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ARTICOLO

TAILOR-MADE CARDIOPULMONARY BYPASS

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ABSTRACT

La standardizzazione e la sicurezza sono spesso due variabili interdipendenti, specialmente in procedure complesse come il bypass cardiopolmonare.

Un grande interesse scientifico e clinico è nato negli ultimi anni, presso la comunità scientifica internazionale sugli effetti legati agli esiti della cardiochirurgia e della circolazione extracorporea.

Ciò ha permesso un'evoluzione della professione e delle competenze, oggi si propone un approccio clinico del perfusionista al bypass cardiopolmonare, strutturato sulle caratteristiche del paziente, questo articolo presenta i risultati in un'analisi comparativa di revisione retrospettiva in un singolo centro di bypass metodologia su misura cardiopolmonare (CPB), in termini di gestione, selezione di metodi e tecniche e materiali rispetto alla tecnica standard.

OBIETTIVO

Dimostrare la superiorità nella selezione delle tecniche di circolazione extracorporee sui tipi di procedure e caratteristiche dei pazienti, rispetto alla non selezione, metodo convenzionale, in termini di out-come.

ABSTRACT

BACKGROUND: often standardization and security are two interdependent variables, especially in complex procedures such as cardiopulmonary bypass.

Great scientific and clinical interest was born in recent years, by the international scientific community on the effects related to the outcome of cardiac surgery and extra-corporeal circulation.

This has allowed an evolution of the profession and skills, today we talk about a clinical approach of the perfusionist to cardiopulmonary bypass, structured on patient characteristics, this article presents the results in a comparative retrospective review analysis in a single center of a Cardiopulmonary bypass (CPB) tailor-made methodology, in terms of management, selection of the methods and technique and materials compared to the standard technique.

OBJECTIVE: Demonstrate the superiority, in the selection of extracorporeal circulation techniques on the types of procedures and patient characteristics, versus non-selection and the conventional method in terms of out-come.

MATERIALS AND METHODS: This article describes a comparative retrospective analysis in a single center ,between 2014 and 2018 on three hundred patients (201men and

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MATERIALI E METODI

Questo articolo descrive un'analisi retrospettiva comparativa in un singolo centro, tra il 2014 e il 2018 su trecento pazienti (201 uomini e 99 donne) candidati a procedure di chirurgia cardiaca elettiva con un'età media di 68,1 ± 11, 4 anni (intervallo da 58 a 79 anni); tra due periodi storici (2014-2016 vs 2016-2018), il primo periodo storico (2014-2016) prevede un solo sistema di circolazione extracorporea convenzionale senza sistemi di monitoraggio metabolico; il secondo periodo storico (2016-2018) prevede un cambio di approccio al bypass cardiopolmonare strutturato sul tipo di procedura, tipo di paziente, tecnica chirurgica con quattro diversi metodi con sistema di monitoraggio metabolico, circolazione extracorporea compatta; Sistema chiuso; Circolazione extracorporea mini-invasiva; Circolazione extracorporea di Fibonacci.

I dati raccolti e confrontati tra i due gruppi erano: consumo di emoderivati, incidenza di insufficienza renale acuta, marker di ischemia miocardica; e il tempo trascorso in terapia intensiva, incidenza di disturbi cognitivi post-operatori (POCD) ed eventi avversi durante le procedure.

RISULTATI

E' stata riportata una differenza statisticamente significativa tra il gruppo di studio che ha utilizzato la tecnica di bypass cardiopolmonare (CPB) personalizzata rispetto al gruppo di controllo che ha utilizzato convenzionale (CPB), in termini di consumo di emoderivati in sala operatoria e in in terapia intensiva meno del 35% nel gruppo di studio p-value (0,035); riduzione dell'incidenza di insufficienza renale acuta del 15% in meno nel gruppo di studio rispetto al gruppo di controllo, p-value (0,046); riduzione del 23% del tempo trascorso in terapia intensiva per il gruppo di studio rispetto al gruppo di controllo p-value (0,037); una riduzione dei marker per ischemia miocardica TnT ng / L (24 h) nel gruppo di studio rispetto gruppo di controllo p-value (0,041);

99 women) candidate for elective cardiac surgery procedures with a mean age of 68.1 ± 11.4 years (range, 58 to 79 years) ; between two historical times (2014-2016 vs 2016-2018) , the first historical period (2014-2016) provides only one system of use conventional extracorporeal circulation without metabolic monitoring systems; the second historical period (2016-2018) involves a change of approach to cardiopulmonary bypass structured on the type of procedure, type of patient, surgical technique with four different methodologies with metabolic monitoring system, Compact extra-corporeal circulation; Closed System; Minimal invasive extra-corporeal circulation; Fibonacci extra-corporeal circulation.

The data collected and compared between the two groups were: the consumption of blood products, the incidence of acute kidney injury, markers of myocardial ischemia; and time of stay in intensive care unit, the incidence of post-operative cognitive disorders (POCD), and adverse events during procedures.

