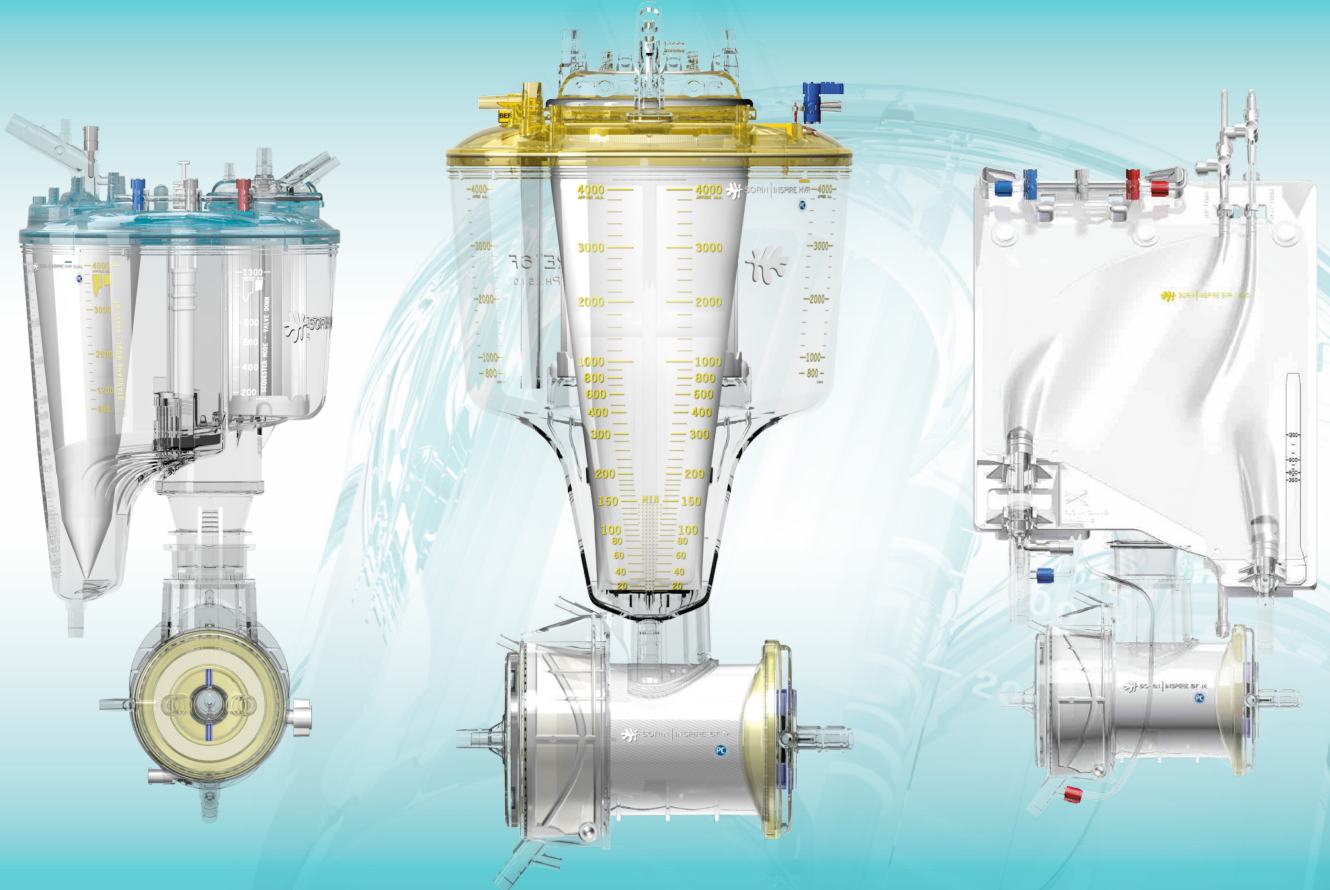


INSPIRE™

Improving Outcomes. Expanding choices.

