

Actualités sur les machines de perfusion cardiaque



*Erwan Flécher, CHU Pontchaillou, Rennes
Ouest Transplant, Orléans, 15 novembre 2019.*

Déroulement de la Transplantation

- ☛ Appel
- ☛ Acceptation du greffon: critères
- ☛ Organisation de la greffe:
plusieurs équipes à coordonner,
horaires, transports
- ☛ Prélèvement cardiaque: excision
du cœur, évaluation à thorax
ouvert++, transport dans liquide
conservation réfrigéré
- ☛ Transplantation



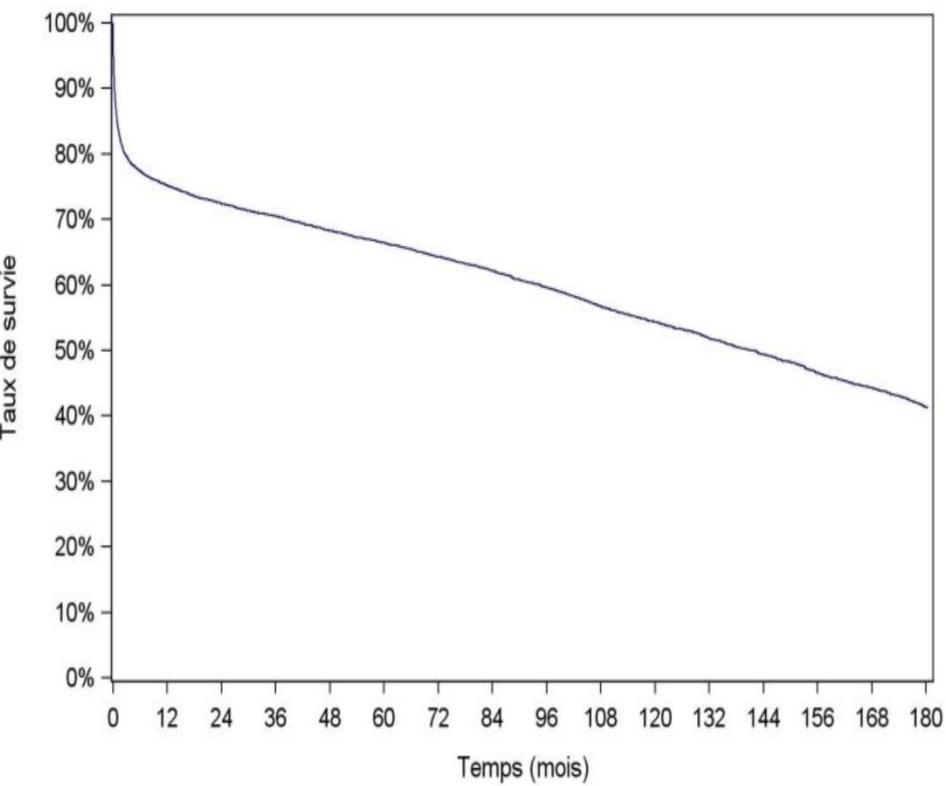








Survie après 1^{ère} greffe en France



Une survie (1 an) en amélioration:

2013-2016: 79%

2009-2012: 77%

2005-2008: 72%



Une population grave!

2017: 53% sous inotropes, 23% sous ECMO, 11% intubés, 25% créat > 120, 16% bili > 35.

Période de greffe	N	Survie à 1 mois	Survie à 1 an	Survie à 5 ans	Survie à 10 ans	Survie à 15 ans	Médiane de survie (mois)
1993-juin 2016	8642	84,6% [83,8% - 85,4%]	75,2% [74,3% - 76,1%]	66,4% [65,4% - 67,5%]	54,3% [53,2% - 55,5%]	41,3% [40,0% - 42,7%]	141,2% [135,4% - 147,1%]
nombre de sujets à risque*		7273	6367	4492	2648	1307	

Gold standard

- ☞ Froid (4°C)
- ☞ Liquide préservation
- ☞ Economique (très)
- ☞ Bons résultats
- ☞ Historique



PARAGONIX®

Advancing Organ Preservation

What Else?



Innovative cold storage of donor organs using the Paragonix Sherpa Pak™ devices

S.G. Michel^{1,2}, G.M. LaMuraglia II¹, M.L.L Madariaga¹, Lisa M. Anderson^{3,4}¹Transplantation Biology Research Center, Department of Surgery, Massachusetts General Hospital and Harvard Medical School, Boston, MA, USA; ²Department of Cardiac Surgery, Ludwig-Maximilians-University, Munich, Germany;³Paragonix Technologies, Inc., Braintree, MA, USA; ⁴Corresponding author: Lisa M. Anderson

Testing Conditions	
Temperature profile	“Hot” run: 1h @ 22°C, 1h @ 31°C, 15h @ 22°C, 1h @ 31°C, then 22°C until 30h “Cold” run: 1h @ 22°C, 1h @ -8°C, 15h @ 22°C, 1h @ -8°C, then 22°C until 30h

Individual Test Run Data

	Wetted probe				
Run#1	“Hot” Run #1	24 h	26 h	28 h	30 h
Sample Size		8641	9361	10081	10801
Range (°C)		4.2-5.7	4.2-5.9	4.2-6.5	4.2-7.2
Mean ± St. dev.		4.65±0.41	4.74±0.49	4.84±0.60	4.97±0.77
Run#2	“Hot” Run #2				
Sample Size		2881	121	3361	3601
Range (°C)		6.6-7.5	6.6-8.0	6.6-8.6	6.6-9.2
Mean ± St. dev.		6.96±0.29	7.02±0.35	7.11±0.47	7.23±0.64
Run#3	“Cold” Run #1				
Sample Size		8641	9361	10081	10801
Range (°C)		4.6-6.2	4.6-6.6	4.6-7.2	4.6-7.8
Mean ± St. dev.		5.53±0.33	5.59±0.39	5.68±0.50	5.80±0.66
	“Cold” Run #2				
Sample Size		2881	3121	3361	3601
Range (°C)		4.6-6.7	4.6-7.3	4.6-7.8	4.6-8.6
Mean ± St. dev.		5.93±0.33	6.01±0.43	6.12±0.57	6.26±0.76
Major Finding	Maintenance of temperatures within a range of 4°C - 8°C for 24 h				

CONCLUSION

The Paragonix Sherpa Pak™ device may decrease cold injury of donor organs by maintaining the temperature consistently between 4°C and 8°C and therefore may decrease primary graft failure after organ transplantation.