RESULTS: A statistically significant difference was reported, among the study group that used cardiopulmonary bypass (CPB) tailormade technique Vs the control group that used conventional (CPB) , in terms of consumption of blood products in operating room and intensive care units 35% less in the study group p-value (0.035); reduction in the incidence of acute kidney injury (AKI) 15% less in the study group vs. control group , p-value (0.046); 23% reduction time of stay in intensive care unit for the study group vs. control group p-value (0.035); an reduction of markers for myocardial ischemia TnT ng/L (24 h) in the study group vs. control group p-value (0.041) ; the reduction in incidence of post-operative cognitive disorders (POCD) 15% less in the group of study vs. control group (0.005); no adverse events (accidents) were recorded in the two groups, study and control.

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la riduzione dell'incidenza dei disturbi cognitivi post-operatori del 15% in meno nel gruppo di studio rispetto al gruppo di controllo p-value(0,005); non sono stati registrati eventi avversi (incidenti) nei due gruppi, studio e controllo.

DISCUSSIONE

Negli ultimi anni c'è stato un grande sviluppo di tecnologie e strumenti di monitoraggio, nadir di riferimento efficaci sono stati sviluppati, supportati da studi e letteratura ; poiché il valore di trasporto di O2 (DO2i) <280 ml / min / m2 è stato associato come un metodo predittivo metodo di valore dell'insufficienza renale.

Questo valore ha maturato nella nostra esperienza, un approccio diverso sul percorso da raggiungere questi nadir o ridurre i fattori correttivi durante la condotta, (somministrazione di liquidi e derivati del sangue, uso di ultrafiltrazione, uso di diuretici e vasocostrittori) lavorando attraverso una selezione di materiali e tecniche di (CPB), attraverso diverse tecniche di circolazione extracorporea, meno emolitiche, bassa superficie da contatto, bassa emodiluizione, ridotto contatto sangue-aria e bassa attività micro-embolica (GME).

L'approccio su misura prevede una conoscenza della fisiopatologia e un metodo di lavoro condiviso; I limiti principali di questo studio sono: 1 solo i pazienti selezionati sono stati scelti principalmente con un basso rischio di mortalità.

CONCLUSIONE

Il CPB su misura ha mostrato in questa analisi retrospettiva un risultato migliore nel paziente candidato alla chirurgia cardiaca con valori statisticamente significativi per l'incidenza del tempo trascorso in unità di terapia intensiva, il consumo di emoderivati, i markers di ischemia miocardica, incidenza di POCD e AKI. Tuttavia questa tecnica richiede campioni più grandi e un applicazione sui pazienti fragili per avere maggiore evidenza scientifica.

DISCUSSION: In recent years, there has been a great development in technologies and monitoring tools, effective reference nadirs have been developed supported by studies and literature as the delivery value of O2 (DO2i) <280ml / min / m2 is been associated as a predictive value of renal insufficiency.

This value has matured in our experience, a different approach on the way to reach these nadirs or reducing the corrective factors during the conduct, (administration of liquids and blood derivatives, use of ultrafiltration, use of diuretics, and vasoconstrictors) working through a selection of materials and techniques on (CPB), through different extracorporeal circulation techniques, less hemolytic, low surface, low hemodilution, low blood-air contact and low micro-embolic activity (GME).

The tailor-made approach involves a knowledge of the pathophysiology and a shared working method; The main limitations of this study are: 1 only selected patients were chosen mainly with a low risk of mortality.

CONCLUSION: The tailor-made CPB showed in this retrospective analysis a better outcome in the patient candidate for cardiac surgery with statistically significant values for incidence of time of stay in intensive care units, consumption of blood products, markers of myocardial ischemia , incidence of POCD, and AKI.

However, this technique needs larger samples and the treatments of more fragile patients to have more evidence.

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INTRODUCTION

Cardiac surgery is, by definition, a "non-physiologic" intervention associated with systemic adverse effects.

Despite advances in surgical technique, cardiopulmonary bypass (CPB) technology as well as anesthesia management and patient care, there is still significant morbidity and subsequent mortality.

Cardiopulmonary bypass (CPB) in adults is associated with morbidity due to systemic inflammatory response syndrome (SIRS).

Strategies to mitigate SIRS include management of perfusion temperature, hemodilution, circuit miniaturization, and biocompatibility.

Traditionally, perfusion parameters have been based on body weight. However, intraoperative monitoring of systemic and cerebral metabolic parameters report that often, nominal CPB flows may be overestimated.

The aim of the retrospective study was to compare two different time periods: the first periods (2014-2016) managed with only conventional CPB without continuous metabolic monitoring (control group) , versus the seconds periods (2016-2018) with different methods and for types of CPBs (Compact Extra-corporeal circulation , Closed extra-corporeal circulation, Minimal invasive extra-corporeal circulation, Fibonacci extra-corporeal circulation) selected on the typologies of patients and procedures, with the integration of continuous metabolic parameters (study group) .

The primary end-point of this research were: one, evaluation of the corrective factors during CPB between the two groups for the goal directed perfusion strategy; two, consumption of blood products; three, the time of stay in intensive care units.