SCIENTIFIC PUBLICATIONS

Abstract Book



October 2016

Focusing on neurological protection

1 EFFECT OF OXYGENATOR SIZE ON AIR REMOVAL CHARACTERISTICS: A CLINICAL EVALUATION.

Stehouwer MC, De Vroeghe R, Kelder JC, Hofman FN, De Mol BA, Bruins P

Source: Department of extracorporeal circulation, St Antonius Hospital, Nieuwegein, The Netherlands

2 CLINICAL EVALUATION OF EMBOLI REMOVAL BY INTEGRATED VERSUS NON-INTEGRATED ARTERIAL FILTERS IN NEW GENERATION OXYGENATORS.

Jabur GN, Sidhu K, Willcox TW, Mitchell SJ

Source: Green Lane Clinical Perfusion, Auckland City Hospital, Auckland, New Zealand

3 GASEOUS MICROEMBOLI REMOVAL IN SMALL ADULT AND FULL ADULT OXYGENATORS, WITH AND WITHOUT INTEGRATED ARTERIAL FILTERS: AN IN VITRO INVESTIGATION.

Fabbri F, Lancini B, Mazzoli A, Pandolfini C, Spro S

Source: R&D Cardiac Surgery, LivaNova, Mirandola, Italy

Reducing AKI & Blood transfusions

4 EFFECTS OF PRIMING VOLUME REDUCTION ON ALLOGENEIC RED BLOOD CELL TRANSFUSIONS AND RENAL OUTCOME AFTER HEART SURGERY.

Ranucci M, Pistuddi V, Carboni G, Cotza M, Ditta A, Boncilli A, Brozzi S, Pelissero G; Surgical and Clinical Outcome Research (SCORE) Group.

Source: Departments of Cardiothoracic and Vascular Anesthesia and Intensive Care, IRCCS Policlinico San Donato, Milan, Italy

5 ACUTE KIDNEY INJURY AND HEMODILUTION DURING CARDIOPULMONARY BYPASS: A CHANGING SCENARIO.

Ranucci M, Aloisio T, Carboni G, Ballotta A, Pistuddi V, Menicanti L, Frigiola A; Surgical and Clinical Outcome Research (SCORE) Group.

Source: Departments of Cardiothoracic and Vascular Anesthesia and Intensive Care, IRCCS Policlinico San Donato, Milan, Italy

6 MIECC IN MINIMALLY INVASIVE AORTIC VALVE SURGERY.

Starinieri P, Robic B, Wen W, Yilmaz A

Source: Department of Cardiothoracic Surgery, Jessa Hospital, Hasselt, Belgium

7 IN ENDOSCOPIC MITRAL VALVE SURGERY.

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Source: Department of Cardiothoracic Surgery, Jessa Hospital, Hasselt, Belgium

Enhancing system biocompatibility

8 INITIAL RESULTS OF AN OPTIMIZED PERFUSION SYSTEM.

Starck CT, Bettex D, Felix C, Reser D, Dreizler T, Hasenclever P, Falk V

INSPIRE™

Improving outcomes. Expanding choices.

The INSPIRE family has been designed to be fully modular, allowing clinicians an unprecedented choice. The family features integrate single and dual chamber hard-shell venous reservoirs, a new soft-shell venous reservoir and oxygenator modules with and without integrated arterial filter. The clinicians can combine these elements and create the oxygenation system version fitting best their clinical needs.



Fig. 1

INSPIRE has been designed with patient outcome in mind, to provide clinicians a valuable device to address the key challenges in modern perfusion. INSPIRE key features and related benefits are:

- **Reducing AKI & blood transfusions**

Minimizing hemodilution contributes to decreased blood transfusions and improved clinical outcomes after cardiopulmonary bypass (CPB).

