECC and that bubbles larger than the filter pore size might be well-conveyed.[18] On the other hand, other authors reported reduced bubble volume and formation of smaller bubbles with integrated arterial filter systems than without it.[18] A recent study reported that the oxygenators without integrated filters exhibited the highest degree of emboli-trapping capabilities, although they found no disadvantage for oxygenators with integrated filters.[19]

The present study compared newly emerging embolic foci in cerebral diffusion-weighted MRI studies pre- and postoperatively in patients undergoing CABG using oxygenators with or without integrated arterial filters. Cerebral silent infarctions known to occur after cardiac procedures can be readily detected using diffusion-weighted MRI. Sun et al.[20] reviewed 12 recent reports in which diffusion-weighted MRI scans were used. Of the pooled population of 446 patients, 127 (29%) had new DWI lesions. Lesions were multiple and showed a widespread distribution across all cerebrovascular zones. Similarly, in our study, lesions were scattered across various cerebrovascular territories in both groups, showing no significant difference between the groups in terms of the distribution frequency as shown in Table 2. Also, in the aforementioned study, the occurrence of new lesions did not correlate with the type of cardiac surgery undertaken.[20] In a recent study, new diffusion-weighted MRI lesions were found in five of 16 patients (31%) undergoing off-pump CABG.[21] In our study, new lesions were assessed using the same imaging modality and we found no statistically significant difference between the two groups in terms of the frequency and number of these lesions.

Nonetheless, there are certain limitations to our study. Our sample size was small, and although the study had a randomized prospective design, a similar study involving larger groups of patients would provide more meaningful results. Another limitation is the lack of a control group undergoing off-pump CABG. Also, only a single cognitive measurement tool was used for assessing the cognitive functions. This was based on the fact that the MoCA can be easily utilized in a busy clinical practice and enables health professionals to identify mild cognitive impairment through practical administration and interpretation steps.[5] Prolonged intensive care unit stay due to any reason, hemodynamic instability, and cerebrovascular event history were also among the exclusion criteria, which significantly limit the generalizability of our results to all patients undergoing cardiac surgery. In addition, ultrasonographic measurement of the gaseous micro-emboli at the entry of the venous site and way out of the arterial site might provide us more valuable results. Therefore, further large-scale studies including patients undergoing different types of cardiac surgery would provide more insight into the potential differences between these two oxygenator systems.

In conclusion, our results did not show any superiority of oxygenators with integrated arterial filters over those without integrated arterial filters in terms of cerebral outcomes based on assessments with cerebral diffusion-weighted imaging studies and cognitive tests. Therefore, further studies on larger series including control groups are required to corroborate our findings.

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