Evaluation of extracorporeal membrane oxygenation application in marginal heart transplantation

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【Abstract】 Objective To review the efficacy and clinical outcomes of extracorporeal membrane oxygenation (ECMO) used for donor hearts with long cold ischemic times (LCIT) during heart transplantation. Methods From February 2005 to April 2009, 11 patients were received allografts with LCIT over 7 hours underwent both intraoperative ECMO circuit treatment and ECMO support postoperation (i-ECMO group). Another 11 patients with ischemia time of heart grafts less than seven hours were received postoperation ECMO support as a salvage therapy after perioperative standard cardiopulmonary bypass CPB (s-CPB group). Rate of weaning ECMO, length of ICU stay, volume of packed red blood cell (PRBC) transfusion, left ventricular ejection fraction (LVEF), cost of hospitalization, rate of perioperative survival and rate of 1-year postoperative survival were compared between the two groups. ECMO-related complications were observed. Results There was a significant difference in cold ischemic time between the two groups ($P<0.01$), with cold ischemic time ranging from 422 to 485 minutes (mean 448 minutes) in i-ECMO group while 110 to 400 minutes (mean 218 minutes) in s-CPB group. Ten patients (91%) in i-ECMO group were weaned off ECMO and all survived to discharge. Only a patient in this group died of massive intraoperative bleeding (not ECMO-related). Rate of weaning ECMO in the s-CPB group was 82% (9/11). The overall weaning rate of ECMO application during heart transplantation was 86%. The overall 30-day and 1-year survival rates for i-ECMO and s-CPB groups were 91% and 82%, 73% and 64%, respectively. There was no difference in mortality between the two groups ($P>0.05$). Compared with s-CPB group, the length of stay in ICU, the requirement for PRBC administration and the total in-hospital cost were significantly reduced in the i-ECMO group ($P<0.05$). The preoperative and postoperative LVEF of i-ECMO and s-CPB groups were 0.23±0.06 and 0.25±0.10, 0.65±0.12 and 0.66±0.06, respectively. LVEF of both groups significantly improved after operation. An intra-aortic balloon pump (IABP) was applied due to low cardiac output in 5 patients (23%), among them 3 patients weaned from ECMO except another two patients. Among 6 patients (27%) who required continuous renal repacement therapy (CRRT) due to renal dysfunction, 2 were weaned from ECMO and 4 could not be weaned. Conclusions Application of ECMO in postoperative period provides early, continued and effective support for donor hearts with LCIT and efficiently makes use of such marginal organs. Reduced length of ICU stay, reduced transfusion volume of PRBC and reduced in-hospital cost are additional advantages of this technique.

【Key words】 Heart transplantation; Marginal donor; Extracorporeal membrane oxygenation; Cardiopulmonary bypass

The critical shortage of donor grafts urges transplantation surgeons to use suboptimal or so-called marginal hearts with cold ischemic time (CIT) over conventional limits[1]. Donor hearts with long cold ischemic times (LCIT) are associated with higher rates of perioperative acute graft failure (PAGF) —— a major cause of mortality within the first 30 days after transplantation[2-4].

Use of mechanical circulatory support (MCS) is the ultimate choice for PAGF if any other medical treatment failed. In the present study, we report our cumulative experience with the use of extracorporeal mem-

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braneoxygenation (ECMO) in the adult heart transplantation (HTx). Furthermore, in order to improve outcomes of donor hearts with LCIT, we evaluate the efficacy of a strategy based on both intraoperative extracorporeal membrane oxygenation (i-ECMO) circuit and postoperative ECMO cardiopulmonary support.

Methods

Patients

From February 2005 to April 2009 a total of 122 HTx were performed in our department, among which ECMO was utilized in 22 patients (18%). Transplant recipients included 17 males and 5 females, with age of (48±9) years (range from 29 to 70 years). All patients were diagnosed as class III/IV according to New York Heart Association (NYHA) assessment criteria preoperatively. Informed consent has been obtained for all the patients before operation. This study was approved by a research ethics committee or institutional review board.