- The INSPIRE family minimized the overall impact on hemodilution through an outstanding low Dynamic Operating Volume (DOV). See Fig. 2

Dynamic Operating Volume

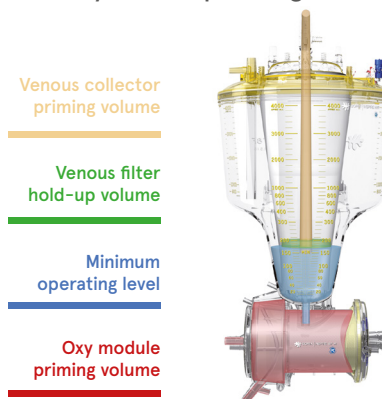


Fig. 2

- **Focusing on neurological protection**

During cardiopulmonary bypass, gaseous microemboli (GME) can be delivered into arterial circulation, potentially damaging organs through multiple mechanisms and contributing to neurocognitive deficits following cardiac surgery.

- Dedicated solutions to within INSPIRE HVR, HVR DUAL and SVR1200 have been developed to ensure effective GME control. The integrated arterial filter, thanks to its dedicated compartment, offers superior GME handling compared to other design solution. See Fig. 3

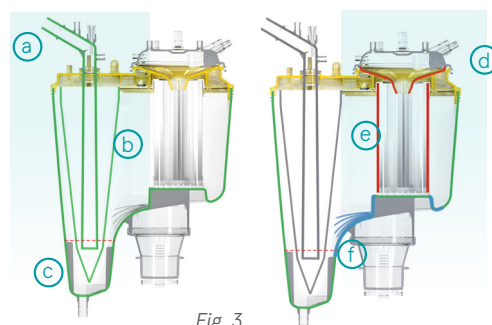
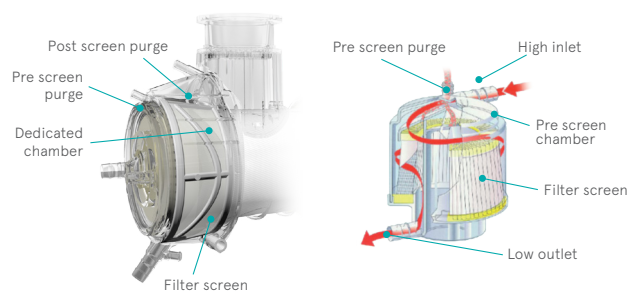


Fig. 3

- **Enhancing system biocompatibility**

Full biocompatibility includes reducing the multiple sources of cellular activation and inflammatory reaction. Coatings reduce platelet activation and white blood cell adhesion to the circuit. Suction blood contains activated cells and stimulates blood activation. Combined, sequestering suction blood and using coated circuits offers maximum biocompatible benefit. The INSPIRE HVR DUAL provides clinicians new options for activated suction management.

- The combination of INSPIRE DUAL reservoir, PC PHISIO coating and Sorin XTRA autotransfusion system is a comprehensive, global approach to enhanced biocompatibility. See Fig. 4

PH.I.S.I.O

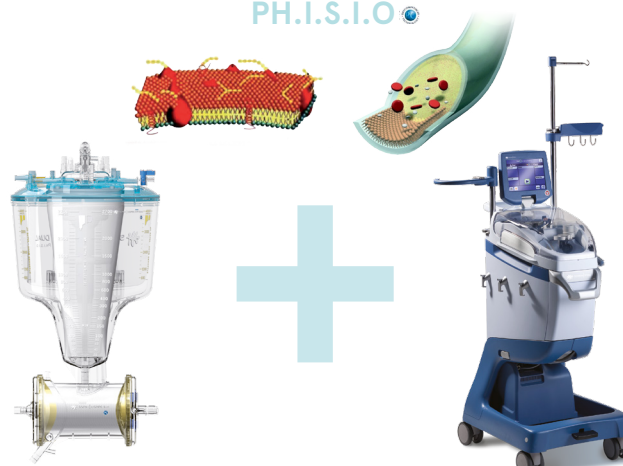


Fig. 4

Focusing on neurological protection

ASAIO J. 2016 Feb 25. [Epub ahead of print]

EFFECT OF OXYGENATOR SIZE ON AIR REMOVAL CHARACTERISTICS: A CLINICAL EVALUATION.

