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REVIEW

DCD lung donation: donor criteria, procedural criteria, pulmonary graft function validation, and preservation

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SUMMARY

In an era where there is a shortage of lungs for transplantation is increased utilization of lungs from donation after circulatory death (DCD) donors. We review the reports of 11 controlled and 1 uncontrolled DCD programs focusing on donor criteria, procedural criteria, graft assessment, and preservation techniques including the use of *ex vivo* lung perfusion. We have formulated conclusions and recommendations for each of these areas, which were presented at the 6th International Conference on Organ Donation. A table of recommendations, the grade of recommendations, and references are provided.

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Introduction/background

The first lung transplantation was performed with an organ recovered from a donation after circulatory death (DCD) donor [1]. Renewed interest in DCD lung transplantation was raised in the 1995 following the publication by D'Alessandro and co-workers in which they reported the first successful DCD donor lung transplantations as part of an institutional DCD program [2]. They used DCD donors after withdrawal of life support on an ICU, nowadays referred to as controlled DCD (Maastricht DCD category III).

Further interest for DCD lung donation was triggered by Steen and co-workers in 2001 who successfully transplanted a single lung from a donor after failed cardiac resuscitation, a so-called uncontrolled DCD donor [3]. In this case, the successful pretransplant, *ex vivo* evaluation of graft function with a machine, now called *ex vivo* lung perfusion (EVLP), was a crucial step. EVLP allowed both subjective assessment of donor lung function and prolongation of the ischemic time (in this case to 17 h) simplifying the logistics of transplantation in this unpredictable setting. The basic principle of EVLP is the use of a preservation fluid with a high oncotic pressure, pure or mixed with red blood cells (RBC), which is perfused by a pump in a pressure-controlled manner into the

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pulmonary artery and recollected in a reservoir. The perfusion fluid is gradually warmed to 37°C. Gentle ventilation of the lungs is resumed for testing at 37°C after the perfusate is deoxygenated with a N_2/CO_2 gas mixture via a membrane gas exchanger inserted in the circuit before it enters the pulmonary artery. The feasibility to establish a successful uncontrolled DCD lung transplant program was shown by the Madrid group headed by A. Varela [4].

Today, 11 centers [5–23] have published results after lung transplantation in a controlled DCD program. Only the pioneering Madrid group have reported experience in an uncontrolled DCD program [4,24–28]. Recently, a working group within the International Society for Heart and Lung Transplantation has taken an initiative to collect multicenter data to gain insight into selection, procedures, and outcome after DCD lung donation). Over 300 DCD lung transplants were included in the Registry, but it is likely that the total is in excess of 450 worldwide [29].

This article is based on the reports of 11 controlled DCD programs and the 1 uncontrolled DCD program. We focus on donor criteria, procedural criteria, graft assessment, and preservation techniques. For outcome after DCD lung transplantation, these four steps are closely interlinked. Therefore, we formulated conclusions and recommendations for each topic. These were discussed at the 6th International Conference on Organ Donation in Paris in 2014. This article represents a summary of the conclusions from this initiative.

Donor and procedural criteria

For controlled DCD lung donation, most centers use the same donor criteria as for DBD donation. In addition, specific procedural criteria play an important role in determining whether to accept the controlled DCD lung or not. Clinical criteria for uncontrolled DCD lung donation are scarce and based on a few patients.

Controlled DCD lung donation

The generally agreed DBD donor criteria for suitability for transplantation form the background of the controlled DCD donor criteria (Table 1). In addition, most groups also use lungs from 'extended' criteria donors defined as age > 65, smoking > 20 pack years, ICU period > 5 days, and abnormal chest X-ray. A PO_2/FiO_2 < 40 kPa is generally not accepted for DCD. Functional criteria may be relaxed if EVLP is to be used to recondition and evaluate the lungs. Significant aspiration remains a contraindication but may be difficult to recognize, particularly if the first bronchoscopic examination is carried out after death. It is important to realize is that the criteria are applied in the situation of a potential donor as the DCD procedure itself might affect the value of the criteria. Therefore, although arbitrary, specific procedural DCD criteria may play a role such as heparin pretreatment, the allowed length of the agonal phase, withdrawal of the tracheal tube, maximum length of initial warm ischemic period, timing of re-inflation, and the use of EVLP. Of note using only the period of warm ischemia is based on experimental data alone [30], other factors are mainly based on clinical practice. Recently, some centers advocate standard *ex vivo* evaluation of graft function with EVLP for all controlled DCD lungs [23].

