Featured Article

# Heart transplantation in controlled donation after circulatory determination of death: the Italian experience

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**Background:** Donation after circulatory death (DCD) donation is becoming more and more popular worldwide. However, in this setting of donation, heart graft suffers from the ischemic injury related with the cardiac arrest. In Italy, the declaration of death with cardiac parameters requires the registration of electrocardiograph for twenty minutes resulting in a very prolonged grafts' warm ischemia time. The aim of this study is to present the Italian preliminary experience on heart transplantation (HTx) from controlled DCD (cDCD) donors.

**Methods:** Despite a very long period of warm ischemic time (WIT) expected, in April 2023, a DCD heart program was started in Italy and in May 2023 the first DCD heart transplant was performed. In the present paper, preliminary results of the national program are analyzed.

**Results:** Since May 2023 until December 2024, 40 DCD heart transplants were performed in Italy. Donors' characteristics were the followings: 31 male, nine female, mean age of 46.6±14.7 years. Causes of death were: 19 trauma, eight cerebral bleeding, four post-anoxia coma, nine others. Three donors showed mild coronary artery disease at angiography. Mean WIT was 43.2±10.8 minutes. Thoraco-abdominal normothermic regional perfusion (T-A NRP) was used in all cases. Recipients' characteristics were the followings: 33 males, seven females, mean age 59.1±12.3 years, 16 re-operations (REDO), 18 on an urgent list. Eight (21%) patients required post-transplant extracorporeal membrane oxygenation (ECMO), four (50%) of whom were successfully weaned. Thirty-day mortality was 10%. Median duration of post-transplant mechanical ventilation, intensive care unit stay and hospital stay was 45 hours, six days and 28 days respectively. At discharge, mean ejection fraction (EF) was 57.8%±10% and tricuspid annular plane systolic excursion (TAPSE) 18.2±3.1 mm, without any significant valvular disfunction.

**Conclusions:** Italian preliminary results suggest that DCD heart transplantation can be successful despite a very long WIT and marginal donors' characteristics. A larger experience and data about medium and long-term results are mandatory to better confirm the short-term findings.

**Keywords:** Donation after circulatory death heart transplantation (DCD HTx); DCD donation; normothermic regional perfusion (NRP)

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## Introduction

Solid organ transplantation remains the gold standard for end-stage organ disease in selected patients. However, the main limitation to its wider application is represented by the number of donors and grafts suitable among the donor pool (1). Organs can be donated in the setting of donation after brain death (DBD) or after the determination of death with cardiac parameters [donation after circulatory death (DCD)]. DCD donation is increasing worldwide although it may pose critical issues related to the ischemia the grafts may suffer from among the different Maastricht donor categories (2). In Italy, the declaration of death with cardiac parameters requires the registration of electrocardiogram (EKG) for twenty minutes, resulting in a very prolonged graft warm ischemia time (3). This requirement explains why DCD donation has been applied in Italy later than in other countries and why DCD donation is almost always performed with the use of normothermic regional perfusion (NRP).

The Italian preliminary experience on DCD heart donation will be presented in this paper.

## Methods

In 2022, the Italian National Transplant Center [Centro Nazionale Trapianti (CNT)] established a dedicated working group among the Italian Heart Transplant Centers to define a national document regarding the DCD heart donation in the setting of Maastricht three' category DCD donation [controlled DCD (cDCD)]. The document was created to implement the cDCD donation national program already ongoing for liver, kidney and lungs since 2015. The document was approved in March 2023, and all the Italian Heart Transplant Centers defined their own operative protocol in the respect of the general rules defined in the national documents (4,5).

### National DCD heart donation and transplantation working document

Due to the Italian legislation regarding the determination of death with cardiological criteria that requires a 20-minute registration of EKG, for DCD donation, NRP results mandatory in this setting of donation. The Italian working document is based on eight fundamental principles: (I) the declaration of cardiac death must be accomplished according to the fulfillment of the ongoing cardiac criteria. (II) The willingness of donation must be respected. (III) Operative protocols must ensure the perfusion of the abdominal organs. (IV) The perfusion must be limited to those organs that will be donated. (V) Lung graft must be preserved. (VI) Heart must be re-perfused without cerebral reperfusion. (VII) The heart graft must be evaluated *in situ* with an adequate afterload. (VIII) Heart graft can be eventually re-evaluated *ex-situ* by the use of perfusion machines (MPs).