Stehouwer MC, De Vroeghe R, Kelder JC, Hofman FN, De Mol BA, Bruins P

ABSTRACT

During cardiopulmonary bypass (CPB), gaseous microemboli (GME) are released into the patients' arterial bloodstream. GME may contribute to the adverse outcome after cardiac surgery. Recently, two oxygenator models with or without integrated arterial filter (IAF) were designed and only differ in size, leading to a change of 20 % in surface area of the hollow-fibers and 25 % in blood velocities. The aim of this study was to assess the air removal characteristics of the Inspire oxygenators with or without IAF. Sixty-eight patients were randomly assigned to four different groups: Optimized Adult and Full Adult and an additional IAF. GME reduction rates were measured with a bubble counter. The number of GME reduction rates showed no differences. However, both models reduced significantly less volume of GME (Optimized Adult: 40.6 and Full Adult: 50.3 %) compared to both models with IAF (respectively: 88.7 and 88.5 %). No significant differences of reduction rates were found between both devices without IAF and also not between both models with IAF. In conclusion, the larger Inspire oxygenator tends to remove more GME. No effect from size of oxygenator device with integrated screen filter on GME reduction was observed. The Inspire oxygenators with IAF may be considered as an adequate GME filter.

HIGHLIGHTS

"The Inspire oxygenators with IAF may be considered as an adequate GME filter".

CLINICAL EVALUATION OF EMBOLI REMOVAL BY INTEGRATED VERSUS NON-INTEGRATED ARTERIAL FILTERS IN NEW GENERATION OXYGENATORS.

Jabur GN, Sidhu K, Willcox TW, Mitchell SJ

ABSTRACT

Objective:

To compare the emboli filtration efficiency of five integrated or non-integrated oxygenator-filter combinations in cardiopulmonary bypass circuits.

Methods:

Fifty-one adult patients underwent surgery using a circuit with an integrated filtration oxygenator or non-integrated oxygenator with a separate 20 μ m arterial line filter (Sorin Dideco Avant D903 + Pall AL20 (n=12), Sorin Inspire 6 M + Pall AL20 (n=10), Sorin Inspire 6 M F (n=9), Terumo FX25 (n=10), Medtronic Fusion (n=10)). The Emboli Detection and Classification quantifier was used to count emboli upstream and downstream of the primary filter throughout cardiopulmonary bypass. The primary outcome measure was to compare the devices in respect of the median proportion of emboli removed.

Results:

One device (Sorin Inspire 6 M + Pall AL20) exhibited a significantly greater median percentage reduction (96.77%, IQR=95.48 - 98.45) in total emboli counts compared to all other devices tested ($p=0.0062 - 0.0002$). In comparisons between the other units, they all removed a greater percentage of emboli than one device (Medtronic Fusion), but there were no other significant differences.

Conclusion:

The new generation Sorin Inspire 6 M, with a stand-alone 20 μ m arterial filter, appeared most efficient at removing incoming emboli from the circuit. No firm conclusions can be drawn about the relative efficacy of emboli removal by units categorised by class (integrated vs non-integrated); however, the stand-alone 20 μ m arterial filter presently sets a contemporary standard against which other configurations of equipment can be judged.

HIGHLIGHTS

"Among the units used, the new generation Sorin Inspire 6 M with a stand-alone 20 μ m ALF appeared most efficient at removing incoming emboli from the circuit."

GASEOUS MICROEMBOLI REMOVAL IN SMALL ADULT AND FULL ADULT OXYGENATORS, WITH AND WITHOUT INTEGRATED ARTERIAL FILTERS: AN IN VITRO INVESTIGATION.