MATERIALS AND METHOD

POPULATION AND STUDY DESIGN

This article describes a comparative retrospective analysis in a specialized regional tertiary cardiac surgery center in Italy, between 2014 and 2018 on three hundred patients (201men and 99 women) candidate for elective cardiac surgery procedures with a mean age of 68.1 ± 11.4 years (range, 58 to 79 years) (**TABLE 1**).

The present investigation was approved by the Institutional Review Board and written informed consent was obtained from each patient.

The distribution of subsequent cardiac surgeries was as follows: (1) isolated aortic valve replacement (AVR) (n=70); (2) AVR + Coronary artery bypass graft (CABG) (n=30); (3) Aortic surgery ± CABG (n=30); (4) Mitral valve repair in minimally invasive approach (MVR in MICS) (n=70) and (5) isolated CABG (n=100) 57% needed multivessel revascularization (**TABLE 2**).

Patients with chronic renal failure, type 1 or 2 diabetes mellitus, septic shock or endocarditis, patients whose hemoglobin (Hb) was below 8 g/dl before the procedure and procedures not in election were excluded.

This comparative retrospective analysis has been realized between two historical times (2014-2016 vs 2016-2018): the first historical period (2014-2016) provides only one system of use conventional extracorporeal circulation without metabolic monitoring systems; the second historical period (2016-2018) involves a change of approach to cardiopulmonary bypass structured on the type of procedure, type of patient, surgical technique with four different methodologies with metabolic monitoring system, Compact extra-corporeal circulation; Closed System; Minimal invasive extra-corporeal circulation; Fibonacci extra-corporeal circulation.

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The data collected and compared between the two groups were: the consumption of blood products, the incidence of acute renal failure, markers of myocardial ischemia; and time of stay in intensive care unit, the incidence of post-operative cognitive disorders (POCD), and adverse events during procedures.

TAB.1 : BASIC CHARACTERISTICS OF THE STUDY SAMPLES TOTAL SAMPLE (N=300) NYHA, NEW YORK HEART ASSOCIATION; CPB, CARDIOPULMONARY BYPASS; HB, HEMOGLOBIN

	Control Group (n=150)	Study Group (n=150)
Age (y) (mean)	69.7	68.4
Body surface area (m2)	1.85	1.86
Left ventricular ejection fraction % (mean)	49	48
NYHA class (median)	2	2
Euroscore II	4.4	4.9
Pre-CPB Hematocrit (%, mean ±SEM)	32.4±1.2	32.6±1.9
Pre-CPB Hb (g/dl)	10.4±1.1	10.8±1.2
Creatinine (mg/dl) (mean)	1.17 ±0.6	1.06 ±0.9
Obstructive coronary artery disease	37%	29%
CPB time (min)	112±15.2	90±8.37
Aortic cross-clamp time (min)	59±9	69±7
Elective	148	146
Urgent	2	4

TAB.2 : SURGICAL PROCEDURES - AVR, AORTIC VALVE REPLACEMENT; CABG CORONARY ARTERY BYPASS GRAFT; MVR, MITRAL VALVE REPAIR; MICS, MINIMALLY INVASIVE CARDIAC SURGERY

Surgical Procedures	Total= 300 Number
Isolated AVR	70
AVR + CABG	30
Aortic surgery + CABG	30
MVR in MICS	70
Isolated CABG	100

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SURGICAL PROCEDURE

Full median sternotomy was conducted in isolated aortic valve replacement (AVR); AVR + Coronary artery bypass graft (CABG); Aortic surgery ± CABG and isolated CABG, under CPB by arterial and venous central cannulation.

Antegrade normothermic cardioplegia was achieved by infusion in the aortic bulb. Aortic prosthesis (Bicarbon LivaNova; Mosaic Medtronic) was used to replace the aortic valve (the model and size were selected according to the characteristics of the patient), and a Dacron INTERGARD woven graft (Maquet Holding B.V. & Co. KG, Rastatt, Germany) prosthesis was used to replace the ascending aorta.

CO2 was applied to the surgical field to reduce the concentration of nitrogen in the chambers of the heart, and this application was suspended during closure.

Cannulation was the same for the procedures: a 32/40 Fr double-stage venous cannula (Medtronic) was used for the right atrium; an EOPA 3D® (Medtronic) 24 Fr arterial cannula was used for the ascending aorta; a 9 Fr needle (DLP®, Medtronic) was used for cardioplegia and the removal of air; a 20 Fr DLP® cannula was used in the right superior pulmonary vein for the aspiration of blood and air from the ventricle; and 8-9 Fr 135°/90° coronary selective cannule (Medtronic) were used for cardioplegia [(12)].

Right anterior mini-thoracotomy was conducted in isolated Mitral valve repair in minimally invasive approach with central cross clamp (MVR in MICS) was used to repair the mitral valve (Memo 3D Semi-Rigid ring Livanova) the model and size were selected according to the characteristics of the patient; with right femoral artery and vein cannulation through a groin incision and 300 IU/kg of heparin was administered before cannulation.

Under TEE guidance, the tip of the venous cannula 22- 23 Fr (Livanova RAP femoral venous cannula) was placed at the junction of the inferior vena cava and right atrium over a flexible J-wire. Femoral Arterial cannulation was performed using 17-19 Fr (Medtronic Biomedicus arterial femoral cannula).