The document also codifies all the phases of DCD donation.

#### *From the withdrawal of life supporting therapies to the declaration of death*

The potential donors must be transferred to the operative room and prepared for donation. Life supporting therapies are withdrawn with the potential donor already prepped and draped for surgery. After the suspension of the advanced therapies, cardiac arrest is waited for a maximum time of three hours. By convention, the functional warm ischemic time (fWIT) is considered to start when the systolic pressure falls below 50 mmHg and/or the peripheral oxygen saturation is below 70%. Once the cardiac arrest occurs, EKG recording begins for at least 20 minutes.

#### *Thoraco-abdominal normothermic regional perfusion (T-A NRP)*

After the declaration of death, two surgical teams start the retrieval. One cardiac surgical team opens the chest and clamps the cerebral vessels and another surgical team cannulates the femoral vessels. The thoraco-abdominal NRP is and the donated organs are perfused. The cardiac chambers are vented through the pulmonary vein and/or the pulmonary artery. Once the heart recovers its

 

contractility, NRP is optimized and managed to ensure an optimal perfusion evaluated with hemodynamic parameters by a Swan-Ganz catheter, transesophageal echocardiogram (TEE) and direct inspection. If required, temporary pacing, blood transfusion, vasopressor or inotropic drugs can be used to reach hemodynamic stability. After this period of mechanical assistance, adequate ventilation is restarted and NRP can be gradually weaned. Heart venting is stopped and the mechanical support is slowly reduced. During the weaning of NRP, hemodynamic parameters are carefully monitored.

### *'Heart-beating' phase*

Once the NRP is stopped, perfusion is guaranteed physiologically by the heart contractility, transforming the setting of DCD donation into a kind of 'DBD-like' situation. In this phase, the heart graft can be evaluated *in situ* similar to a DBD donor. Echocardiographic, hemodynamic and laboratory tests are of paramount value, in addition to the surgical direct inspection. The graft is observed for an adequate period of time, before the definite decision regarding its suitability for transplant. During this period, the cannulas are flushed with heparin and kept on site and the circuit of NRP is recirculating through a shunt between the arterial and venous lines in case of hemodynamic instability requiring the restoration of extracorporeal support.

### *Perfusion machines*

MPs can be used in the setting of DCD donation. In other international series, their utilization is mandatory in cases of direct procurement (although this way of procurement is not possible in Italy due to the very long ischemic time before cardiac reperfusion). MPs are highly recommended if the heart graft has been evaluated with an inadequate afterload only (i.e., only during NRP without a complete weaning of extracorporeal support). Furthermore, MPs can be used in cases where circulatory support has been completely weaned if an additional evaluation is required or to reduce the ischemic time related to transport or logistical reasons. The primary limitation of MPs remains the inability to evaluate the graft under loaded conditions.

So far, among the 15 heart transplant centers active in Italy, eight centers (Padua, Verona, Turin, Bologna, Rome, Milan, Bergamo and Pavia) have performed at least one DCD Heart transplant. Two centers (Bari and Palermo) are authorized for the procedure without any procedure performed yet. DCD grafts are allocated on a local geographical basis. In case the donor is located in an area without an authorized DCD Heart Transplant Center, the graft is assigned to one of the active centers according to a national rotation list. The aim of this paper is to describe the Italian experience on DCD heart transplantation (HTx) and all the data available in the national database regarding patients receiving a heart transplant with a graft coming from a DCD donor in Italy have been analyzed.

Baseline characteristics and outcomes are presented as frequency (percentage) for categorical variables and mean ± standard deviation or median for continuous variables.