Table 1. DCD donor criteria.

Age	<65 years
Smoking	<20 pack years
Chest X-ray	Clear
Mechanical ventilation	<5 days
Blood transfusion	<5 units RBC
Oxygenation	PO_2 > 40 kPa

Premortem 'management' in the donor

There are widely varying ethical frameworks for interventions in the premortem management of patients. These need to reconcile appropriate treatment of the patient who is not a donor until death occurs, with good outcomes after transplantation, the presumed wish of the patient, and the reason for considering donation. Steps that are consistent with both aims are the most acceptable. These should certainly include a mode of ventilation which reduces lung injury (i.e., a tidal volume of 6–8 ml/Kg ideal body weight, with PEEP of 8 cm H_2O, frequent suctioning and appropriate recruitment maneuvers). Ideally, they should also include a premortem bronchoscopy, to assess the mucosa when perfused and the placement of a naso-gastric tube.

Heparin pretreatment

Several centers reported good outcome without heparin pretreatment. This is often based on ethical consideration [16,20,22]. Importantly, these centers all use retrograde flushing during preservation. In assessing this heparin-free scenario, no emboli or thrombi could be detected in DCD lungs that were harvested to search for

thrombo-embolic lesions by pathologic and histopathologic investigation [31]. Other centers do use heparin pretreatment of the potential DCD donor [5,7,10,11]. Experimentally, pretreatment with heparin of DCD donor lungs was shown to be beneficial in a way that it prevented worsening of lung function during EVLP [32]. No clinical study is available comparing both strategies. With current data and criteria available, no conclusion can be drawn. Theoretically, heparin pretreatment seems to be beneficial.

The agonal phase

The maximal length of the agonal phase (withdrawal of life support until circulatory arrest) is arbitrarily set at 2 h. There is no information to determine the maximal save length of the agonal phase for lungs based on clinical research. Multiple definitions of agonal phase are described in the literature. The most often used definition for the agonal phase in papers concerning lung transplantation is the period between withdrawal of life support and the declaration of death. Definitions and criteria to declare a donor death might, however, differ between countries and centers (e.g., absent peripheral pulsation, flat ECG). For lungs, re-inflation might be an important extra step in the agonal phase, most often before flush perfusion. It is well known that inflation is an effective preservation method to maintain lung cell viability. In practice, the duration of the agonal phase is greatly based on logistics of the procedure. A waiting time of more than 2 h is generally too significant of a workforce burden. As shown in kidney DCD donation, the save agonal phase might be influenced by injury caused by hypotension after withdrawal of life support [33]. The Leuven group in an experimental model of porcine EVLP demonstrated that pulmonary function is worse in lungs coming from donors dying from hypoxic cardiac arrest (mimicking clinical situation in controlled donation after ventilator switch off) compared to exsanguination and acute ventricular fibrillation (mimicking clinical situation in uncontrolled donation) [34]. Only one clinical study [22] showed a slightly worsening oxygenation capacity of transplanted controlled DCD lungs when the period from the start of hypotension (RR < 6.6 KPa [50 mm Hg]) till circulatory arrest became longer during the agonal phase.

Withdrawal of tracheal tube

Good results are reported with or without withdrawal of the tube. There is no clear consensus whether withdrawal of the tracheal tube is harmful or beneficial for the process. It might protect the airways for aspiration, but it also might prolong the agonal phase by preventing a collapse of the upper airway with asphyxia of the donor.

Maximum length of initial warm ischemic period

The initial warm ischemic period, defined as the period after circulatory arrest and start of flush perfusion preservation, reported in clinical series is approximately 30 min. Nevertheless, success is reported in cases with a period up to 93 min [15]. Most centers have protocols with a maximum tolerable length of initial warm ischemic period of 1 h based on experimental data [30].

Lung preservation in case of normothermic regional perfusion (NRP) of the abdominal organs

A number of liver teams have introduced perfusion of the abdominal organs with oxygenated blood, using an ECMO-like circuit. Clamping of the descending aorta to prevent any possibility of restarting brain perfusion is an absolute requirement. The abdominal team will cannulate the abdominal aorta and IVC, and the cardiothoracic team will then clamp the lower thoracic aorta and then immediately proceed to flush the lungs *in vivo*. Limited topical cooling should be used. The intrapericardial IVC should be clamped at an early stage to reduce the chance of entraining air into the perfusion circuit. While abdominal perfusion continues, the thoracic team removes the lungs, for retrograde perfusion on the back table. Ensuring complete hemostasis in the chest, given the donor is systemically heparinized, is important [35].