Data were retrospectively collected from the department's ECMO forms. Indications for HTx included dilated cardiomyopathy (DCM) in 18 patients (82%), valvular cardiomyopathy (VCM) in 2 patients (9%) and ischemic cardiomyopathy (ICM) in 2 patients (9%). Bicaval orthoppic heart transplantations were performed in all the patients. A triple immunosuppression regimen was used after HTx including ciclosporin (CsA), mycophenolate mofetil (MMF) and prednisone. All patients received interleukin-2 (IL-2) receptor blocker (basiliximab) as immunosuppressive induction.

Study groups

Eleven patients receiving donor hearts with CIT over 7 hours underwent i-ECMO support (i-ECMO group). i-ECMO circuit for this group specifically was set up for convenient conversion to postoperative ECMO support (described below). Standard cardiopulmonary bypass group (s-CPB group) consisted of 11 contemporary HTx patients who either were not able to wean off CPB or underwent femoral veno-arterial ECMO ICU as a salvage therapy. The indications for postoperative ECMO in these patients are as follows: systolic blood pressure less than 80 mmHg (10 mmHg=1.33 kPa), poor myocardial contractility diagnosed by transthoracic echocardiography (ECHO), central venous pressure over 26 7 mmH_2O, urinary output less than 0.5 ml·kg^{-1}·h^{-1} and failure to wean off CPB.

Set-up of i-ECMO circuit and subsequent conversion into postoperative ECMO

The circuit was based on a centrifugal bpod pump (CB4649, Medtronic Inc USA), heparin-coated tubes (CB2994, Medtronic Inc USA) and cardiotomy reservoir with integrated membrane oxygenator and heat exchanger (541T, Medtronic, Inc USA). The arterial return cannula was inserted directly into the ascending aorta and used until the removal of the aortic cross-clamp during the cardiac arrest. Venous drainage from the inferior vena cava (IVC) was achieved with a 19 F or 21 F cannula (CB96560, Medtronic Inc USA) inserted directly into the femoral vein with placement of the tip just proximal to the right atrium. The second venous drainage was performed with cannula inserted into the superior vena cava (SVC). The femoral artery was also surgically exposed and preserved during a cutdown of femoral vein for the later cannulation. Except the ordinary non-heparin coated SVC cannula, both the aortic artery and IVC cannulas were heparin-coated. A cardiotomy reservoir was inserted in the venous line and the hemofilter was placed in the arterial line. Establishing such a circuit patients in i-ECMO group were allowed implementation of cardiotomy suction and immediate return of the lost fully heparinized chest cavity blood into the reservoir.

At the end of operation the conventional ECMO support was created using the following procedures: the arterial cannula was transferred into femoral arterial cannulation via the prior cutdown of femoral artery and the cardiotomy reservoir with its lines and hemofilter was removed. Femoral vein cannulation remained intact and was connected to the venous line. Chest was closed and patients were transferred to ICU wards with