## Results

### Donors

The first DCD heart transplant was performed in Padua in May 2023 and, as of December 2024, 40 transplant procedures have been performed (Padua ten, Turin nine, Bologna eight, Verona seven, Milan four, Rome one, Pavia one). Donors' characteristics are reported in detail in *Table 1*. Thirty-one (77%) donors were male with a global mean age of 46.6±14.7 (range, 16–70) years. Causes of death were: 19 trauma, eight cerebral bleeding, four post-anoxia coma, nine others. Hospital stay before donation was 14.4±5.8 (range, 6–29) days. Thirteen donors were smokers, four had a positive history for alcohol abuse, and three for drug addiction. At echocardiogram before withdrawal of life-sustaining therapies (WLST), mean ejection fraction (EF) was 60.1%±4.3%, tricuspid annular plane systolic excursion (TAPSE) 21.1±4.3 mm. Three donors showed mild coronary artery disease at angiography. In 18 cases donation took place in a remote hospital at a mean distance from recipient's hospital of 127.1±161.1 (range, 45–716) km. WLST took place in the operative room in all cases. Mean warm ischemic time (WIT) (defined as the time between WLST and cardiac reperfusion) and fWIT (defined as the time between when arterial pressure is below 50 mmHg and or oxygen saturation below 70% and cardiac reperfusion) were 43.2±10.8 and 39.5±8.5 minutes, respectively. T-A NRP was used in all cases, by a cardiopulmonary bypass (CPB) circuit in 24 (60%) cases and by an extracorporeal membrane oxygenation (ECMO) in the remaining 16 cases. Femoral vessels were cannulated in the majority of the procedures (n=39, 95%), and central cannulation was performed only in two cases. Mean duration of T-A NRP and heart beating alone period (after T-A NRP weaning

 

**Table 1** Donors' characteristics

| Characteristics | Values |
|---|---|
| Age (years) | 46.6±14.9 |
| Sex, male/female | 31/9 |
| Causes of WLST | |
| Trauma | 19 [48] |
| Cerebral bleeding | 8 [20] |
| Post-anoxic coma | 4 [10] |
| Others | 9 [22] |
| Hospital stay before WLST (days) | 14.4±5.8 |
| Smoking history | 13 [32] |
| Alcohol abuse | 4 [10] |
| Drug addiction | 3 [7] |
| Coronary artery disease | 3 [7] |
| LV EF before WLST (%) | 60.1±4.3 |
| TAPSE before WLST (mm) | 21.1±4.3 |

Values are expressed as mean ± standard deviation or absolute value [percentage]. WLST, withdrawal of life sustaining therapies; LV EF, left ventricular ejection fraction at echocardiogram; TAPSE, tricuspid annular plane systolic excursion.

**Table 2** Donation details

| Variables | Values |
|---|---|
| Remote donation (cases) | 18 [45] |
| Distance of donation-transplant hospital (km) | 127.1±161.1 [45–716] |
| WIT (minutes) | 43.2±10.8 |
| fWIT (minutes) | 39.5±8.5 |
| T-A NRP (cases) | 40 [100] |
| CPB | 24 [60] |
| ECMO | 16 [40] |
| Cannulation | |
| Femoral | 39 [97.5] |
| Central | 1 [2.5] |
| Duration of T-A NRP (minutes) | 126.3±56.2 |
| Duration of 'beating heart' alone (minutes) | 167.3±74.9 |

Values are expressed as mean ± standard deviation [min and max] or absolute value [percentage]. WIT, warm ischemic time (defined as the time between withdrawal of life sustaining therapies and cardiac reperfusion); fWIT, functional warm ischemic time (defined as the time between arterial pressure below 50 mmHg and or oxygen saturation below 70% after withdrawal of life sustaining therapies and cardiac reperfusion); T-A NRP, thoraco-abdominal normothermic regional perfusion; CPB, cardiopulmonary by-pass; ECMO, extracorporeal membrane oxygenation.

till cardiac procurement) was 126.3±56.2 and 167.3±74.9 minutes, respectively (*Table 2*).