Ex vivo lung perfusion

Recently, the Toronto group advocated the use of EVLP for all controlled DCD donors [23]. Nine DCD lung transplantations were performed. There is, however, no detailed information about the specific behavior or injury of the 9 controlled DCD lungs during EVLP evaluation. The growing evidence that EVLP improves suboptimal lungs supports the use of EVLP after controlled DCD donation, especially when the outer ranges of accepted criteria are applied.

Uncontrolled DCD lung donation

The Madrid group is currently the only group who has reported clinical experience with uncontrolled DCD

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lung transplantations [27]. Using the procedural criteria of acceptable cold *in vivo* blood gas measurement and acceptable visual inspection, they reported on 29 transplantations with uncontrolled DCD lungs. This led to a similar 1-year survival but to a higher percentage of primary graft dysfunction as compared to results in their DBD program. The group is now investigating the use of EVLP on the OCS Lung™ device as a tool to assess and to condition the pulmonary graft prior to transplantation [36]. Stig Steen (Lund, Sweden) was the first author to report in 2001 in a detailed way on a successful transplantation of lungs from an uncontrolled DCD after EVLP [3].

Uncontrolled DCD lung donor criteria (as used by the Madrid group) reference

1. Witnessed cardiac arrest.
2. Basic and advanced resuscitation maneuvers within 15 min.
3. Continuing resuscitation during transportation.
4. Decision on failed resuscitation and declaration of death by ICU personnel.
5. Legal permission to proceed with donation.
6. Adequate blood gas measurement with *in vivo* single flush technique (53.3 KPa [400 mm Hg] or above corrected for temperature) and acceptable at visual lung inspection (collapse test, correct flushing, no thrombi on retrograde perfusion, etc.).
7. Chest X-ray on ICU.
8. Age 7–70 years.
9. No specific contraindications other than for DBD lung donation.

Uncontrolled DCD lung procedural criteria

1. A total warm ischemia time (cardiac arrest + resuscitation + 5 min hands-off, ventilatory, and circulatory support until start of topical cooling) of maximal 120 min. This arbitrary period of warm ischemia was adopted by the Madrid group as the adequacy of lung perfusion during resuscitation is unknown. The 'true warm ischemia time' starting at end of resuscitation was not defined but is probably of importance.
2. *In vivo* topical cooling period of up to 240 min. The cooling fluid returning from the pleura should reach a temperature below the 21°C (personal communication). To control the cooling of the lungs is of specific importance when normothermic iRP of the abdominal organs is performed as described above.

Using above criteria, 40% of lungs are rejected after cold *in vivo* blood gas measurement and visual lung inspection.

Steen *et al.* mentioned in their case report an age below 70 years and an initial warm ischemic period of 1 h as acceptable for transplantation after uncontrolled DCD donation. EVLP was used for lung validation and preservation. No specific EVLP criteria to decide on uncontrolled DCD lung function are yet available.

Pulmonary graft assessment and preservation techniques

Controlled DCD lung donation

Traditionally in heart beating brain-dead donors (DBD), lung function is validated before the donation procedure. This is made by interpretation of the partial oxygen pressure (PaO_2) in relation to the percentage-inhaled oxygen (FiO_2) in a peripheral arterial blood sample and ventilation pressure settings (PEEP 5 cm H_2O). The same validation technique is being used for controlled DCD lung donation although potentially, the cessation of ventilation and circulation and the subsequent unavoidable period of warm ischemia may decrease the quality of the DCD lung. To preserve the lung in the period between circulatory arrest and cold flush preservation with the lung untouched in the thorax of the donor, topical cooling might be used [3]. To be successful, the preceding period of warm ischemia should be within 1 h as stated earlier [29]. Because of the uncertain effect of this period, some groups advocate the use of EVLP in the setting of controlled DCD lung donation. EVLP enables pulmonary graft validation after the potentially inflicted injury and, importantly, before implantation.