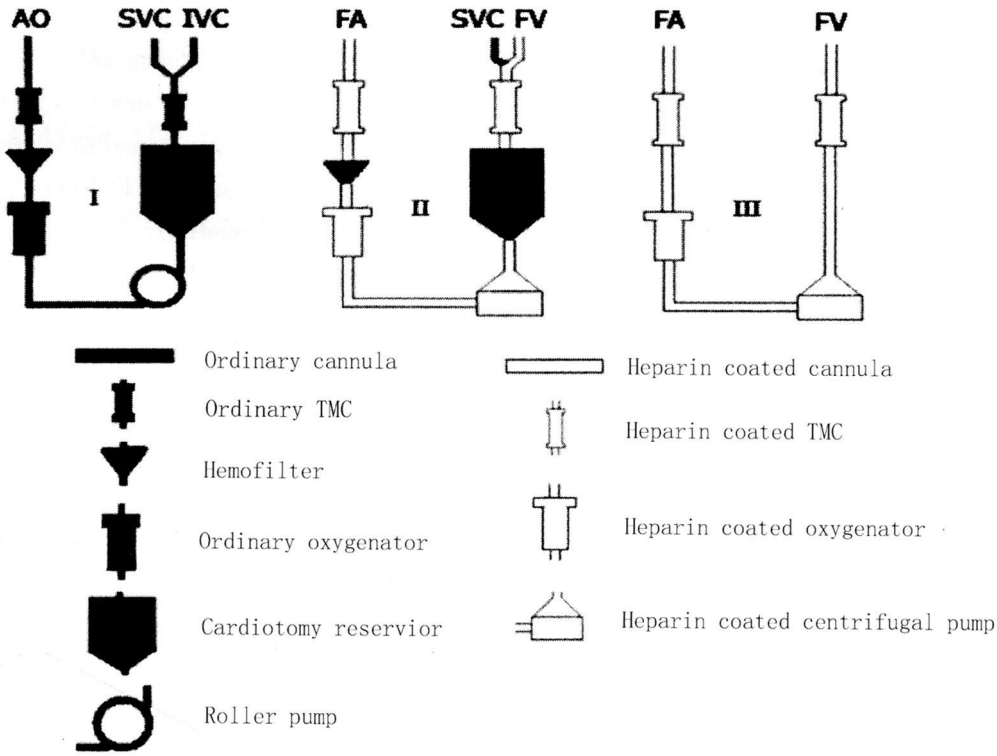

Figure 1 A schematic illustration of the standard CPB circuit, i-ECMO circuit and its subsequent conversion into postoperative ECMO

Legends: I: standard CPB; II: i-ECMO; III: conversion from i-ECMO into postoperative ECMO (discarded hemofilter and cardiotomy reservoir); AO: aorta; SVC: superior vena cava; IVC: inferior vena cava; FA: femoral artery; FV: femoral vein; TMC: trioptic measurement cell

Management of ECMO and weaning

Ventilator settings were reduced to minimum. Minimal inotropic support (dopamine 5 mg·kg^{-1}·min^{-1}) was continued during ECMO support to maintain left ventricular ejection against increased afterload and to prevent overdistension. A distal cannula for optimization of lower limb was used if early signs of ischemia were observed. Intravenous heparin was administered continuously to maintain an activated clotting time of 180 to 220 seconds. Patients were weaned from ECMO support once they were hemodynamically stable on minimal ECMO flow (5 ml·kg^{-1}·min^{-1}) with good recovery of myocardial contractility as monitored by ECHO.

Observation item

Rate of weaning ECMO, length of ICU stay, volume of packed red blood cell (PRBC) transfusion, left ventricular ejection fraction (LVEF), cost of hospitalization, rate of perioperative survival and rate of the two groups. ECMO-related complications were observed.

Statistical analysis

Statistical analyses were performed by SPSS 12.0 for Windows. Descriptive statistics were used to analyze the patients' courses and clinical outcomes. Continuous variables were expressed as mean ± SD and were evaluated by Student's *t* or the Wilcoxon rank sum tests. Categorical variables are expressed as percentages and were evaluated with the χ^2 or Fisher's exact test. $P<0.05$ was considered statistically significant in all analyses.

Results

General patient's data and two groups outcomes

No differences were observed between the two groups in donor gender (male 73% vs 82%), age and the cause of death. Mean age of donor in both groups was (32 ± 2) years. There was a significant

with CIT ranging from 422 to 485 minutes (mean 448 minutes) in i-ECMO group while 110 to 400 minutes (mean 218 minutes) in s-CPB group. Although patients in i-ECMO showed a lower LVEF and a higher pulmonary arterial pressure (PAP), no significant difference was observed (Table 1).

Table 1 Comparisons of demographic data and preoperative characteristics between two groups ($\bar{x}\pm s$)

Data	i-ECMO (n=11)	s-CPB (n=11)	P value
Weight (kg)	70±16	71±17	>0.05
LVEF	0.23±0.06	0.25±0.10	>0.05
PAP (mmHg)	55±9	49±17	>0.05
NYHA status	3.6±0.5	3.3±0.5	>0.05
Total bilirubin (μmol/L)	26±10	27±9	>0.05
Serum creatinine (μmol/L)	96±22	75±45	>0.05
CIT (min)	448±24	218±81	<0.01