Avantages/inconvénients

- ☞ Régulation permanente de la température souhaitée
- ☞ Monitorage et enregistrement
- ☞ Température homogène
- ☞ Greffon immergé
- ☞ Facilité de mise en œuvre
- ☞ Sans énergie électrique
- ☞ Design, manipulation
- ☞ Surcout



Une glacière « active »?

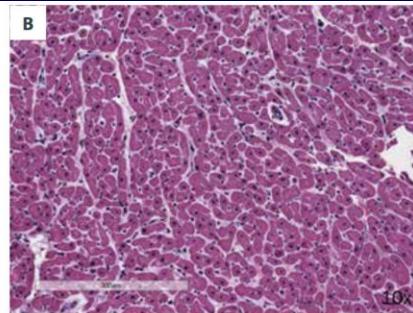
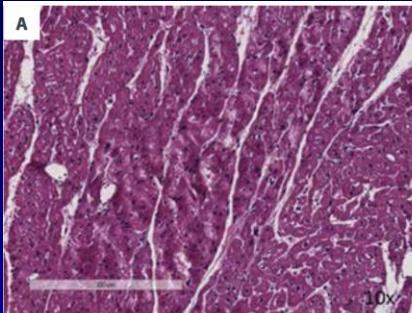
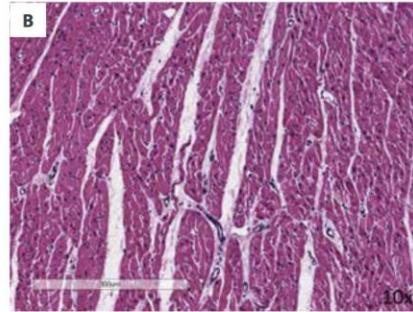
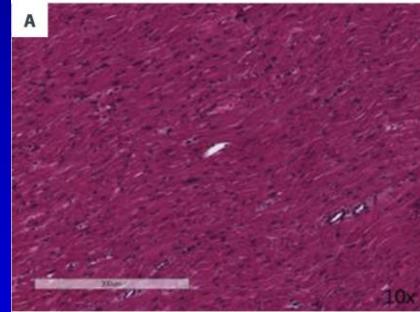


Figure 5. Histology of hearts after reperfusion on the Langendorff system. Representative H&E stains show signs of myocyte injury in the 4-h CS group (A) and no injury in the 4-h PP group (B).



Preservation of Donor Hearts Using Hypothermic Oxygenated Perfusion



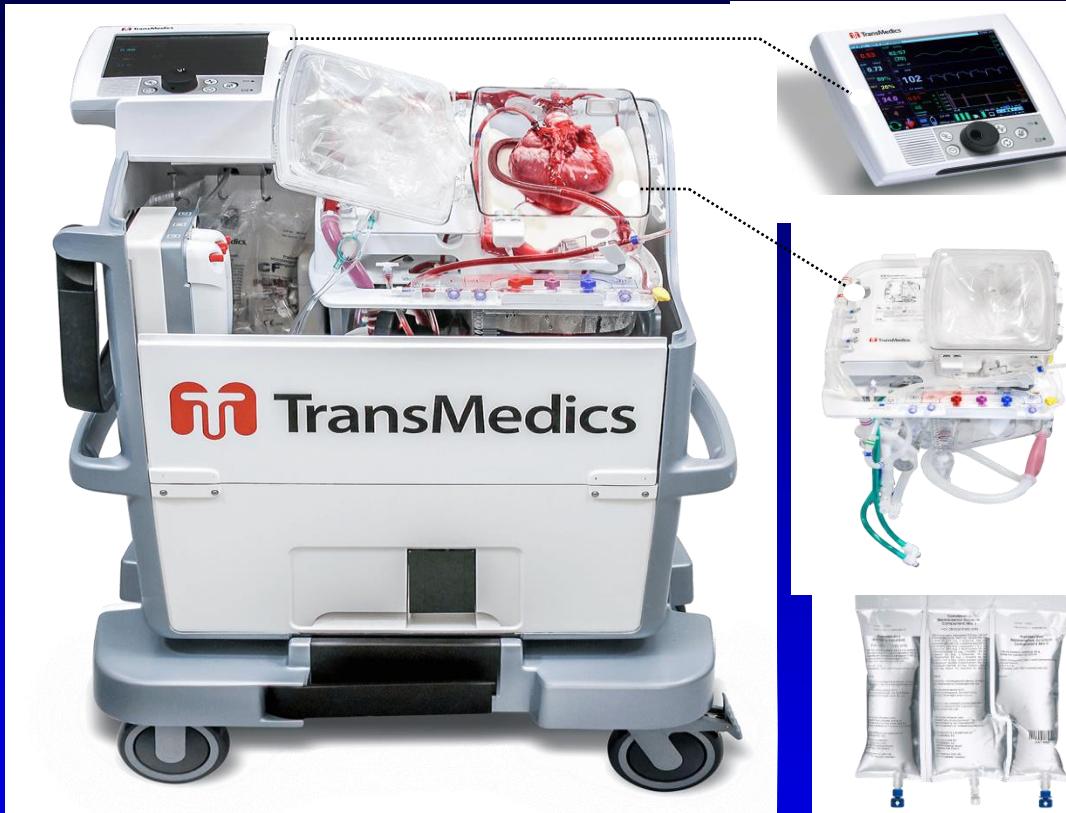
Conclusions

Hypothermic pulsatile perfusion of donor hearts during the storage interval is a simple technique that leads to a better-preserved cell structure compared to the conventional cold storage method. This may lead to less risk of primary graft failure

Mais faut-il rester à l'Age de glace?