Fabbri F, Lancini B, Mazzoli A, Pandolfini C, Spro S

ABSTRACT

Purpose:

This study examines in vitro gaseous microemboli (GME) handling in modern full adult and small adult membrane oxygenators, with and without arterial filters. Comparisons of microemboli conduct were made between several Sorin Group oxygenators (Inspire 6 M, Inspire 6F M, Inspire 8 M, Inspire 8F M) and several Terumo Corporation oxygenators (RX15, FX15, RX25, FX25), using a common venous reservoir to eliminate variables.

Methodology:

Under in vitro conditions, two series of tests were conducted using a whole blood (bovine) perfusate with two types of blood pumps. The first test was conducted using a positive displacement roller pump, while the second test was conducted using a centrifugal blood pump. Flow rates were set at 4 liters/minute (l/min) for all experiments to ensure the same testing condition without exceeding the manufacturers rated flows in any device studied. In order to have standardized controls over input conditions for all oxygenator modules examined, the same type of hard shell venous reservoir (Inspire HVR) was used for all membrane oxygenator testing. GME measurement (count/size and volume) was accomplished using the GAMPT BCC200 bubble counter, with two microemboli sensors used to detect both input and output gaseous microemboli.

Conclusions:

In this study, it was found that blood pump type (roller or centrifuge) had no statistically meaningful effect on GME count/size or volume removal. Inspire oxygenators with integrated arterial filters (Inspire 6F M and Inspire 8F M) demonstrated the highest GME count and volume removal, in respect to all other tested oxygenator modules. In addition, no significant differences were found in GME count or volume removal between any of the Terumo adult and small adult oxygenators, with and without arterial filter.

HIGHLIGHTS

"Inspire oxygenators with integrated arterial filters (Inspire 6F M and Inspire 8F M) demonstrated the highest GME count and volume removal, in respect to all other tested oxygenator modules."

Reducing AKI & Blood transfusions

Perfusion. 2015 Mar;30(2):120–6. doi: 10.1177/0267659114535649. [Epub 2014 May 19]

EFFECTS OF PRIMING VOLUME REDUCTION ON ALLOGENEIC RED BLOOD CELL TRANSFUSIONS AND RENAL OUTCOME AFTER HEART SURGERY.

Ranucci M, Pistuddi V, Carboni G, Cotza M, Ditta A, Boncilli A, Brozzi S, Pelissero G

Surgical and Clinical Outcome Research (SCORE) Group.

ABSTRACT

Introduction:

Excessive hemodilution during cardiopulmonary bypass (CPB) is associated with an increased rate of red blood cell (RBC) transfusion and acute kidney injury (AKI). Minimization of the oxygenator priming volume is a measure to contain hemodilution. In this study, we evaluated the new oxygenator, Sorin Inspire 6™, with respect to its ability to limit hemodilution, RBC transfusion rate and postoperative AKI rate.

Methods:

A retrospective study on a consecutive series of 1,724 adult patients receiving heart surgery with CPB. Patients treated with the Inspire 6™ were assigned to the low priming volume oxygenator (LPVO) group (N=383) and patients treated with conventional oxygenators to the conventional group (N=1,341). Dynamic priming volume, time course of the hematocrit, RBC transfusions and AKI rate were compared between the groups.

Results:

Priming volume was significantly ($p=0.001$) lower in the LPVO group (624 ± 113 mL) vs. the conventional group (775 ± 150 mL), with higher values of hematocrit during and after CPB. After correction for other confounders, patients in the LPVO group had a significantly lower RBC transfusion rate (odds ratio 0.68, 95% confidence interval 0.52–0.90, $p=0.006$) and AKI rate (odds ratio 0.55, 95% confidence interval 0.32–0.93, $p=0.032$).

Conclusion:

The Inspire 6™ oxygenator allows a significant containment of hemodilution during CPB, reducing the risk of RBC transfusions and postoperative AKI.