TEE guidance was routinely used to follow the guidewire during cannulation in order to avoid cannula malposition and vascular traumas such as dissection and rupture [(13)].

ANESTHESIA

The operation was performed under general anesthesia (using propofol, fentanyl, midazolam and rocuronium) using the SedLine® Brain Function Monitoring system (Masimo Corporation, Irvine, CA).

The patient was intubated and anesthetized.
The arterial and venous lines were prepared.

A single-lumen endotracheal tube was used for pulmonary ventilation.

A transesophageal echocardiographic (TEE) probe (iE33, Philips) was inserted to examine the anatomy and morphology of the valves, the cardiac systolic and diastolic performance and the ascending aorta , and to evaluate aortic valve function after corrections and the removal of air , before removal of the cross-clamp.

The adhesive pads of the defibrillator were correctly placed on the thoracic wall.

The patient was positioned on his or her back and an air bag was placed under their right scapula so that their position could be adjusted during the operation for better exposure of the working field, depending on the surgeon's preferences.

The trigger for the administration of RBC units was a hemoglobin level of less than 8 g/dl both during CPB and in the ICU.

For antagonization of heparin, 0.5-0.75 mg protamine was applied for every 100 heparin units [(9)].

The nasopharyngeal and rectal temperatures were monitored (35.5-36.2°C).

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Air embolism was managed through echocardiography-guided TEE; the heart sections were filled, thus obstructing the venous return from the ECC and increasing the cavity diameter, and the lungs were manually expanded by an Ambu® resuscitator (Ambu A/S, Ballerup, Denmark) at a rate of 4 inflations per minute.

CONVENTIONAL PERFUSION TECHNIQUES; FIRST HISTORICAL PERIOD (2014-2016)

Materials: Oxygenator (Inspire® 6F with a biopassive Ph.i.s.i.o phosphorylcholine coating; Admiral Eurosets with a biopassive Agile phoporylcholine coating);

Hardware (Stockert S5, LivaNova; VAVD, Eurosets);

Safety system (Stockert S5, LivaNova;);

Transesophageal echocardiography (iE33, Philips);

Bubble counter (BCC200®, GAMPT)

It was used in isolated aortic valve replacement (AVR) (n=35); AVR + Coronary artery bypass graft (CABG) (n=15); Aortic surgery ± CABG (n=15);

Mitral valve repair in minimally invasive approach (MVR in MICS) (n=35) and isolated CABG (n=50) (**TABLE 3**).

Methods: This circuit takes particular advantage of a VAVD master pump.

Intracavitary aspiration into the venous reservoir is realized with a roller pump, and extra-cavitary aspiration is realized with a roller pump in a second chamber of the reservoir.

The ECC components are slowly filled with 850ml crystalloid solution plus heparin (5000 IU) by using a roller pump.

The prime is heated to 36°C until micro-bubbles are completely eliminated, as evaluated by a bubble counter.

The circuit is horizontal and measures 160cm long and 65cm high, with 220cm aspirating lines between the patient and the device.

The venous drainage line (3/8 inch) and the arterial delivery line (3/8) are each 180cm long, the lines to the pump (3/8 and 1/2) are each 80 cm, and the cardioplegia line (1/16) is 190cm.

The aspiration lines are 1/4. This circuit uses a serial pump with VAVD. The oxygenating module is placed at the height of the patient to reduce the surface length.

Roller pumps are used because aspiration has a management nadir below 800 ml/min.

A negative pressure of -40 mmHg VAVD is applied to the reservoir. The intracavitary aspirator managed with a roller pump is channeled into a venous reservoir, while the extra-cavitary aspirator managed with a roller pump is channeled into a hard-shell reservoir provided with a leukocyte-lipid filter for the removal of fat embolisms from the stirred extra-cavitary blood.

Arterial blood is maintained at 35.5 °C and alpha-stat is used for blood-gas analysis.

The security system uses a level alarm, and a bubble probe is used to detect micro-bubbles leaving the venous reservoir.

Anticoagulant therapy consisted of heparin sodium before CPB at 300 IU/kg to give an ACT of greater than 480 seconds.

Cardioplegia was performed in an antegrade manner with normothermic blood in a 190cm closed circuit with a collapsible bag and a bubble-trap filter by a serial micrometric pump with St. Thomas solution with procaine as described by Durandy repeated every 30 minutes.

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TAB.3 : SURGICAL PROCEDURES AND PERFUSION TECHNIQUES
ECC, EXTRA-CORPOREAL CIRCULATION; MIECC, MINIMALLY INVASI E EXTRA-CORPOREAL CIRCULATION; AVR, AORTIC VALVE REPLACEMENT; CABG CORONARY ARTERY BYPASS GRAFT; MVR, MITRAL VALVE REPAIR; MICS, MINIMALLY INVASIVE CARDIAC SURGERY

	Control Group (n=150)	Study Group (n=150)			
Surgical Procedures	Conventional ECC	Compact ECC	Closed ECC	MiECC	Fibonacci ECC
Isolated AVR	35			18	17
AVR + CABG	15	7		8	
Aortic surgery + CABG	15		7		8
MVR in MICS	35	17			18
Isolated CABG	50		25	25	