The OCS Heart The world's only portable ex-vivo heart perfusion system



Organ Care System Console

Portable, integrated perfusion & assessment system, fits in all standard modes of transportation for donor organs

Wireless Monitor

Controls and displays physiologic and functional parameters of the heart

Perfusion Module

A sterile, protective, biocompatible chamber that houses the heart and circulating perfusate



Heart Solution Set

Infused into blood circulation; provides nutrients and substrates



OCS System Designed to Address Limitations of Cold Storage

REDUCE ISCHEMIC INJURY



Warm Oxygenated Blood Perfusion – Heart is Beating

OPTIMIZE ORGAN CONDITION



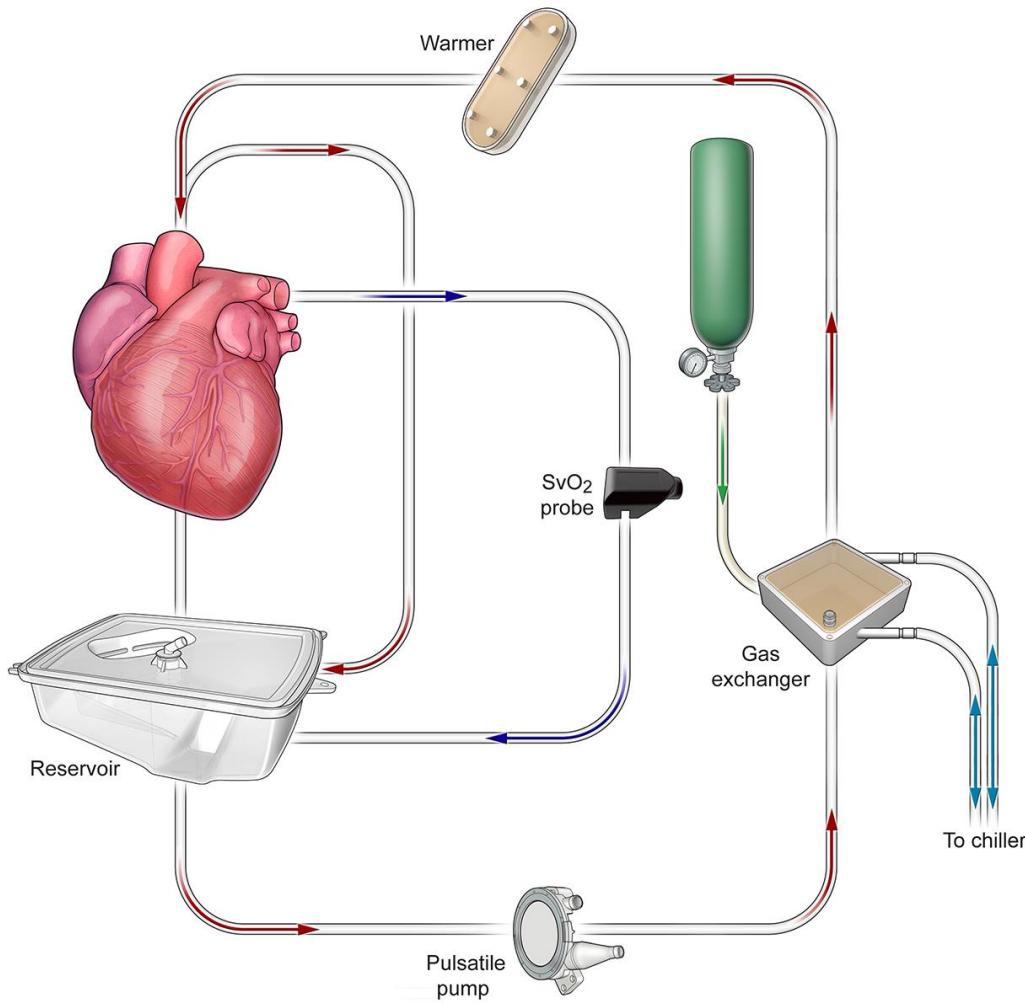
Optimize O₂ Delivery
Replenish Substrates & Hormones

EX-VIVO ASSESSMENT



Metabolic Assessment & Perfusion Parameters

Une CEC portative et transportable...



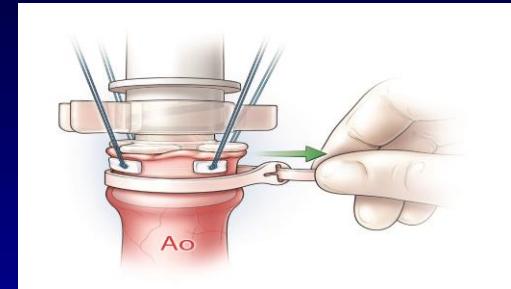
Un monitorage du greffon « Wifi »



The OCSTM Heart in Clinical Practice

☞ Sur Site PMO

- Optimisation donneur
- Prélèvement sang (1,5L) et cardioplégie
- Cannulation Ao et AP
- Démarrage
- Stabilisation