HIGHLIGHTS

“This study demonstrates that the Inspire 6™ LPVO allows a significant containment of hemodilution during CPB and that this lower degree of hemodilution results in a lower number of patients requiring RBC transfusions, in an overall lower number of patients suffering from postoperative AKI.”

ACUTE KIDNEY INJURY AND HEMODILUTION DURING CARDIOPULMONARY BYPASS: A CHANGING SCENARIO.

Ranucci M, Aloisio T, Carboni G, Ballotta A, Pistuddi V, Menicanti L, Frigiola A

Surgical and Clinical Outcome REsearch (SCORE) Group.

ABSTRACT

Background:

Severe hemodilution during cardiopulmonary bypass (CPB) is a risk factor for acute kidney injury (AKI) after heart operations. Many improvements to CPB technology have been proposed during the past decade to limit the hemodilution-related AKI risk. The present study is a retrospective analysis of the relationship between hemodilution during CPB and AKI in cardiac operations in the setting of different interventions applied over 14 years.

Methods:

We retrospectively analyzed 16,790 consecutive patients undergoing heart operations from 2000 to 2013. Various risk factors for AKI were collected and analyzed, together with a number of interventions as possible modifiers of the relationship between a nadir hematocrit (HCT) value during CPB and AKI.

Results:

The relationship between the nadir HCT value during CPB and AKI was confirmed in a multivariable analysis, with the relative risk of AKI increasing by 7% per percentage point of decrease of the nadir HCT value during CPB. The relative risk of AKI decreased by 8% per year of observation ($p = 0.001$) despite a significantly increased risk of AKI ($p = 0.001$). A sensitivity analysis based on differences before and after different interventions demonstrated a beneficial effect of the application of goal-directed perfusion (aimed at preserving oxygen delivery during CPB), with a reduction in the AKI rate from 5.8% to 3.1% ($p = 0.001$). A policy restricting angiographic examination on the day of operation was also useful (reduction of AKI rate from 4.8% to 3.7%; $p = 0.029$).

Conclusion:

A bundle of interventions mainly aimed at limiting the renal impact of hemodilution during CPB is effective in reducing the AKI rate.

HIGHLIGHTS

"GDP routine application in synergy with INSPIRE provided the most important contribution to AKI reduction over years".

MiECTiS Congress. 2016, 9-11 June.

MIECC IN MINIMALLY INVASIVE AORTIC VALVE SURGERY.

Starinieri P, Robic B, Wen W, Yilmaz A

ABSTRACT

Background:

The number of cardiac surgical procedures increases worldwide with improvements focused mainly on reducing surgical trauma. The use of cardiopulmonary bypass still remains the gold standard performing cardiac surgery, but is associated with adverse effects (e.g. haemodilution and blood-air interface). Minimally invasive extracorporeal circulation (MiECC) has been developed to integrate all advantages in CPB technology in one single circuit. The combination of surgical and perfusion attempts in minimal invasive approach could lead to better outcomes in an ageing and more comorbid population.

Methods:

Prospective collected retrospective data from three hundred patients undergoing isolated aortic valve replacement with use of MiECC (n=250) or conventional system (CPB) (n=50). Patients were operated by minimal access upper J-sternotomy approach with groin cannulation.

Results:

No significant differences in mortality or hospital stay (MiECC: 9.5 ± 7.9 days vs CPB: 10.7 ± 6.1 days, $P = .45$) were seen. No difference in inflammatory response as judged from leucocyte counts (MiECC: 7.9 ± 5.5 $10^3/\mu\text{L}$ vs CPB: 7.8 ± 4.9 $10^3/\mu\text{L}$, $P = .30$) were shown. Intraoperative blood product requirements were significantly lower in the MiECC group than in the CPB group (0.3 ± 0.8 units vs 0.9 ± 1.2 units, $P = .004$). No significant differences in postoperative blood loss (MiECC: 202.7 ± 139.4 mL vs CPB: 189.7 ± 156.1 mL, $P = .28$).