TAILOR-MADE PERFUSION TECHNIQUES, SECONDS HISTORICAL PERIODS (2016-2018)

Materials: Oxygenator (Inspire® 6F with a biopassive Ph.i.s.i.o phosphorylcholine coating;

LivaNova PLC, London, UK;

Remowell Eurosets with a biopassive Agile phoporylcholine coating);

Centrifugal Pump (Medtronic Bio-Medicus, Inc., Eden Prairie, MN) and hardware (Stockert S5, LivaNova;

EVADO, Eurosets, Medolla, Italy;

Landing, Eurosets); Safety system (Stockert S5, LivaNova);

Hardshell reservoir for extracavitary suction (RemoweLL, Eurosets);

Transesophageal echocardiography (iE33, Koninklijke Philips)

GOAL-DIRECTED PERFUSION AND THE TYPE OF CPB

The benchmark of management during ECC is oxygen delivery DO2, calculated as

DO2(mL/minute/m2) = 10 × pump flow (L/minute/m2) × arterial O2 content (mL/100 mL) arterial O2 content (mL / 100 mL) = Hb (mg / dL) × 1.34 × Hb saturation (%) + 0.003 × O2 tension (mmHg)

The benchmark value of several studies of AKI is a DO2 lower than 280 ml / min / m2.

Different approaches can be used to achieve this benchmark during the management of CPB.

We believe that refining the technique and selecting the proper components will help to reduce co-morbidities of ECC, including SIRS, POCD, coagulation disorders, transfusion-related acute long injury (TRALI), AKI and distributive alteration of tissue perfusion [(2)].

To increase DO2 / VCO2 (oxygen availability) during CPB, we must achieve certain Hb (g / dl) values, which will depend on the patient's characteristics, particularly on volemia, haemoglobin base, hydration and any co-morbidity (renal, respiratory, or hematopoietic system diseases), the type of ECC

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(contact surface, filling volume of the circuit and liquid type, haemolysis, and retro-priming air-blood contact, and adjustments during CPB (ultrafiltration, use of a diuretic or vasoconstrictors (Norepinephrine, Dopamine) [(6)], and administration of concentrated red cells).

Hb level is an indirect expression of blood viscosity, and thus contributes to maintaining vascular resistance during CPB.

COMPACT EXTRACORPOREAL CIRCULATION

It was used in isolated aortic valve replacement (AVR) (n=0); AVR + Coronary artery bypass graft (CABG) (n=7); Aortic surgery ± CABG (n=0); Mitral valve repair in minimally invasive approach (MVR in MICS) (n=17) and isolated CABG (n=0) (**TABLE 3**).

Compact ECC (cECC) represents an evolution in selecting and maximizing the materials used in ECC. It was developed in 2007 by Borrelli et al. and particularly seeks to improve the coating biocompatibility and reduce the contact surface and hemodilution [(3) (1)] (**FIGURE 5**).

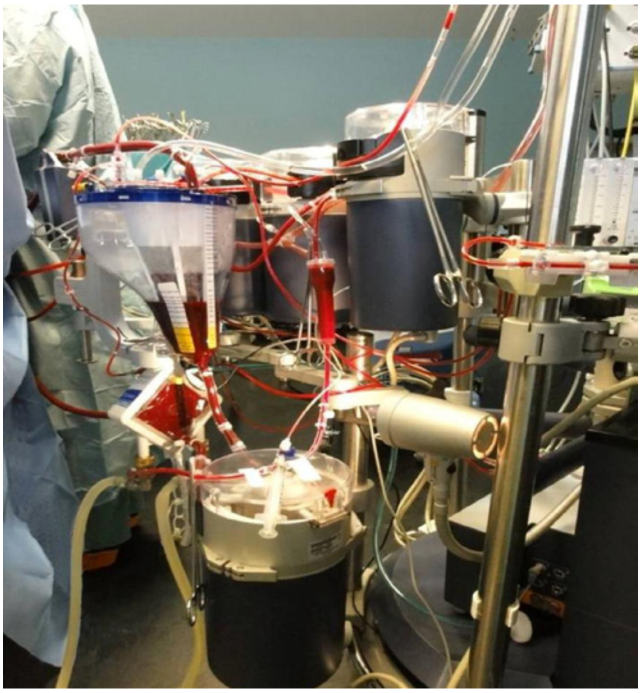
It uses a venous reservoir and an oxygenator module at the patient's shoulder height; venous drainage is ensured through a 3/8-inch line via a low negative pressure (-25 mmHg) with VAVD.

The roller modules are very close to the reservoir, just as the roller pump module is close to the oxygenator, to minimize the length of the tube and reduce filling volumes, eased by retrograde autologous priming (RAP).

This circulation significantly reduces two of the main contributors to SIRS (hemodilution and contact surface), improves metabolic management during CPB. However, there is still some air-blood contact, which is typical of conventional ECC, in addition to a single reservoir for intra-/extra-cavitary aspirators through the use of roller pumps, which leads to stress due to the breakup of red cell as well as the generation of GME.