Ao Cannulation



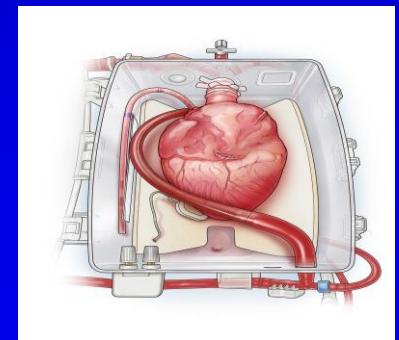
PA Cannulation

☞ Transport

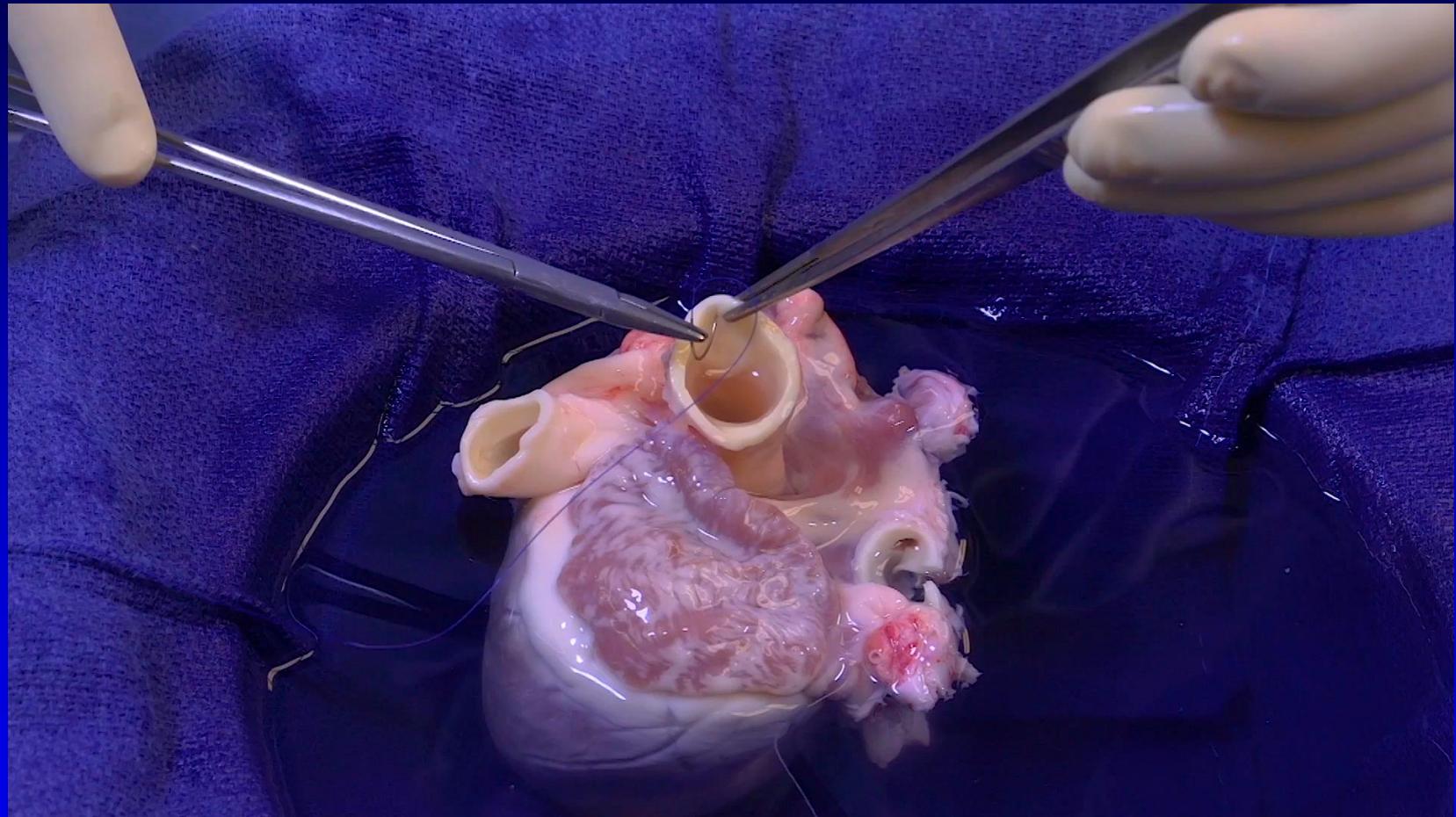
- Monitorage continu du greffon
- Ajustement paramètres de perfusion

☞ A la maison:

- Echo? Coro?
- Nouvelle cardioplégie
- Greffe



Cannulation Process

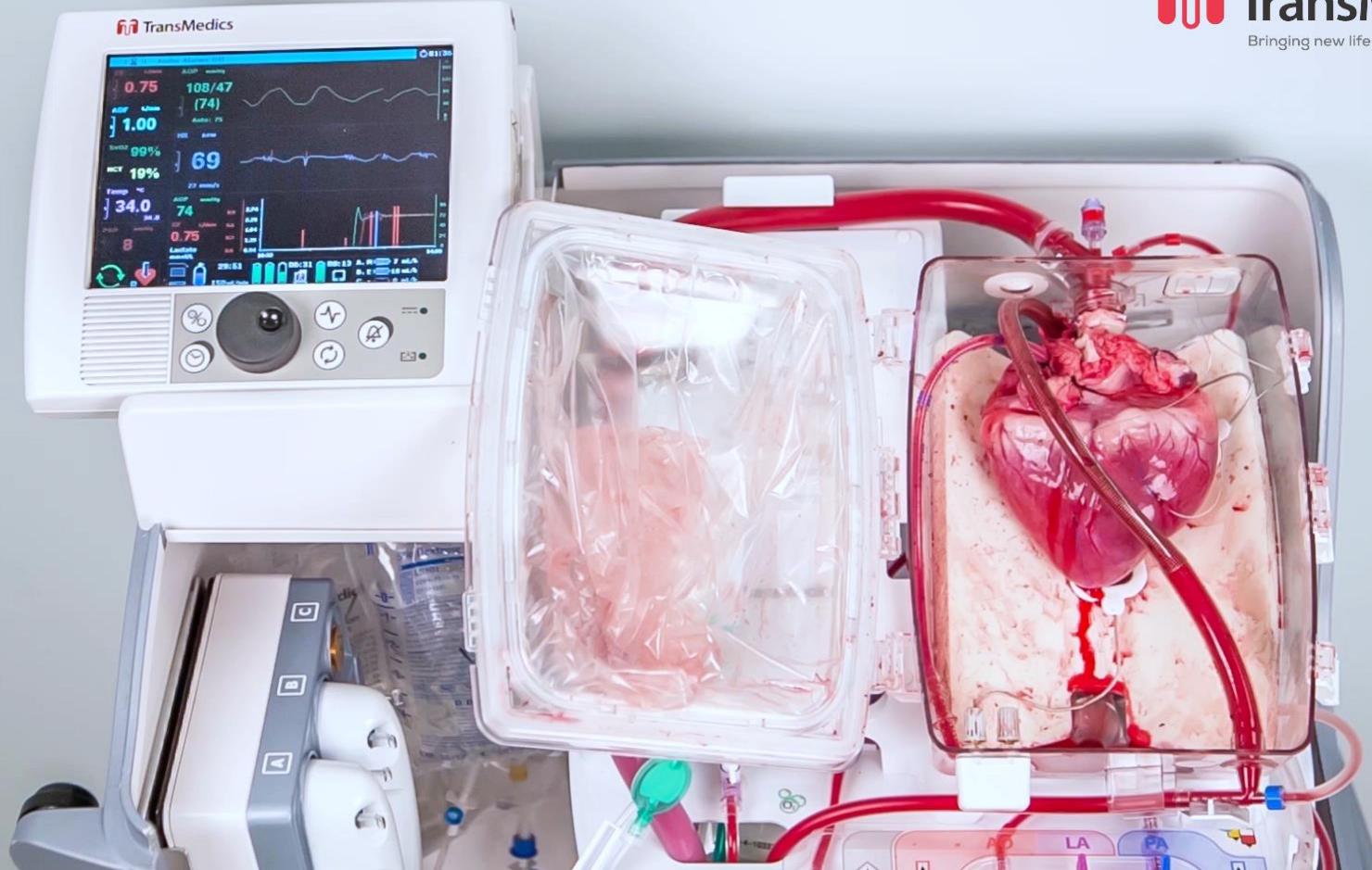


Instrumentation Process



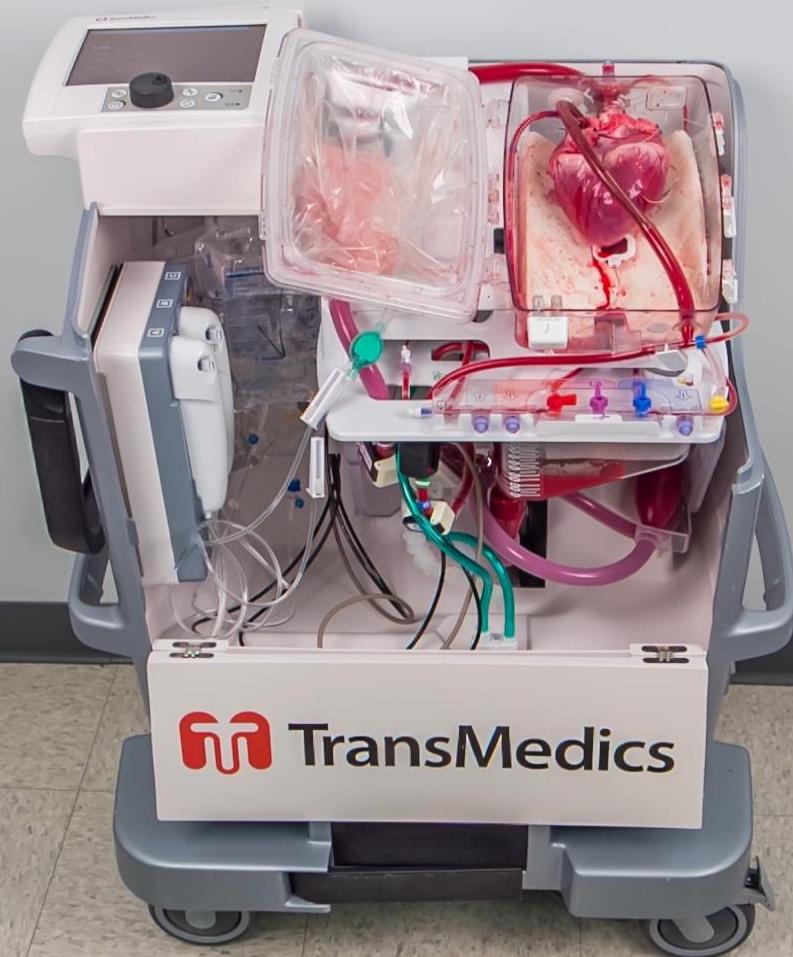
The OCSTM Heart

Confidential © 2018 TransMedics, Inc.



The OCSTM Heart

Confidential © 2018 TransMedics, Inc.



Inconvénients

- ☞ **Cout: 30 à 35 000 euros/greffon !!!!!!!**
- ☞ Encombrement, poids, ergonomie
- ☞ PMO plus compliqué, plus de personnel impliqué
- ☞ Working mode non fonctionnel à ce jour...
- ☞ Non inférieur, mais est ce supérieur?

Et en France?



Hôpital
Marie Lannelongue

3 hôpitaux
Financements...



OCS Heart Published Data

THE LANCET

Ex-vivo perfusion of donor hearts for human transplantation (PROCEED II): a prospective multicentre, randomised non-inferiority trial

Ahmed Anayati,¹ Farhad Smailani,¹ Maria Dray,¹ David Salloum,¹ Oliver Hinch,¹ Venkateswaran Nair,¹ Gaurav Patel,¹ Leanne Roberts,¹ Robert Pober,¹ and Kuhn Ngan,¹ for the PROCEED II Trial Investigators¹

Summary
Background The Organ Care System is the only clinical platform for ex-vivo preservation of donor hearts. It preserves the donor heart in a warm beating state during transport from hospital. We aimed to assess the clinical outcomes of the Organ Care System compared with standard cold storage.

Methods We did a multicentre, open-label, multicentre, randomised trial in centres in the USA and France. Eligible heart transplant candidates aged ≥18 years were randomised to the Organ Care System or standard cold storage. Donor staff were not masked to group assignment. The primary endpoint was a 10% non-inferiority margin. We did an intention-to-treat analysis. This trial is registered with ClinicalTrials.gov (NCT00803572).