Ten out of 11 patients (91%) in i-ECMO group weaned off ECMO and all survived to discharge. The cause of the only death in this group was not associated with ECMO support, but with massive intraoperative bleeding (Table 2). In s-CPB group, 11 patients required ECMO after the surgery, including 5 patients (46%) in whom ECMO was initiated in the condition that the patients were unable to wean from CPB. The interval from cessation of CPB to starting ECMO was range 0 to 35 hours (mean 11 hours). Weaning off ECMO was successful in 9 patients (82%) and 8 patients (73%) survived to hospital discharge. Two patients died during the ECMO support, one due to liver failure and the other due to cardiac failure. The third patients died of overwhelming sepsis 10 days after the weaning.

Intraoperative and postoperative status

Although CPB times, ventilation times and length of postoperative ECMO support were shorter in i-ECMO patients, no significant difference was observed. Postoperative outcomes of patients were shown in Table 3.

Overall weaning rate was 86% (19/22) and survival to hospital discharge was 82% (18/22). The 30-day and 1-year survival for i-ECMO group and s-CPB group patients were 91% vs 73% and 82% vs 64% respectively with no significant difference (all in P>0.05). Overall 16 patients (73%) were in NYHA status I or II without any ECMO related complications at 1-year follow up, except two cases of death.

Complications

An intra-aortic balloon pump (IABP) was applied due to low cardiac output in 5 patients (23%),

Table 2 i-ECMO group data in HTx patients

Case	Gender	Age (y)	CIT (min)	Diagnosis	LVEF	PAP (mmHg)	Post HTx stay (d)	Outcome
1	M	44	480	DCM	0.15	60	15	Wean, survive
2	F	49	425	VCM	0.23	50	1	Death (intraoperative bleeding)
3	M	41	482	DCM	0.22	55	26	Wean, survive
4	F	38	433	DCM	0.30	62	22	Wean, survive
5	M	55	441	DCM	0.20	67	24	Wean, survive
6	M	45	455	DCM	0.17	62	29	Wean, survive
7	M	49	435	DCM	0.24	62	22	Wean, survive
8	M	49	424	DCM	0.33	37	43	Wean, survive
9	M	57	485	DCM	0.18	43	27	Wean, survive
10	F	70	450	DCM	0.21	52	20	Wean, survive
11	M	29	422	DCM	0.27	52	25	Wean, survive

Table 3 Comparisons of postoperative outcomes between two groups ($\bar{x}\pm s$)

Data	i-ECMO (n=11)	s-CPB (n=11)	P value
Aortic cross-clamp duration(min)	94±14	92±27	>0.05
i-ECMO/CPB duration (min)	140±26	158±42	>0.05
Ventilation duration(h)	25±12	47±17	>0.05
Length of ECMO support (h)	44±12	62±17	>0.05
Length of ICU stay(h)	53±17	142±33	>0.05
Total transfusion of PRBC(U)	13±6	32±12	<0.05
Postoperative hospital stay(d)	23.1±10.1	27.4±12.1	>0.05
Interval from CPB to ECMO(h)	—	9.8±3.3	<0.05
LVEF at hospital discharge	0.65±0.12	0.66±0.06	>0.05
Total in-hospital cost (USD)	26 079±5 547	40 436±16 673	<0.05

among them 3 patients weaned from ECMO except another two patients. Among 6 patients (27%) who required continuous renal replacement therapy (CRRT) due to renal dysfunction, 2 (33%) were weaned from ECMO and 4 could not be weaned.

Discussion

PAGF is the main cause of mortality associated with HTx within the first 30 days[5,6]. Major causes which contribute to PAGF are primary graft dysfunction (PGD), right ventricular failure (RVF) secondary to pulmonary hypertension (PH) and severe acute or hyperacute rejection. PGD is severe and poorly understood complication generally related to donor age, poor quality of the organ, weight mismatch and prolonged ischemic time.

For treatment of PAGF, it is critical to implement early MCS to avoid potentially irreversible graft injury. Although right ventricular assist device (RVAD) seems to have the most widespread use in the literature, the results of RVAD are still poor. Noon and associates[7,8] reported the use of RVAD in 17 and 7 patients with cardiac allograft failure with a mortality of 85% and 100%, respectively. Ihrkin et al[9] also were supported by either left ventricular assist device (LVAD) or RVAD died.