Lung function validation in the donor

Most groups in Europe and the USA successfully use the lung validation technique in the donor for DCD as used for DBD donation after BD [5–22]. The lung function validation is based on measurement of the PO_2 at a FiO_2 of 100% oxygen with a standardized PEEP of 5 cm H_2O during mechanical ventilation. Generally, a cutoff point of >40 kPa (300 mm Hg) is used to accept the lungs. Important prerequisites that are reported in combination with this method are as follows:

1. An agonal phase not exceeding 2 h (period between stop treatment and circulatory arrest).
2. A warm ischemia time (WIT) (time between circulatory arrest and start flush perfusion preservation) of 30 min or shorter.

As part of graft evaluation, inspection of the pulmonary artery for possible clots and of deflation of the lungs during a collapse test is recommended. Based on these methods, the immediate pulmonary graft function of DCD lungs is comparable to DBD lungs [15–18,21,22]. As scaled with the primary graft dysfunction (PGD) score proposed by the ISHLT, PGD grades after controlled DCD donation are found to be similar to those after DBD donation and transplantation [16,17,22].

Lung preservation

Measures to improve preservation might already start before withdrawal of life support. Some centers administer heparin iv to the donor. As described above in the procedural criteria, till now no differences in outcome are seen between series with or without heparin. Topical cooling might be used in controlled DCD, but is not often described. The most used method of preservation is flush perfusion although no clinical studies are available on the best flush solution and on the best flush route (antegrade versus retrograde) for DCD lungs. The Leuven group has demonstrated in a porcine model evaluating DCD pulmonary function during EVLP that *in vivo* topical cooling was effective up to 7 h after circulatory arrest including 90-min warm ischemia [37]. In another study from the same group using the same model, it was demonstrated that retrograde flush of DCD lungs was superior compared to antegrade flush after both warm ischemia [38] and after topical cooling [39]. The current clinical practice is antegrade and retrograde flush with Perfadex, Celsior, or UW as mostly used flush solutions. The antegrade flush is performed during slow ventilation or inflation. The retrograde flush is performed on a back table by cannulating four lung veins separately. Lungs are stored inflated on ice.

Ex vivo lung perfusion

The Toronto group was the first to use EVLP in a standard fashion for controlled DCD lungs. Their series compromise till now 22 controlled DCD lungs that were perfused and ventilated for 4–6 h and transplanted successfully [23]. Four DCD lungs did not meet the acceptance criteria and were rejected after EVLP. Ten of the 22 successfully transplanted DCD lungs would normally have been rejected due to low oxygenation capacity while ventilated in the donor but were judge suitable after EVLP. A recent experimental study from the same group looking at pulmonary function in a porcine model after 10 h brain death and 24 h cold ischemia demonstrated that an *ex vivo* measured low PO_2 during EVLP may not be the first indicator of lung injury and, taken alone, may be misleading in assessing the *ex vivo* lung. Thus, evaluation of other physiologic parameters like compliance and pulmonary vascular resistance during EVLP takes on greater importance [40].

Uncontrolled DCD lung donation

In uncontrolled DCD lung donation, a method to validate lung function after donation is a necessity as lung function is unknown before donation. EVLP is thought to be a good method to evaluate lungs from uncontrolled DCD donors. However, the largest experience with lung validation in uncontrolled DCD is with an *in vivo* single flush technique as described by the Madrid group.

Lung preservation

After failed resuscitation and certification of death, lungs will suffer an obligatory period of warm ischemia. As described by the Madrid group, this expands up to 2 h [26]. After this period, chest tubes are inserted for topical lung cooling [3,26] and the patient can be connected to a veno-arterial ECMO system via catheters inserted in the groin for preservation of abdominal organs. The subsequent generally used flush perfusion is already described in the *Controlled DCD section*. The retrograde flush might be of great importance in programs not using heparin before withdrawal of life support. The method for lung preservation differs for category IV DCD, where the heart stops prematurely during organ retrieval in a brain-dead patient and prior to aortic cross-clamp and cardioplegia. In this infrequent, uncontrolled DCD category a cannula can be rapidly inserted in the pulmonary artery for cold flush perfusion.

In vivo single flush lung validation technique

The *in vivo* single flush technique is a very simple and practical method. It is used after heparinization of the donor that is circulated with some extra chest compressions. After topical lung cooling and subsequent sternotomy and antegrade flush perfusion preservation of the lungs, 300 ml of 4–10°C donor blood is flushed via the pulmonary artery while the lungs are ventilated

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with 100% oxygen. The blood is collected from the lung veins and the PO_2 is measured and corrected for the temperature used during flushing. Cutoff point for PO_2 is <53.3 KPa (400 mm Hg). Acceptance of the lung was further based on visual appearance (collapse test, correct flushing, no thrombi on retrograde perfusion...). Results are described of 29 to 32 uncontrolled DCD lung transplantations. Due to higher incidence of PGD and early mortality compared to DBD donation with this *in vivo* single flush technique, the Madrid group now recommends that some form of *ex vivo* validation of pulmonary graft function should be adopted in uncontrolled DCD lung donation.