Findings Between June 29, 2010, and Sept 14, 2012, we randomly assigned 138 patients to the standard cold storage group (n=69) or the Organ Care System group (n=67). In the standard cold storage group, 37% (26/70) of day patients and 49% (17/36) of night patients had a graft 90% upper confidence bound 5–6; p=0.45. Eight (11%) patients in the Organ Care System group had grafts related to ischemic times >48 min and medical staff were not masked to group assignment. The primary endpoint with a 10% non-inferiority margin, We did an intention-to-treat analysis. This trial is registered with ClinicalTrials.gov (NCT00803572).

Interpretation Heart transplantation using donor hearts adequately preserved in standard cold storage yield similar short-term clinical outcomes. The metabolically stable OCS system needs further study.

Funding TransMedics.

Introduction

Heart transplantation is the treatment of choice for many patients with end-stage heart disease.^{1–3} Despite significant improvements in mean aspects of heart transplantation, donor matching, operating technique, post-operative care, and immunosuppressive regimens, the technique of preservation of donor hearts is still cold ischemic storage. Cold storage leads to mitochondrial damage and subsequent reperfusion injuries of the donor heart, which impair heart function after transplantation. Pre- and cold ischemic time is an important risk factor for early mortality of the donor heart and of the recipient.^{4–6} The use of cold donor organs is also adversely affected by donor heart availability and organ sharing.^{7–9} There are donor heart availability issues in the scientific and clinical literature due to the low perfusion with oxygenated and nutrient-enriched blood to the myocardium, injury to the donor heart and potentially avoidable reperfusion of the myocardial and mechanical fibrosis. Several studies of heart transplantation use of continuous inflation steps of glucose, low acids, muriatic, heparin, mercuric, and anticoagulants to maintain a steady state of metabolism of the heart tissue for preserva-

THE LANCET

Adult heart transplantation with distant procure ex-vivo preservation of donor hearts after circulation: a case series

Kurtul Ozlu,¹ Arjan Japé,¹ Mark Cawdron,¹ Hong-Chen Ling,¹ Gao-Che Chen,¹ Mark Hicks,¹ Gopeshwar Kumarasing,¹ Andrew Grieve,¹ Bruce Curnow,¹ Peter Nott,¹ Emily George,¹ Paul Jones,¹ Anil Khurana,¹ Eoghan McEvily,¹ Anne Keay,¹ Robert Grahams,¹ Philip Sykes,¹ Peter Macdonald²

Summary
Background Heart-lung transplantation is the gold-standard long-term treatment for a severe heart failure. However, suitable cardiac donors are scarce. Although donation after circulatory death is used for kidney, liver and lung transplants, it is not used for heart transplantation.

Methods The recipients were patients at St Vincent's Hospital, Sydney, Australia. They received donor hearts during their circulatory death from people younger than 65 years and a ischemic time <30 min. We recorded four hours through vital arterial pressure and cardiopulmonary bypass and transferred to an Organ Care System (TransMedics) for preservation after reperfusion from donors after circulatory death.

Findings The recipients were patients at St Vincent's Hospital, Sydney, Australia. They received donor hearts during their circulatory death from people younger than 65 years and a ischemic time <30 min. We recorded four hours through vital arterial pressure and cardiopulmonary bypass and transferred to an Organ Care System (TransMedics) for preservation after reperfusion from donors after circulatory death.

Interpretation This study demonstrates that the Organ Care System can be used for heart transplantation using donor hearts after circulation.

Conclusion The Organ Care System can be used for heart transplantation using donor hearts after circulation.

Keywords Transplantation • Organ preservation • Organ transplantation

Funding NHMRC, T1 Reld Charitable Trust, EVOS Trust Fund, Harry Windsor Trust Fund

Organ preservation with the organ care system

Applied Cardiopulmonary Pathophysiology 15: 207–212, 2011

THE ANNALS OF THORACIC SURGERY

Official Journal of The Society of Thoracic Surgeons and the Southern Thoracic Surgical Association

Evaluation of the Organ Care System in Heart Transplantation With an Adverse Donor/Recipient Profile

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Background Organ transplantation is limited by the shortage of donor organs. The recent development of new donor organ maintenance systems may help to increase the utilization of available organs. This article reviews current experience with the Organ Care System for heart transplantation.

Methods The recipients were patients at St. Vincent's Hospital, Sydney, Australia. They received donor hearts during their circulatory death from people younger than 65 years and a ischemic time <30 min. We recorded four hours through vital arterial pressure and cardiopulmonary bypass and transferred to an Organ Care System (TransMedics) for preservation after reperfusion from donors after circulatory death.

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Organ preservation with the organ care system

Applied Cardiopulmonary Pathophysiology 15: 207–212, 2011

Heart Lung and Circulation

Official Journal of The Society of Thoracic Surgeons and the Southern Thoracic Surgical Association

Successful Heart Transplant after Hours Out-of-body Time using the TransMedics Organ Care System

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Objective

Patients

We report the successful transplantation of a heart following an recipient with dilated cardiomyopathy and left ventricular assist device.

Results

Our patient was urgently waiting for a cardiac transplant whilst receiving repeated AED shocks necessitated this action.

Conclusion

Although requiring ECMO and inotropic support in the first 17 days following transplant, our patient has survived 1 year.

Keywords Organ transplantation • Heart transplantation • Organ preservation • Organ transplantation

Funding

Organ preservation with the organ care system

Applied Cardiopulmonary Pathophysiology 15: 207–212, 2011

Organ preservation with the organ care system

Applied Cardiopulmonary Pathophysiology 15: 207–212, 2011

Organ preservation with the organ care system

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¹Department of Cardiothoracic and Vascular Surgery, Deutsches Herzzentrum Berlin

Abstract

Clinical heart transplantation is limited by the shortage of donor organs. The recent development of new donor organ maintenance systems may help to increase the utilization of available organs. This article reviews current experience with the Organ Care System for heart transplantation.

Key words: organ preservation, warm preservation, heart donor, heart transplantation

Introduction

Heart transplantation presents the most efficient therapy for end-stage heart disease.

