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Expert consensus statement

A conception for the use of mechanical support for the treatment of advanced cardiac or pulmonary failure in the Czech Republic

A joint statement of the Czech Society of Cardiology, Czech Society of Intensive Care Medicine ČLS JEP, Czech Society of Cardiovascular Surgery ČLS JEP, Czech Society of Anesthesiology, Resuscitation and Intensive care Medicine ČLS JEP, Czech Transplantation Society, Czech Society for Extracorporeal Circulation and Society for Organ Transplantations ČLS JEP



P. Němec^{a,o,p}, J. Bělohávek^{b,l,*}, M. Balík^{b,n}, K. Cvachovec^{c,m}, Š. Černý^{d,o}, V. Černý^{e,m}, P. Dostál^{f,n}, R. Lischke^{j,r}, I. Netuka^{g,r}, J. Malý^{g,r}, J. Mašín^{b,q}, F. Mlejnský^{b,q}, P. Ošťádal^{h,l}, R. Rokyta^{i,l}, M. Želízko^{k,l}

^a Center of Cardiovascular Surgery and Transplantation, Czech Republic

^b Complex Cardiovascular Center, General University Hospital and 1st Medical School in Prague, Czech Republic

^c Department of Anesthesiology, Resuscitation and Intensive Medicine, 2nd Medical School and Faculty Hospital Motol, Prague, Czech Republic

^d Department of Cardiac Surgery, Cardiac Center, Homolka Hospital, Prague, Czech Republic

^e Department of Anesthesiology, Perioperative and Intensive Medicine, Masaryk Hospital in Ústí nad Labem, Czech Republic

^f Department of Anesthesiology and Intensive Medicine, Charles University, Faculty of Medicine Hradec Kralove, University Hradec Králové, Czech Republic

^g Department of Cardiac Surgery, IKEM, Prague, Czech Republic

^h Cardiology Department, Cardiac Center, Homolka Hospital, Prague, Czech Republic

ⁱ Cardiology Department, Complex Cardiovascular Center, Czech Republic

^j 3rd Department of Surgery, 1st Medical School and Faculty Hospital Motol, Prague, Czech Republic

^k Department of Cardiology, IKEM, Prague, Czech Republic

^l Czech Society of Cardiology, Czech Republic

^m Czech Society for Anesthesiology, Resuscitation and Intensive Medicine ČLS JEP, Czech Republic

* Corresponding author at: Complex Cardiovascular Center, General University Hospital and 1st Medical School in Prague, Czech Republic.
E-mail address: jbelo@vfn.cz (J. Bělohávek).

<http://dx.doi.org/10.1016/j.crvasa.2017.03.008>

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ⁿ Czech Society of Intensive Medicine ČLS JEP, Czech Republic

^o Czech Society of Cardiovascular Surgery ČLS JEP, Czech Republic

^p Czech Transplantation Society, Czech Republic

^q Czech Society for Extracorporeal Circulation, Czech Republic

^r Society for Organ Transplantations, ČLS JEP, Czech Republic

ARTICLE INFO

Article history:

Received 13 March 2017

Accepted 13 March 2017

Available online 5 April 2017

Introduction

Cardiovascular diseases are the most common and pulmonary diseases the third most common causes of death in the Czech Republic. Majority of cardiac diseases ultimately lead to acute or chronic heart failure. Respiratory diseases may result in severe respiratory failure, but also, similar to cardiovascular diseases, may lead to heart failure.

Rapidly developing circulatory support technologies offer modern and highly effective therapy for critically ill patients. However, this therapy bears increased cost. To increase effectivity while using these advanced technologies, such advanced care should be concentrated to clearly defined centers. Above mentioned scientific societies suggest three-staged system of Centers for mechanical heart and lung support, which corresponds and follows the current structure of the Centers for highly specialized complex cardiovascular care in the Czech Republic defined in the bulletin of the Ministry of Health of the Czech Republic 20/2015 and 4/2016.

Current document is addressing both the conception of support and replacement of the heart and lung function due to circulatory failure and also the conception of using extracorporeal oxygenation and/or carbon dioxide removal as a support or replacement of lung function due to advanced respiratory failure.

This document aims to propose organization of the care for critically ill patients who need any of the mechanical support systems as specified below. The reason is to change the current status, when population of the Czech Republic does not have geographically balanced availability of the methods for extracorporeal heart and lung support and therefore does not have an assured rightful and equal access to this life saving care. This document is not a recommendation on the treatment of advanced cardiac or pulmonary failure (these topics are covered in recommendations of respective scientific societies).

Definition of the terms

a. Long-term mechanical heart support

Stands for an implantable support device of the left, right or both heart ventricles, implanted surgically, which is certified for a minimum of 3 months of the use.

This type of mechanical support is usually indicated as a bridge to heart transplantation or as a long-term cardiac failure therapy as an alternative to heart transplantation.

b. Short- and mid-term mechanical heart support

Stands for paracorporeal heart support device of the left, right or both ventricles, implanted usually surgically, which is certified for a maximum of 3 months of the use.

This type of mechanical support is indicated as a bridge to recovery of the heart function or as a bridge to heart transplantation or as a bridge to long-term mechanical support.

c. Short-term mechanical circulatory or pulmonary support with an oxygenator (ECLS – extracorporeal life support, ECMO – extracorporeal membrane oxygenation, ECCO₂R – extracorporeal CO₂ removal)

Stands for short-term, percutaneously or surgically implanted mechanical support of failing heart, heart and the lungs or only lungs. Can be used for days or weeks based on the type of the system used. The aim of this support is to bridge to heart or lung recovery or to bridge to implant of other short-, mid- or long-term heart support, eventually as a bridge to heart or lung transplantation.