It is an extremely versatile technique that can be applied to all kinds of heart surgery, has been shown to significantly improve patient outcomes in terms of a reduced need for intensive care, reduced mechanic ventilation, reduced lactate dehydrogenase levels, and reduced administration of blood products.

FIG. 5 - COMPACT ECC BORRELLI MAQUET HOLDER



EXTRACORPOREAL CIRCULATION, CLOSED SYSTEM

It was used in isolated aortic valve replacement (AVR) (n=0); AVR + Coronary artery bypass graft (CABG) (n=0); Aortic surgery ± CABG (n=7); Mitral valve repair in minimally invasive approach (MVR in MICS) (n=0) and isolated CABG (n=25) (**TABLE 3**).

Closed-system ECC aims to minimize air-blood contact, which is a main contributor to SIRS, by eliminating depth filters in the reservoir, making use of a volumetric collapsible bag as a venous reservoir (**FIGURE 3**), which takes advantage of gravitational drainage even though many centers use a centrifugal kinetic pump kinetic-assisted venous drainage in series with the venous line to improve the venous return, and reducing the caliber and length of the

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circuit.

Intracavitary suction is managed by gravitation in-series with the venous return and takes advantage of the venturi effect to reduce the generation and transport of GME, which often limits the management of valvular heart surgery.

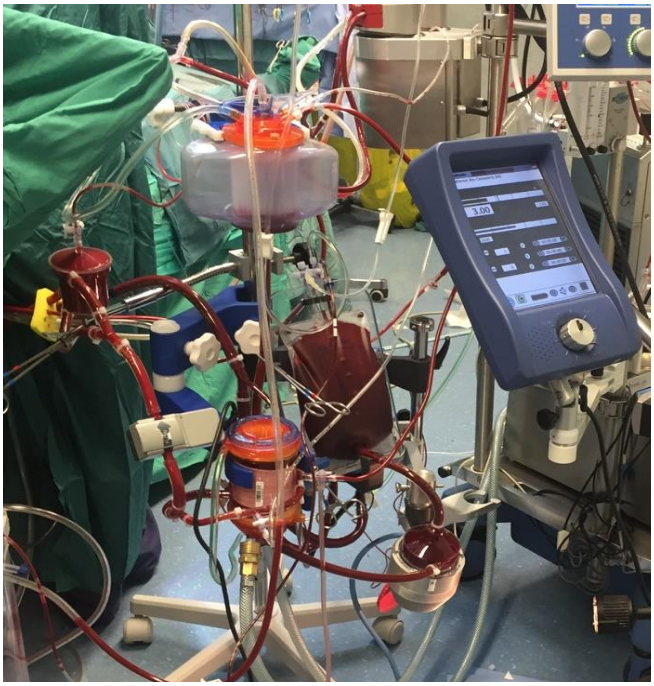
The extra-cavitary aspirator is managed in a container equipped with a filter separated from the volumetric bag, which offers the possibility of processing it or injecting it into the circulation.

A limitation of this technique is the high contact surface which, in hypovolemic patients, is associated with excessive hemodilution, both of which contribute to SIRS.

There is also a procedural limitation of hematic intracavitary evacuation in valvular surgery in patients who have developed collateral pulmonary circulation.

The features of the safety systems and the oxygenator module in the coating and cardioplegia circuit are specific to conventional ECC.

FIG. 3 - CLOSED ECC ,(EUROSETS CLOSED)



MINIMAL INVASIVE EXTRA-CORPOREAL CIRCULATION

It was used in isolated aortic valve replacement (AVR) (n=18); AVR + Coronary artery bypass graft (CABG) (n=8);
Aortic surgery ± CABG (n=); Mitral valve repair in minimally invasive approach (MVR in MICS) (n=0) and isolated CABG (n=25) (**TABLE 3**).

Minimal invasive ECC (MiECC) was proposed in a position paper from MiECTiS (Minimal invasive Extracorporeal Technologies International Society) and is based on the potential advantages of a reduction in biological invasiveness (**FIGURE 4**). [7]

A Type 3 circuit, which is the most flexible in terms of volume management, consists of a venous line and intracavitary aspirators linked to a venous bubble trap, a centrifugal pump and an oxygenator, with a line dedicated to cardioplegia and an arterial line.

The volume is actively managed in a post-oxygenator volumetric bag and then returned to the venous line.

This methodology addresses several of the factors that contribute to SIRS: it reduces the contact surface, eliminates air-blood contact, reduces hemodilution, and does not use roller pumps for the aspirators.

The intracavitary blood is strictly selected and processed; this implies improved metabolic management and more physiologic perfusion during CPB. MiECC reduces the generation and transport of GME that is seen in conventional ECC [5], especially in the cerebrovascular system. This is associated with considerable benefits in terms of the patient's outcome, including cognitive function, incidence of acute kidney injury (AKI) and atrial fibrillation (AF), reduction of bleeding, mechanic ventilation, ICU stay, and quality of life after coronary aortic bypass, especially in patients at high risk.