Until today orthotopic heart transplantation has been performed in 89,000 patients worldwide (1). With the success of heart transplantation the criteria for acceptance of donor hearts have been continuously expanded. Nevertheless, transplantation is limited by the shortage of suitable donor organs.

In this context the cold hypothermic static preservation is the standard of care for heart transplantation. After four hours, graft function may be compromised by extended ischemic times, especially in older donors (2–4). Warm ex vivo organ perfusion, such as provided by the TransMedics[®] Organ Care System (OCs), is being explored as an alternative means of preserving donor organs (5–7).

The OCs is a high-risk, high-reward technology. It is a closed, high-pressure, oxygenated system that allows for rapid cooling and rewarming of the donor heart. It is designed to maintain a donor heart in a warm, oxygenated state during transport and storage.

The OCs also has the potential to reduce cold ischemic time and improve graft function.

Despite the promising improvements in mechanical circulatory support, heart transplantation remains the gold standard treatment for appropriately selected patients with end-stage heart failure, leading to the best long-term outcome (8). However, heart transplantation has a high early mortality, caused almost entirely by donor heart failure. Under conventional conditions of donor organ preservation, the cardiopulmonary bypass time is often >2.5 hours, resulting in a significant increase in the cold ischemic time.

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Evaluation of the Organ Care System in Heart Transplantation With an Adverse Donor/Recipient Profile

Conclusions. Use of the OCS is associated with markedly improved short-term outcomes and transplant activity by allowing use of organs previously not considered suitable for transplantation or selection of higher risk recipients, or both.

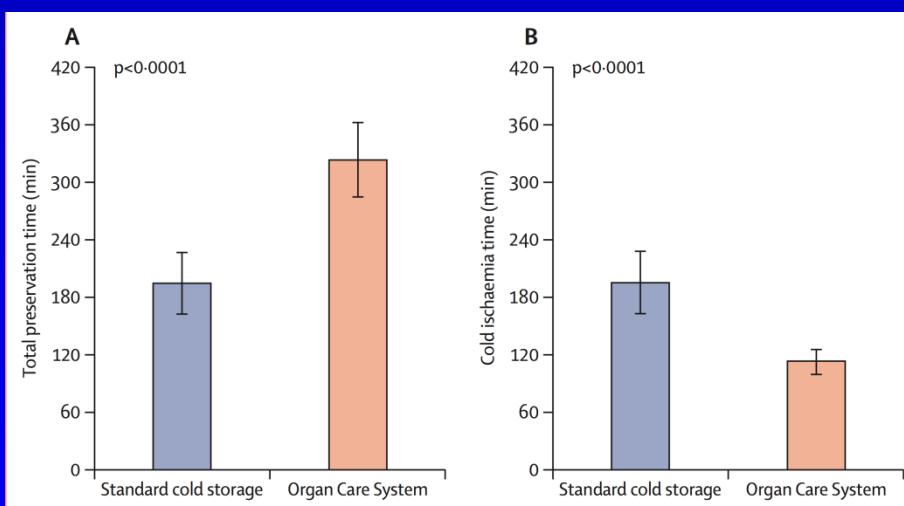
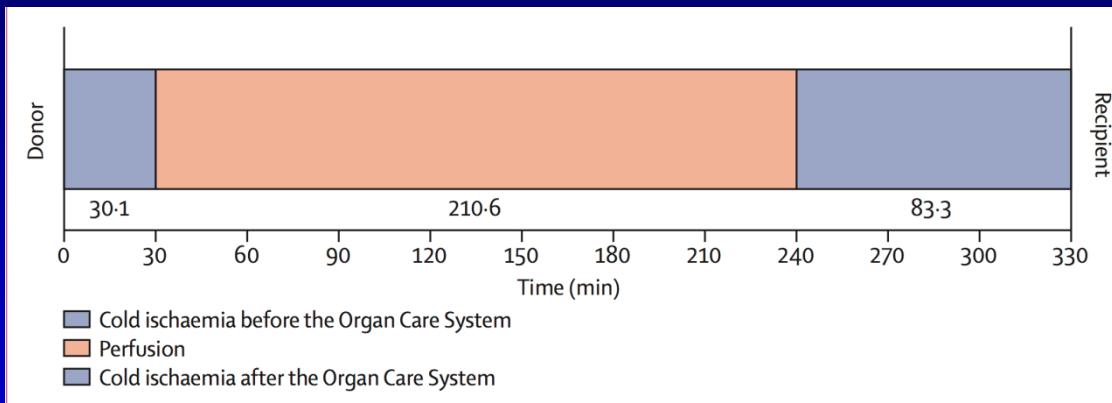
Risk Factors	Outcome
Estimated ischemic time > 4 h	Transplanted
Cardiac arrest, diabetes mellitus	Transplanted
Estimated ischemic time > 4 h	Transplanted
Obesity, alcohol abuse, palpable coronary artery disease	Transplanted
...	Transplanted
Cocaine-alcohol overdose, cardiac arrest	Transplanted
Obesity, palpable coronary artery disease	Transplanted
LVH (diastolic interventricular septum 15 mm)	Transplanted
Estimated ischemic time > 4 h	Transplanted
Estimated ischemic time > 4 h, LVH (diastolic interventricular septum 15 mm)	Transplanted
...	Transplanted
Estimated ischemic time > 4 h	Transplanted
Reduced LVEF, cardiac arrest	Declined
Estimated ischemic time > 4 h	Transplanted
LVH (diastolic interventricular septum 16 mm)	Transplanted
Estimated ischemic time > 4 h, reduced LVEF	Transplanted
LVH (diastolic interventricular septum 14 mm), alcohol abuse	Transplanted
Estimated ischemic time > 4 h	Transplanted
Estimated ischemic time > 4 h	Transplanted
Palpable coronary artery disease	Transplanted
Alcohol abuse, cardiac arrest	Declined
Electrocardiographic ischemia	Transplanted
Cardiac arrest, estimated ischemic time > 4 h	Transplanted
Cardiac arrest, LVH (diastolic interventricular septum 16 mm), Estimated ischemic time > 4 h	Declined
Reduced LVEF, palpable coronary artery disease	Transplanted
Estimated ischemic time > 4 h, palpable coronary artery disease	Transplanted
Cocaine overdose, estimated ischemic time > 4 h, right ventricular dysfunction	Transplanted
Cardiac arrest, estimated ischemic time > 4 h	Declined
Cardiac arrest, reduced LVEF, LVH (diastolic interventricular septum 15 mm)	Transplanted
Cardiac arrest	Transplanted