Indications for this type of support are:

1. Severe or rapidly progressive cardiogenic shock, refractory to standard therapy or refractory cardiac arrest.
2. Prevention of circulatory compromise/cardiac arrest in high risk catheterization or surgical procedures.
3. Acute respiratory failure refractory to standard therapeutic approaches.

d. Short-term mechanical circulatory support without oxygenator

Stands for short-term, percutaneously or surgically implanted mechanical circulatory support.

This type of mechanical support is indicated for severe or rapidly progressive cardiogenic shock or as a prevention of circulatory compromise/cardiac arrest in high risk catheterization or surgical procedures.

The aim of this support is the bridge to recovery of the heart function including perioperative use, bridge to implant of other short-, mid- or long-term heart support, eventually as a bridge to heart transplantation.

Conception

- a. Center for the long-term mechanical heart support
 - The department belongs to a Center of highly specialized complex cardiovascular care for adults or a Center for specialized complex cardiovascular care for children
 - Fulfills requirements for a potentially covered geographical area, preoperative diagnostics, peroperative and postoperative care and is capable to solve complications as stated in the Bulletin of the Ministry of Health of the Czech Republic 20/2015
 - The center is capable to admit patients from the whole Czech Republic
 - The center has a functioning program of the heart transplantation
 - Number of procedures performed:
 - Heart transplantations: minimally 20/year (not valid for centers for children)
 - Long-term mechanical heart support implantations (minimally 10/year), not valid for centers for children
 - Personal prerequisites: minimally 2 surgeons certified in implantation of long-term mechanical heart support
 - Bed requirements: ICU or resuscitation beds of highest level as stated in the Bulletin of Ministry of Health of the Czech Republic 20/2015.
- b. Center for the short- and mid-term mechanical heart support
 - The department belongs to a Center of highly specialized complex cardiovascular care for adults or a Center for specialized complex cardiovascular care for children
 - Fulfills requirements for a potentially covered geographical area, preoperative diagnostics, peroperative and postoperative care and is capable to solve complications as stated in the Bulletin of the Ministry of Health of the Czech Republic 20/2015
 - The center is capable to admit patients from the whole adjacent geographical area belonging to a Center of highly specialized complex cardiovascular care
 - Number of procedures performed:
 - Open heart surgeries: minimally 500/year (400 for centers for children)
 - Short- and mid-term mechanical heart support implantations (minimally 10/year), not valid for centers for children
 - Personal prerequisites: minimally 3 surgeons certified in implantation of mid-term mechanical heart support
 - Bed requirements: ICU or resuscitation beds of highest level as stated in the Bulletin of the Ministry of Health of the Czech Republic 20/2015.
- c. Department for the short-term mechanical support
 - The department belongs to a Center of highly specialized cardiovascular care for adults (i.e. PCI center) as stated in the Bulletin of the Ministry of Health of the Czech Republic 20/2015
 - Fulfills requirements for a potentially covered geographical area, diagnostics and therapy and is capable to solve complications as stated in the Bulletin of Ministry of Health of the Czech Republic 20/2015

- The center is capable to admit patients from the whole adjacent geographical area belonging to a Center of highly specialized cardiovascular care and is available in a 24/7 regimen for collaborating departments
- Number of procedures performed:
 - Implantation of any type of the mechanical heart support (minimally 10/year)
- Personal prerequisites: minimally 1 physician certified in implantation and operation of the device and minimally 1 non-physician (perfusionist or nurse), certified in operations of the device
- Bed requirements: ICU or coronary care unit beds of highest level as stated in the Bulletin of the Ministry of Health of the Czech Republic 20/2015.

Organization of the care for patients on mechanical circulatory support

Center for heart and/or lung support may be established within the departments, which fulfill following criteria:

- Availability of cardiac catheterization laboratory 24/7
- Availability of transesophageal echocardiography 24/7
- Availability of resuscitation beds with a possibility to care for patients on extracorporeal mechanical support
- Existence of a defined procedure how indication for mechanical support is being performed
- Existence or SOPs for patients on mechanical support of the heart and/or the lungs
- Established registry of the patients treated by mechanical support, active participation on an educational process, eventually publication of own results in scientific literature

Departments not fulfilling criteria under Conception/c implant mechanical support systems only after consultation with a center defined under Conception/b.

Quality of the care

- All centers and departments implanting mechanical heart or lung support have their own registry of mechanical support and report their data to central registry of mechanical support (number of implantations and outcome results).
- Representatives of the centers and departments implanting mechanical heart or lung supports regularly participate on scientific meetings and conferences covering mechanical support.

Professional guarantee

A professional guarantee is endorsed by following scientific societies (in alphabetical order):

- Czech Society of Cardiology

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- Czech Society for Anesthesiology, Resuscitation and Intensive Care Medicine ČLS JEP
 - Czech Society of Intensive Care Medicine ČLS JEP
 - Czech Society of Cardiovascular Surgery ČLS JEP
 - Czech Transplantation Society
 - Czech Society for Extracorporeal Circulation
 - Society for Organ Transplantations ČLS JEP