Other researchers speculated that PAGF was commonly associated with biventricular dysfunction, and thus was good candidate for ECMO support[10]. Taghavi et al[11] found ECMO to be superior to RVAD after HTx. Results of their retrospective study comparing RVAD with ECMO showed only 13% RVAD patients weaned compared with 77% ECMO patients weaned. Another study by Chou et al[12] also demonstrated better results in the ECMO-treated group. Based on these studies and due to capability to provide biventricular and pulmonary support, ECMO was highly recommended as first line choice for patients with PAGF.

Since 2005, we extended ECMO use to the patients with HTx and observed favorable clinical prognosis. In the present study eleven patients were treated with ECMO after transplatation. Eight (73%) patients survived to hospital discharge, and the 1-year survival was 64%.

In an attempt to expand the donor pool, donor hearts from more remote areas were also accepted now, which inevitably extends ischemic times. Multicenter studies had shown that LCIT had a negative effect on early survival and it was also emphasized by the international society for heart and lung transplantation (ISHLT) registry which identified ischemic time as an important cause of in-hospital and 1-year mortality in HTx[13,14]. The use of allograft with ischemic times greater than 4 to 5 hours was reported to be associated with a requirement of higher inotropic support within the first 48 h, reduced LVEF and right ventricular function, prolonged hospital stay, increased incidence of PGD and higher morbidity and mortality[15-17]. Recipients often developped hypotension and hemodynamic indices were usually marginal at the first week after operation.

Eleven recipients received cardiac allpgrafts transplantation with grafts ischemic time over 7 hours due to long-distance procurement. Importantly, the recipients had also moderate to high PH. Since subsequent need for ECMO in this group was expected, an i-ECMO cir-

MO support was routinely extended into postoperative period. Despite i-ECMO group patients had a considerable number of preoperative risk factors and significant LCIT, no increase of 30-day mortality in these patients was observed compared to overall survival reported in HTx.

The timing of initiation of ECMO before circulatory collapse is critically important to avoid organ injury and it is most difficult to determine the suitable time for setting up an ECMO support for high risk patients. Minev et al[18] reported 80% mortality in all transplant subgroups, including those with PGD, right heart failure and acute rejection. The authors suggested that at the time of initiation of support these patients were generally in a disastrous condition, and that there was no time to adapt to the hemodynamic deterioration. Our experience over the years is to make use of ECMO support as we opposed to waiting until the patient develops PAGF. ECMO provides a means of supporting the grafts function in these patients during a critical period and allows the freshly transplanted heart to work under less stressful conditions.

It may also be true that the recipients of donors with LCIT combined with high preoperative PH may not required ECMO. However, patients in i-ECMO group had a significantly shorter length of stay in ICU, reduced requirement for PRBC administration and lower total in-hospital cost compared with the patients who required ECMO as a salvage therapy. Reduced cost and rapid recovery was achieved by extending ECMO in the postoperative period in this group, while s-CPB group patients required additional cost for ECMO support.

Patients with PH requiring intensive posttransplant management are at significant high risk of acute RVF[19, 20]. Salzberg and colleagues[21] studied the role of LVAD support as bridge to HTx in a subset of patients with PH and high pulmonary vascular resistance (PVR). A period of LVAD as bridge to HTx led to normalization of pulmonary pressures and made these patients amenable for HTx. However, the expensive aim of our present study was to avoid posttransplant RVF by providing immediate support for the transplanted heart and providing time for adaptation of right ventricle (RV). The effect of ECMO includes maximizing coronary perfusion through maintenance of aortic pressure, reducing preload to a distended and ischemic RV, decreasing RV afterload, optimizing myocardial oxygen delivery and limiting ventricular oxygen consumption.