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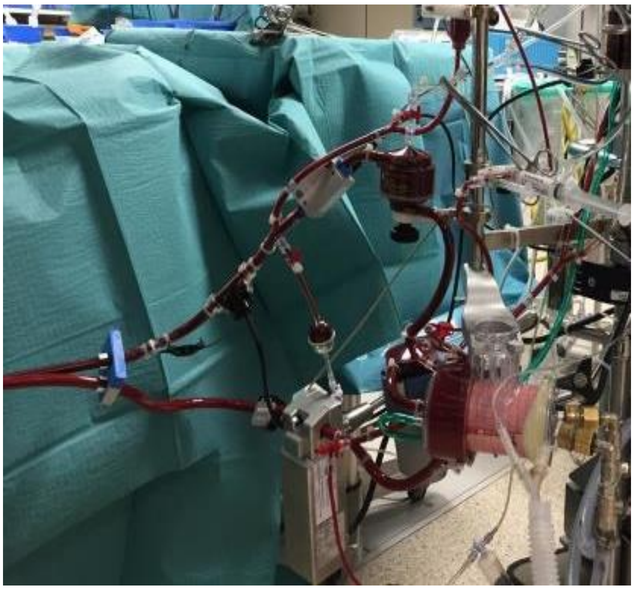
FIG. 4 - MIECC TYPE III, (INSPIRE MIN.I. 6 F LIVANOVA)



FIBONACCI ECC

It was used in isolated aortic valve replacement (AVR) (n=17); AVR + Coronary artery bypass graft (CABG) (n=0);
Aortic surgery ± CABG (n=8); Mitral valve repair in minimally invasive approach (MVR in MICS) (n=18) and isolated CABG (n=0) (**TABLE 3**).

This circuit includes a serial impeller pump along with vacuum-assisted venous drainage (VAVD) for intracavitary aspiration into a venous reservoir and a further VAVD for another hard-shell reservoir (**FIGURE 6**) [4].

The circuit is filled by passive gravitational filling, with the administration of 25 ml of CO2 into the oxygenator for each liter of flow by the pump.

Prime is maintained at 28°C until no micro-bubbles are observed in the bubble counter .

The Fibonacci system (Condello) is about 160 cm high, including the board: the disposable device is 100 cm high, with 120 cm lines to the patient and pump lines of 45 cm (diameters: venous line 3/8, arterial line 3/8, propeller line 3/8, aspiration line 1/4, cardioplegia line 1/16)[6] . The system aims to reduce the contact surface to make the ECC have less of an inflammatory and traumatizing effect on blood components.

Dynamic filling (610 ml) is realized with crystalloid solution and 5000 IU of heparin sodium.

The input and output lines of the circuit are shaped like the Fibonacci Golden Spiral to minimize the transport of GME from the surgical field to the ECC, particularly for the intracavitary aspiration lines, which are managed within the field to reduce turbulence and the creation of GME. Roller pumps are not used for the aspiration lines.

Instead, a maximum negative pressure of -35 mmHg is used in the venous reservoir for intracavitary aspiration and venous drainage, and a negative pressure of -25 mmHg is used in the hard-shell reservoir, which has a leukocyte filter to eliminate fat embolisms and is located 60 cm higher than the venous reservoir for the aspiration of extra-cavitary blood that has been stirred.

Negative pressure of the impeller pump during surgery must not be above -65 mmHg.

These conditions give less turbulence along with a reduction in the creation and transport of GME by echography and a bubble counter.
Our patients, arterial blood was maintained at 35.6 °C and alpha-stat was used for blood-gas analysis. Metabolic parameters were monitored with a DO2 system; the nadir was higher than 278 ml/min/m2.

Security system used was an auto-clamp Stockert S5 (LivaNova) on the exit line of the impeller pump that activated in the case of backflow to avoid the transmigration of bubbles from the oxygenator as a result of VAVD, which never occurred during the procedure.

The probe for detecting micro-bubbles was placed on the exit line of the venous reservoir. The average pressure was maintained above 60 mmHg without

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the aid of vasoconstricting drugs, but rather by exploiting the patient's position (Trendelenburg vs. anti-Trendelenburg).

Anticoagulant therapy consisted of heparin sodium before CPB at 300 IU/kg to give an activated clotting time (ACT) of greater than 480 seconds. Cardioplegia was performed in an antegrade manner with normothermic blood in a 120cm closed circuit with a bubble-trap filter by a serial micrometric pump with St. Thomas solution with procaine as described by Durandy, repeated every 30 minutes [8].

Statistical Analysis

Student's t-test was used to compare continuous variables between groups. A p value of <0.05 was considered significant.

FIG. 6 - FIBONACCI ECC CONDELLO (INSPIRE 6 F LIVANOVA)

RESULTS

A statistically significant difference was reported, among the study group that used cardiopulmonary bypass (CPB) tailormade technique Vs the control group that used conventional (CPB) , in terms of consumption of blood products in operating room and intensive care units 35% less in the study group (110 units group control vs 73 units group of study), p-value (0.035);

reduction in the incidence of acute kidney injury 15% less in the study group (p-value (0.046) (**FIGURE 1**) ;

39% reduction time of stay in intensive care unit for the study group (15.9 h) vs. control group (27.2 h) p-value (0.037) (**FIGURE 2**);

an improvement in reduction of markers for myocardial ischemia TnT ng/L (24 h) in the study group vs. control group p-value (0.041) ;

The rates of major and minor postoperative morbidity were comparable between the groups, except for agitation upon discontinuation of anesthesia (1 patient in the study group vs. 9 in the control group, p=0.004), and postoperative delirium (0 vs. 12 patients; p=0.005).