### Recipients

The DCD heart graft was transplanted in 40 recipients (33 males, seven females, mean age 59.1±12.3 years) suffering from: 21 post-ischemic cardiomyopathies, 12 dilated cardiomyopathies, three post-valvular cardiomyopathies, two hypertrophic cardiomyopathies, one arrhythmogenic cardiomyopathy, one adult congenital heart disease. Sixteen patients were re-operations (REDO) cases and two patients were on a durable ventricular assist device at the time of transplant (one HeartMate III and one total artificial heart). Eighteen patients were on an urgent list. Recipients' characteristics are summarized in *Table 3*. Mean graft ischemic time (defined as the time from aortic cross clamping in the donor to heart reperfusion in the recipient) and CPB time were 165.4±126.3 (median 132) and 183.2±57.8 (median 167) minutes, respectively. Eight (21%) patients required a post-transplant ECMO. After a mean duration of temporary mechanical circulatory support of 5.14±2.8 (median 4) days, in four (50%) cases ECMO was successfully weaned. Among the four patients in which ECMO was not weaned, two showed an excellent graft function but one patient had cerebral ischemia due to carotid artery dissection and one had bowel ischemia related to a pre-existing pro-thrombotic condition. Thirty-day mortality was 10%. Causes of death were: one cerebral ischemia due to carotid artery dissection, one bowel ischemia, two multi organ failure. Median duration of post-transplant mechanical ventilation, intensive care unit stay and hospital stay were 45 hours, 6 days and 28 days, respectively. At discharge, mean EF was 57.8%±10% and TAPSE 18.2±3.1 mm, without any significant valvular disfunction.

## Discussion

Following the previous publications describing the initial results, the paper describes the global experience on HTx

**Table 3** Recipients' characteristics

| Characteristics | Values |
|---|---|
| Age (years) | 59.1±12.3 |
| Sex, male/female | 33/7 |
| Cardiac disease | |
| Post-ischemic cardiomyopathy | 21 |
| Dilated cardiomyopathy | 12 |
| Post-valvular cardiomyopathy | 3 |
| Hypertrophic cardiomyopathy | 2 |
| Arrhythmogenic cardiomyopathy | 1 |
| Adult congenital heart disease | 1 |
| Redo | 16 [40] |
| Durable MCS pre-transplant | 2 [5] |
| Urgent list | 18 [45] |
| Blood group | |
| O | 13 [33] |
| A | 20 [50] |
| B | 6 [15] |
| AB | 1 [2] |

Values are expressed as mean ± standard deviation or absolute value [percentage]. Redo, re-operation, MCS, mechanical circulatory support.

using DCD donors in Italy showing encouraging early clinical results (6-8). The particular feature of this patients' population is represented by the very long ischemic time these grafts are exposed before transplant. This is due to the national legislation requiring the registration of a 20-minute EKG for the declaration of death. The very prolonged stand-off period had been initially considered an impossible barrier to be crossed since the activation of a DCD program in Italy. However, experiences from the Italian national DCD donation program suggested that, even after a prolonged period of ischemia, the heart could start beating again once re-perfused. The CNT and the Italian Heart Transplant Centers worked to define organizing and logistic aspects of a DCD heart donation protocol aiming at not increasing the already prolonged period of ischemia. The national working group identified some general rules with this goal. Some simple suggestions and maneuvers like the WLST performed in the operating room (OR), the pre-mortem heparin administration, the intravascular wires' placement before the WLST, a double surgical team for vessel cannulation and chest opening, the integrated monitoring of absence of cardiac function (EKG, invasive arterial pressure, TEE) are of paramount importance in order to keep as low as possible the required stand-off period.

Nevertheless, the ultimate WIT before heart reperfusion still remains the longest reported so far (9). Worldwide, both Direct Procurement and NRP have been demonstrated as efficient strategies in DCD HTx showing benefits and drawbacks (10). However, in the Italian setting, T-A NRP remains the only strategy to achieve heart donation due to the long 'no-touch' period in our country. T-A NRP still remains a debated procedure from an ethical perspective. However, ethical concerns are less stringent in the Italian setting once it is performed after a very prolonged period of cardiac arrest in patients with severe brain injury (11). According to our experience, it is difficult to provide more insights regarding the optimal configuration of NRP. Both classical CPB and ECMO present advantages and disadvantages (12-14). CPB provides more reliable full support with respect to unloading and cardiac output. Moreover, its circuit is more easily adaptable to supplemental technologies for hemofiltration or cytokines adsorption (15,16). However, this technology is available only in hospitals with a cardiac surgery facility on site, potentially reducing the pool of donation sites. Finally, CPB may have an impact on donation of other organs, particularly lung grafts.