Converting an opened i-ECMO circuit to a closed postoperative ECMO support in the operating theatre has many advantages. Firstly, it minimizes the patient's exposure to new circuit. Secondly, continuous support for grafts with LCIT improves hemodynamic stability following the transplantation. Thirdly, establishing ECMO in theatre rather than in ICU may reduce the incidence of infections. Lastly, this strategy is money saving and reduces the overall in-hospital cost. Other studies also reported the initiation of ECMO outside the theatre was significantly associated with poor outcome[22, 23].

The major limitation of our study was the lack of proper control LCIT group with standard care which would ultimately answer the question of whether or not i-ECMO accounted for improved outcomes in these marginal donors. However, this study was a useful attempt to improve the outcome of marginal donor hearts by utilizing i-ECMO strategy.

In conclusion, our results suggested that the implementation of i-ECMO circuit which can be transformed into a simple, safe and effective postoperative ECMO support had a beneficial effect on cardiac allograft with LCIT compared with s-CPB. It is recommendable to use i-ECMO in patients with high PH or receiving marginal donor hearts for promoting the postoperative functional adaptation of the graft and avoiding PAGF and RVF. Additional advantages of this technique include shorter exposure time to additional blood products or surface area in the priming of a new extracorporeal circuit, hemodynamic stability and cost re-

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体外膜肺氧合在边缘供心移植中的临床应用研究

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【摘要】 目的 探讨体外膜肺氧合 (extracorporeal membrane oxygenation, ECMO) 用于长时间冷缺血 (long cold ischemic time, LCIT) 供心心脏移植术的临床疗效。方法 2005年 2月至 2009年 4月, 11例患者 [ECMO环路 (intraoperative ECMO, i-ECMO) 组] 接受 LCIT超过 7 h的供心移植, 手术采用 i-ECMO进行心肺分流术, 术毕直接转为 ECMO辅助。同期有 11例患者 [心肺分流术 (standard cardiopulmonary bypass, s-CPB) 组, s-CPB组] 行冷缺血少于 7 h的心脏移植手术, 术中常规 s-CPB, 术后接受了 ECMO辅助。比较两组的 ECMO的总体撤机率、 ICU停留时间、浓缩红细胞输注量、左心室射血分数 (LVEF)、住院费用、围手术期生存率、术后 1年生存率, 并了解 ECMO相关并发症。结果 i-ECMO组和 s-CPB组供心缺血时间分别为 422~485 (平均 448) min, 110~400 (平均 218) min, 两组间比较差异有统计学意义 (P<0.01)。 i-ECMO组中 10例患者 (91%) 成功撤离 ECMO并无出院前死亡, 1例死于术中大出血 (与 ECMO无关), s-CPB组中 9例 (82%) 成功撤离 ECMO。心脏移植应用 ECMO的总体撤机率为 86%。两组术后 30 d (围手术期) 和术后 1年的生存率分别为 91%和 82%、 73%和 64%, 两组比较差异均无统计学意义 (P>0.05)。 i-ECMO组的 ICU停留时间、浓缩红细胞输注量以及住院花费均显著低于对 s-CPB组 (均为 P<0.05)。 i-ECMO组的入院和出院 LVEF分别为 0.23±0.06, 0.65±0.12; s-CPB组相应为 0.25±0.10, 0.66±0.06, 两组出院时 LVEF均较术前明显升高, 但两组比较差异无统计学意义 (P>0.05)。 ECMO相关并发症及处理: 5例患者 (23%) 因低心排量而应用了主动脉内球囊反搏 (IABP), 其中 3例为成功撤离 ECMO的病人, 2例为未能撤离 ECMO者; 6例 (27%) 患者由于肾功能不全接受了持续肾替代治疗 (CRRT), 其中 2例为成功撤离 ECMO, 4例为未能撤离 ECMO者。结论 用边缘供心进行心脏移植术时, 术中利用 i-ECMO, 术毕转为 ECMO辅助可以为 LCIT的供心提供早期、持续和有效的循环支持, 从而在相当程度上改善此类边缘供心的移植成功率。同时, 该研究方法还具有 ICU停留时间短, 浓缩红细胞输注量低和显著节省费用的优点。

【关键词】 心脏移植; 边缘供体; 体外膜肺氧合; 心肺分流术

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