Conclusion:

Based on the feasibility and safety aspects of our system, MiECC provides clinical results equivalent to CPB without compromising operative morbidity or mortality resulting in significantly less transfusion requirements.

HIGHLIGHTS

"The Inspire 6F M and 8F M oxygenators with integrated arterial filters demonstrated better GME volume and count removal in respect to the other oxygenators investigated in this study."

MiECTiS Congress. 2016, 9-11 June.

IN ENDOSCOPIC MITRAL VALVE SURGERY.

Starinieri P, Robic B, Wen W, Yilmaz A

ABSTRACT

Background:

Improvements in cardiac surgery are mainly focused on minimizing the trauma in surgical access. Also in perfusion technology, many advances are seen in modern circuits. Safety features similar as in conventional systems will create an enlargement of surgical procedures that can be performed with (modular) MiECC leading to the first endoscopic mitral valve repair with the use of modular MiECC (Inspire mini JESSA). This 360° minimal invasive approach should mean better outcomes and patient satisfaction.

Methods:

A 78-year-old male Jehovah's Witness in cardiogenic shock underwent mitral valve repair and coronary artery bypass grafting through minimal invasive approach. Direct closure of PFO and mitral valve annuloplasty, due to P3 prolapse, was completed through 3 small incisions. Fully arterial revascularization (three distal anastomoses) was performed through left thoracotomy after endoscopic harvesting both internal thoracic arteries.

Results:

After the operation, hemoglobin dropped 1.0 g/dl since arriving in theatre. No complications occurred perioperative. After 6 days, the patient was discharged from the hospital in good condition with resumption of normal daily activities.

Conclusion:

Modular MiECC provides a safe and feasible technique for real minimal invasive cardiac surgery in more complex surgeries.

Perfusion. 2013 Jul;28(4):292-7. doi: 10.1177/0267659113476126. [Epub 2013 Feb 12]

INITIAL RESULTS OF AN OPTIMIZED PERFUSION SYSTEM.

Starck CT, Bettex D, Felix C, Reser D, Dreizler T, Hasenclever P, Falk V

ABSTRACT

Background:

In order to reduce the negative effects of extracorporeal circulation (ECC), the perfusion system and management were optimized at our institution. The goals of optimization were a reduction in the priming volume, in the foreign surface area and in microbubble activity, as well as optimization of suction blood management.

Methods:

Sixty patients were included in this retrospective study. Patients were assigned to two groups, with regard to the use of an optimized perfusion system (OPS-group, n=30) and a standard perfusion system (SPS-group, n=30). All patients underwent elective procedures.

Results:

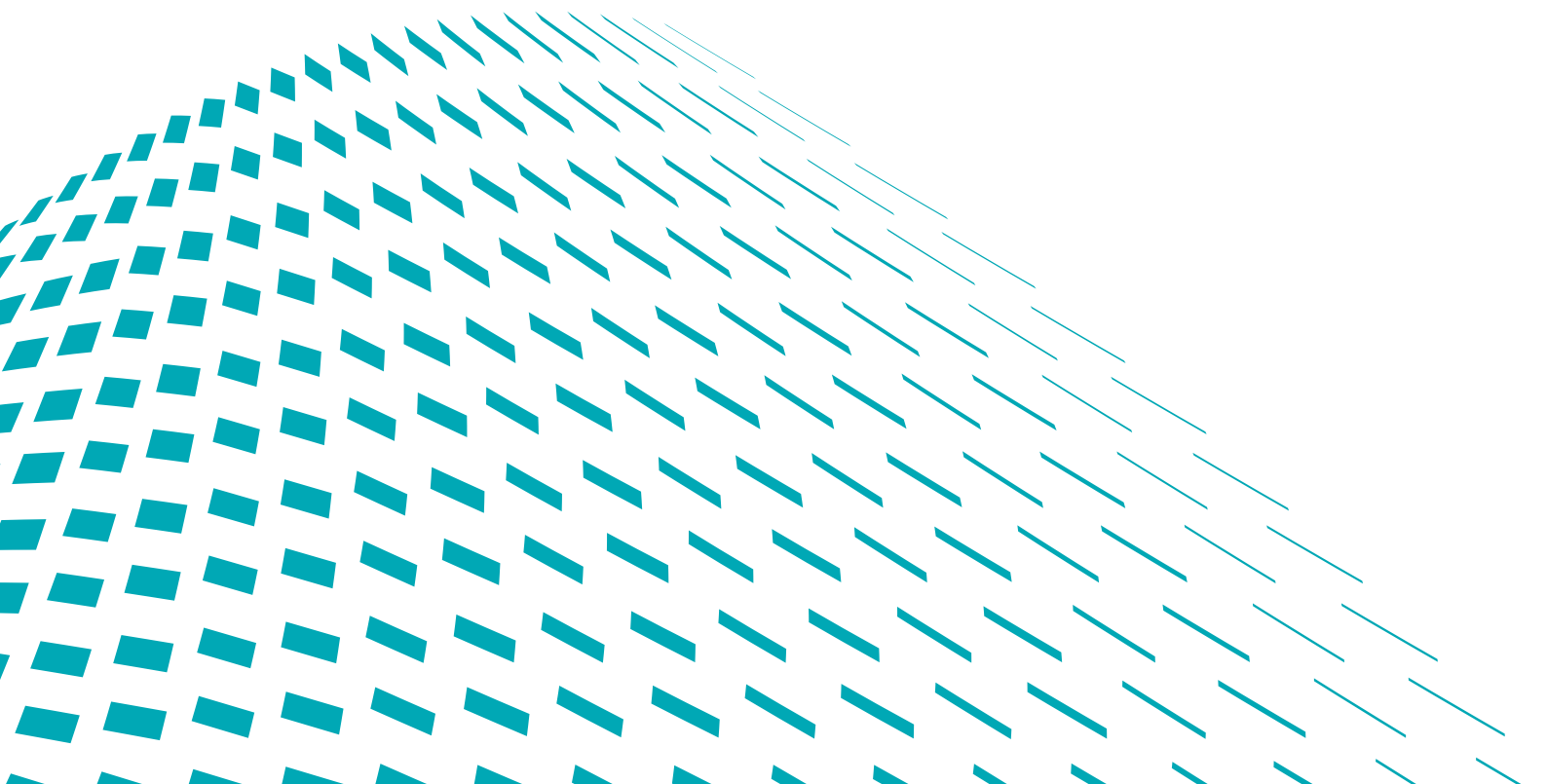
There were no significant differences with respect to patient demographics and operation time. ECC time and cross-clamp time were significantly longer in the OPS group. Statistically significant differences in outcome between the two groups were seen with regard to the following variables: effective priming volume (OPS: 775±447ml; SPS: 1610±0ml; p<0.0001), hemoglobin drop after the start of ECC (OPS: 2.7±1.2g/dl; SPS: 4.2±0.8g/dl; p<0.0001), c-reactive protein on postoperative day 2 (OPS: 121.0±59.4 U/l; SPS: 164.0±50.2 U/l; p=0.003). With regard to the use of blood transfusions, a 33% reduction in the overall amount of transfused units was seen. The rate of patients without transfusions during the entire hospital stay increased from 37% (SPS) to 53% (OPS). The mean transfused red blood cell units per patient was lower in the OPS-group (1.6±2.4 units) than in the SPS-group (2.3±3.5 units).

Conclusion:

With the described optimized perfusion system, a significantly lower priming volume, leading to less hemodilution after the onset of CPB, was achieved. The amount of blood transfusions and the inflammatory response were reduced.

HIGHLIGHTS

"Our optimized perfusion system reduced the inflammatory response with regards to this aspect by separation of the suction blood and a delayed retransfusion, whenever possible".



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