This increased POCD was also associated with a longer ICU stay (17.9 vs. 41.7 hours, p=0.039);

no adverse events (accidents) were recorded in the two groups during CPBs procedures.

The adjustments during CPB for:

ultrafiltration (3 study vs 36 control), use of a diuretic Lasix 5 mg (3 patients study vs 28 patient control) and liquids administration mean value for each procedure during of liquids balance during cardiac surgery procedure (700 ml study vs 2100 ml control).

FIG. 1 - ACUTE KIDNEY INCIDENCE

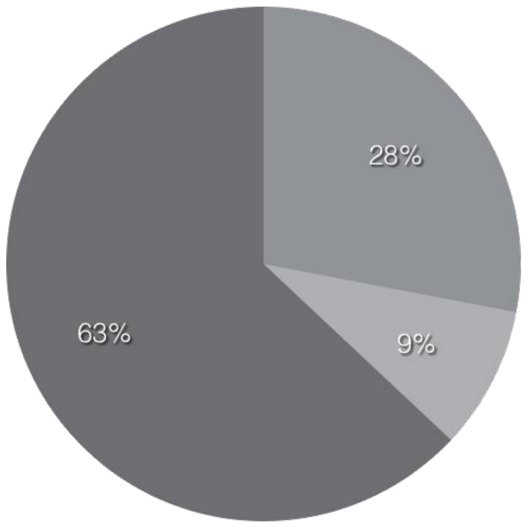

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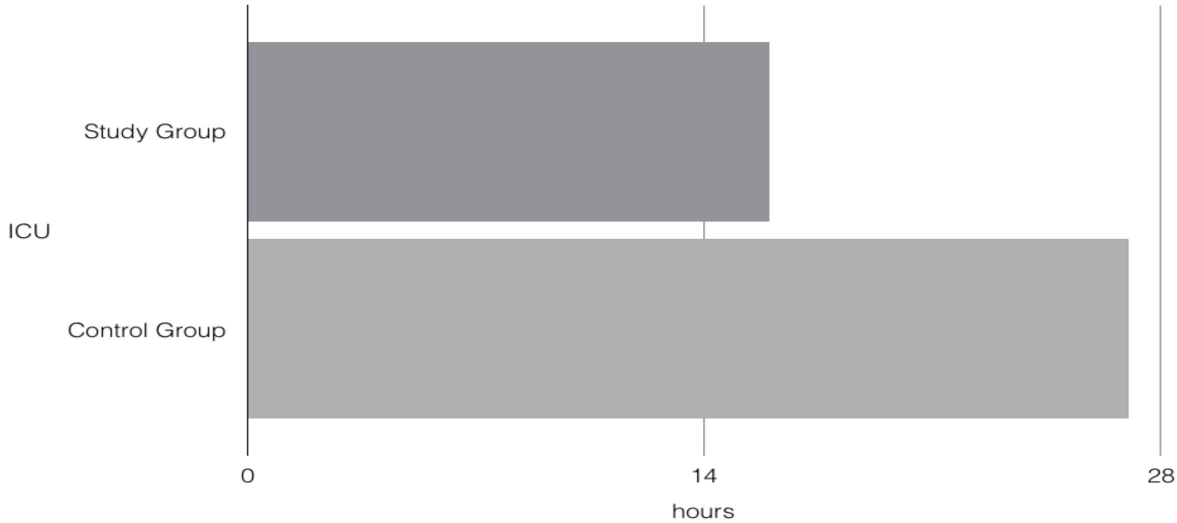
FIG. 2 - MEAN VALUE OF STAY IN INTENSIVE CARE UNIT (ICU)



DISCUSSION

In recent years, there has been a great development in technologies and monitoring tools, effective reference nadirs have been developed supported by studies and literature as the delivery value of O2 (DO2i) <280ml / min / m2 is been associated as a predictive value of renal insufficiency.

This value has matured in our experience, a different approach on the way to reach these nadirs or reducing the corrective factors during the conduct, (administration of liquids and blood derivatives, use of ultrafiltration, use of diuretics, and vasoconstrictors)[(11)] working through a selection of materials and techniques on (CPB), through different extracorporeal circulation techniques, less hemolytic, low surface, low hemodilution[(10)], low blood-air contact and low micro-embolic activity (GME) [(5)].

The tailor-made approach involves a knowledge of the pathophysiology and a shared working method; The main limitations of this study are: 1 only selected patients were chosen mainly with a low risk of mortality.

CONCLUSION

The tailor-made CPB approach showed in this retrospective analysis a better outcome in the patient candidate for cardiac surgery with statistically significant values for incidence of time of stay in intensive care units, consumption of blood products, myocardial suffering marker, incidence POCD, and AKI.

However, this technique needs larger samples and the treatments of more fragile patients to have more evidence.

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