Table 2. Recipient Characteristics^a

Donor Number	Diagnosis	Age (y)	Sex	LVAD	Risk Factors
1	Dilated cardiomyopathy	39	Male	No	PVR > 4 WU
2	Ischemic cardiomyopathy	58	Male	HVAD	LVAD, 5 sternotomies, moderate renal impairment
3	Dilated cardiomyopathy	29	Male	No	Moderate renal impairment
4	Ischemic cardiomyopathy	61	Male	No	Previous sternotomy, liver function impairment
5	Dilated cardiomyopathy	25	Male	HVAD	LVAD
6	Dilated cardiomyopathy	36	Male	Synergy	LVAD
7	Dilated cardiomyopathy	37	Female	No	...
8	Dilated cardiomyopathy	24	Male	HVAD	LVAD, moderate renal impairment
9	Dilated cardiomyopathy	44	Female	No	IABP, moderate renal impairment
10	Dilated cardiomyopathy	56	Male	HeartMate II	LVAD, pump pocket infection, PVR > 4, moderate renal impairment
11	Dilated cardiomyopathy	61	Male	HeartMate II	LVAD, pump pocket infection, moderate renal impairment
12	Dilated cardiomyopathy	48	Male	No	PVR > 4 WU
14	Dilated cardiomyopathy	22	Male	No	IABP, moderate renal impairment
15	Dilated cardiomyopathy	57	Male	No	PVR > 4 WU
16	Dilated cardiomyopathy	26	Female	No	PVR > 4 WU, moderate renal impairment
17	Dilated cardiomyopathy	33	Male	HVAD	LVAD
18	Ischemic cardiomyopathy	48	Male	No	...
19	Ischemic cardiomyopathy	33	Male	HeartMate II	LVAD, pump pocket infection
20	Dilated cardiomyopathy	48	Male	HeartMate II	LVAD, pump pocket infection, 4 previous sternotomies
22	Dilated cardiomyopathy	56	Male	No	...
23	Dilated cardiomyopathy	58	Male	HVAD	LVAD + RVAD Levitronix, severe renal impairment
25	Dilated cardiomyopathy	34	Male	No	-
26	Dilated cardiomyopathy	59	Female	HVAD	LVAD, PVR > 4 WU
27	Dilated cardiomyopathy	30	Male	No	IABP
29	Dilated cardiomyopathy	57	Male	No	PVR > 4 WU
30	Dilated cardiomyopathy	56	Female	No	Moderate renal impairment

Ex-vivo perfusion of donor hearts for human heart transplantation (PROCEED II): a prospective, open-label, multicentre, randomised non-inferiority trial

Abbas Ardehali, Fardad Esmalian, Mario Deng, Edward Soltesz, Eileen Hsich, Yoshifumi Naka, Donna Mancini, Margarita Camacho, Mark Zucker, Pascal Leprince, Robert Padera, Jon Kobashigawa, for the PROCEED II trial investigators*



In conclusion, our findings show that the clinical outcomes of donor hearts adequately preserved with the Organ Care System platform are non-inferior to the outcomes of those preserved with standard cold storage. Evaluation of the metabolic assessment capability of the Organ Care System requires further study.

Pour favoriser le M 3 cœur?

Lancet 2015; 385: 2585-91

Adult heart transplantation with distant procurement and ex-vivo preservation of donor hearts after circulatory death: a case series



To our knowledge, this report describes the first successful clinical heart transplantations after circulatory death with donor organs procured at a distance necessitating reanimation, resuscitation, and transportation with use of an ex-vivo cardiac perfusion device. Our findings confirm that human hearts donated after circulatory death can be adequately preserved and their function assessed in a physiological ex-vivo platform before safe clinical transplantation with excellent outcome. A broader adoption



	Donor 1	Donor 2	Donor 3
Withdrawal parameters			
Location of withdrawal	Operating theatre	Intensive care unit	Anaesthetic bay
Withdrawal to systolic blood pressure <50 mm Hg (min)	7	5	11
Withdrawal to $\text{SaO}_2 <50\%$ (min)	8	2	1
Withdrawal to cessation of circulation (min)	16	10	11
Observation period (min)	2	2	5
Warm ischaemic time (min)*	28	25	22
OCS parameters			
Pacing	Yes	Yes	No
Adrenaline infusion ($\mu\text{g}/\text{h}$)	5	5	5-7
Adenosine infusion (mg/h)	0-21	0-21	0-21
Total OCS perfusion time (min)	257	260	245
Total ischaemic time (min)†	90	96	107
A-V lactate at start of perfusion (mmol/L)	8.30-8.10	6.79-6.48	7.60-7.40
A-V lactate at end of perfusion (mmol/L)	3.60-3.60	2.80-2.30	2.69-2.54

OCS=Organ Care System. A-V=arteriovenous. *Time from withdrawal of support to cardioplegia delivery. †Composite of the time from cessation of circulation to instrumentation on the OCS apparatus plus the time from cardioplegia delivery at the end of OCS perfusion to post-transplant reperfusion.

Table 2: Donor heart management

DCD donors with OCS procurement



>100+ successful DCD heart transplants

- ☞ Australia – St. Vincent's, Sydney
- ☞ UK – Papworth Hospital
- ☞ UK - Harefield Hospital
- ☞ UK - Whythenshawe Hospital

Conclusions



- ☞ Glacière: Gold standard (en tout cas pour les greffes standards...)
- ☞ Intérêt des machines de perfusion +++
- ☞ Evaluation à poursuivre : quelles indications préférentielles? Quelle machine? (registre?)
- ☞ Surcout notable, quel financement?

Merci de votre attention