On the other hand, ECMO can be more easily moved, allowing DCD heart donation regardless of the donor hospital facilities. However, it requires a more accurate cannulation to provide adequate support. Moreover, bleeding, air suction and unloading strategies in a closed circuit may require more complex management. In our series, CPB has been used more frequently in comparison with ECMO (60%) and donation was not limited to the hospitals with the heart transplant program onsite. A remote donation was performed in 45% of our population, with the longest distance of more than 700 km suggesting a potential widespread availability of this type of donation nationally. Donors' characteristics are also quite peculiar and they reflect the usual Italian donor in which marginality is more and more frequent becoming the general rule. One-third of the reported donors had cardiovascular risk factors. WLST was planned after a very long hospital stay (more than two weeks). Mean age was 47 years and nearly half of donors were 50 years or older, seven donors were older

 

than 60 years and the oldest was 70 years. In such marginal donors, cardiac function has to be accurately evaluated both by echocardiogram and coronary angiography before planning the withdrawal of therapies.

Moreover, during the donation process data from Swan-Ganz, catheter and TEE have been used to achieve the most comprehensive graft evaluation in all cases. Compared to other European and extra-European studies, our population is characterized by older donors and extended fWIT. The early report of the St Vincent's Hospital in Sydney in 2015 showed a median donor age of 26 years (17). The same group published its larger experience with a protocol involving donors under 40 years (18). The mean donor age was 32±11 years. The Papworth group presented a cohort with a median age of 35 years (19). D'Alessandro *et al.* published a report of 47 DCD donors with a median age of 32 years (20). According to data of large registries, donors' characteristics show a very young age with a mean value ranging from a 28 to 34 or a median value of 28 years (18,21,22). This aspect is also confirmed in a very recent paper analyzing data from Organ Procurement and Transplantation Network database where the reported median age of nearly five hundred and fifty DCD-NRP HTx recipients in the US is 30 (range, 23–38) years old (23).

One major concern of DCD HTx is the exposition to a definite and sure ischemic time (24,25). However, interpretation of this parameter is not always simple due to different protocols regarding the end of life, the allowed pre-mortem interventions, the not standardized definitions of warm ischemia. Nevertheless, the American Association for Thoracic Surgery 2023 Expert Consensus Document suggests that fWIT should be less than 30 minutes (26). The most striking aspect of the Italian cohort is represented by the very prolonged ischemic time before heart reperfusion. The mean WIT is 43.2±10.8 minutes and the fWIT of 39.5±8.5 minutes far longer than those reported in the literature. This difference is even higher if we consider that in some series, the functional ischemic time has been measured with a higher threshold of blood pressure (80 or 90 mmHg) (18,21). In a very recent analysis of the Organ Procurement and Transplantation Network database, a WIT (calculated from a fall in systolic pressure below 80 mmHg and/or oxygen saturation less than 80%) greater than 36 minutes has been found as a significant risk factor for early mortality (27).

According to our data, recipients' characteristics are those of typical recipients undergoing HTx: 16 patients were REDO cases, and two had a durable ventricular assist device at the time of transplant. The incidence of severe graft disfunction and need of post-transplantation ECMO was 20%. This is in line with other experiences reported in the literature. However, in the 75% of patients requiring ECMO, mechanical support was weaned or weanable, suggesting a reversible injury of the graft, confirmed also by the optimal echocardiogram results at hospital discharge.

This experience suffers from several limitations and must be considered preliminary. First, our data refer to a small cohort of patients (less than 50 cases). Second, the adopted protocol for DCD donation varies from center to center and technical aspects may be extremely different in terms of modality of T-A NRP, duration of NRP, duration of the heart beating period, strategy of myocardial protection, use of machine perfusion, intraoperative and post-operative management. The results are limited to the immediate period following transplant, lacking follow-up data that would, in any case, be minimal.

## Conclusions

Although preliminary, our results suggest that even with very long ischemic times before heart reperfusion, DCD HTx provides comforting short-term outcomes. A larger number of patients and a longer follow-up are mandatory to confirm the efficacy of DCD HTx in the Italian setting. We do also believe that emerging technologies and techniques may help to further push the limits in this rapidly evolving field.

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## Footnote

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