Ex vivo lung perfusion

There are only two clinical reports on EVLP in the situation of uncontrolled DCD donation [3,32]. In the first case report by the group of Stig Steen EVLP showed excellent performance of the uncontrolled DCD lung. The subsequent single lung transplantation procedure was successful. The basic principle of EVLP is the use of a preservation fluid with a high oncotic pressure mixed with RBC's that is perfused by a pump in a pressure-controlled way into the pulmonary artery and recollected in a reservoir. The perfusion fluid is gradually warmed to 37°C. Gentle ventilation the lungs is resumed for testing at 37°C after the perfusate is deoxygenated with a N_2/CO_2 gas mixture via a membrane gas exchanger inserted in the circuit before it enters the pulmonary artery. Recently, the Madrid group reported their experience with EVLP for validation of uncontrolled DCD lungs during the 2011 annual meeting of the ISHLT in San Diego (32 = 34 n). Besides PaO_2, lung compliance and ventilatory pressures might be important parameters to evaluate graft quality similar to EVLP after controlled DCD donation [36].

Conclusions and recommendations

Controlled DCD

The current use of the same DBD donor criteria in controlled DCD results in good lung transplant outcome. Pulmonary graft validation in the donor leads to good results. Combined antegrade and retrograde flush perfusion and inflated storage do preserve the DCD lung as good as the DBD lung. This is true regardless of the use of heparin or withdrawal of the tracheal tube but with a time between withdrawal of treatment and circulatory arrest of <90 min and an initial warm ischemic period of <60 min. EVLP was shown to be beneficial in extending donor criteria and in using donor lungs with initially unacceptable PO_2. Results for DCD lung transplants have been shown in a large number of reports and summarized in a recent meta-analysis [41], to be essentially identical to those from DBD donors. The single, and as yet unconfirmed dissenting report, suggests a slightly higher incidence of PGD and a higher risk of early bronchiolitis obliterans [42].

Uncontrolled DCD

Uncontrolled lung donation has shown to be successful using general criteria and strict procedural criteria with the help of *in vivo* pulmonary graft testing, visual inspection, and chest X-ray investigation. However, outcome remains somewhat inferior as compared to DBD lung transplantation. The use of EVLP to validate and preserve the lung is still under investigation. Combined topical cooling and flush perfusion is currently the only described preservation method.

Recommendation table DCD lung

Recommendation	Grade	References
Use same donor selection criteria for DCD as already established for DBD.	B	[5–23]
DCD lungs should not be discarded as quality and outcome is at least similar to DBD lungs.	B	[5–23]
Perform antegrade and retrograde flush perfusion.	C	[35–37]
Use same terminology and definition for warm ischemia times as used for other organs	D	
Protect the airway early after declaration of death to avoid aspiration during abdominal organ retrieval.	D	
Pretransplant *ex vivo* lung perfusion (EVLP) is advised in case of uncertain graft performance to safely extend donor and procedural criteria (long WI, bad flush, clots), lungs with a PO_2/FiO_2 < 40 kPa and/or agonal phase >90 min and/or warm ischemia >60 min might be used after testing with EVLP.	C–D	[23]

Continued.

Recommendation	Grade	References
Acceptance criteria on EVLP may include measures of pulmonary compliance, vascular resistance, and gas exchange.	C	[23,31,34]
Uncontrolled DCD lung donation should adhere to the strict procedural criteria of		[3,4,24–28,34]
1. Witnessed cardiac arrest.	D	
2. Basic and advanced resuscitation maneuvers within 15 min.	D	
3. Continued resuscitation during transport of potential donor.	D	
4. Total warm ischemia period (cardiac arrest – start preservation) should be <120 min.	D	
5. Effective *in vivo* topical cooling prior to flush preservation 20°C.	D	
6. Transplant suitability of these lungs should in general be tested *ex vivo* using EVLP before acceptance based on measures of pulmonary compliance, vascular resistance, and gas exchange.	D	

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Conflicts of interest

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