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Use of extracorporeal membrane oxygenation (ECMO) in adults in Quebec

English summary

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The complete version of this guidance (in French) is available on the website of INESSS in the Publications section.

Membres de l'équipe projet

Auteurs principaux
Nicolay Ferrari, Ph. D.
Véronique Gagné, M. Sc.
François Désy, Ph. D.
Catherine Gonthier, M. Sc.

Collaboratrices internes
Leila Azzi, M. Sc.
FaizaBoughrassa, M. Sc.
Lucy Boothroyd, Ph. D.

Collaborateur externe
Jason Robert Guertin, Ph. D.

Coordonnatrice scientifique
Catherine Truchon, Ph. D., M. Sc. Adm.

Directrice
Michèle de Guise, M.D., FRCPC

Repérage d'information scientifique
Julien Chevrier, M.S.I.
Flavie Jouandon, *tech. doc.*

Soutien administratif
Jacinthe Clusiau

SUMMARY

Extracorporeal membrane oxygenation (ECMO) is a temporary life support technique that provides cardiopulmonary assistance exclusively for the management of patients with refractory and potentially fatal severe cardiac failure or severe respiratory failure. ECMO allows desaturated blood to be pumped into an oxygenator where gas exchange between oxygen and carbon dioxide takes place before blood is returned into the circulation (thus artificially recreating alveolar gas exchange). This technique can temporarily overcome failure of heart or lung functions ensuring adequate oxygenation for a few days, or even weeks or months. There are two main configurations of ECMO depending on the indication: venovenous(VV) ECMO for patients with severe respiratory failure, and venoarterial (VA) ECMO for severe cardiac failure or to provide assistance during cardiopulmonary resuscitation (CPR) following cardiac arrest (know as ECPR).

Since the early 2000s, the number patients treated with ECMO has increased, in particular among the adult population, and its application has diversified. However, evidence for clinical benefit compared to conventional therapeutic modalities for the management of severe cardiac or severe respiratory failure remains relatively scarce.

Currently in Quebec thereis no formal structure or process delineating which centres can or should use ECMO, nor how ECMO services should be organized. It isknown, however, that ECMO is currently being used in a number of centres to treat adult patients.

The main objectiveof this work is to develop a set of recommendationsto guide the practice and optimal use of ECMO in adult patients (≥18 years) in Quebec. This is part of a broader initiative aimed at improving the quality of careand services for critically ill patients, as well asoptimizing the use of resources.

Methodology

To inform the development of the recommendations, we conducted a systematic literature review and a field evaluation in the “real-world” context of care. The field evaluation among Quebec’s adult ECMO health care centresconsisted of: 1) a data collection for all patients treated with ECMO between 2010 and 2016, 2) a survey at the facilities with an ECMO service, 3) interviews with administrators and clinical teams to understand the current organization of services and processes, 4) a group discussion with patients and their family members to obtain their perspective on the shareddecision-making process, and 5) an estimate of hospitalization costs for patients treated with ECMO.

Results

Based on available evidence, it is at present challenging to make definitive conclusions about the clinical efficacy of ECMO (VA and VV) for patients with severe cardiac or respiratory failure. Current evidence does show that ECPR for in-hospital cardiac arrest could be beneficial, under certain conditions, compared to conventional CPR. For out-of-hospital cardiac arrest, however, the literature does not allow a conclusion to be made about the benefit of ECPR. For all types of ECMO, certain criteria such as age could facilitate the selection of those patients whow would be most likely to benefit from the treatment.

In Quebec, ECMO is currently available at 8 adult centres. Consistent with the trend observed worldwide, use of ECMO increased from 21 cases in 2010 to 97 in 2016. The patients being reated or now older (mean age having increased from 40.5 to 54.7 years during the same period), mostly in cardiogenic shock (for 94 of the 178 VA-ECMO patients), having acute respiratory distress syndrome (ARDS) (for 55 of the 68 VV-ECMO patients) or requiring assisted CPR following in-hospital cardiac arrest (for 84 of the 98 ECPR patients). While ECMO services tend to be somewhat organized in recent years, some variations in structure, processes, volumes, indications and outcomes were found. Survival rates have improved over the years, while remaining relatively low, comparable numbers reported in the literature (in 2016, survival was 34.6% for VA-ECMO, 76.5% for VV-ECMO and 35.7% for ECPR). In 2015-2016, the mean cost of hospitalization per patient treated with ECMO was $61,291.78.

Main findings and recommendations

When conventional treatment modalities fail, ECMO can be a rescue therapy option when the risk of mortality is high. In some cases, ECMO can provide the greatest chance of survival. However, there are risks associated with this intervention, which can affect quality of life in the long term, ECMO also requires considerable expertise, calls upon resources which are scarce (perfusionists for example) and requires expensive equipment. The current level of evidence on clinical benefit of ECMO compared to other, more conventional therapeutic approaches limits our ability to make firm conclusions.

Key findings and recommendations drawn from this analysis were discussed and deliberated upon by a scientific expert committee and an advisory committee of stakeholders.

The final 18 recommendations are grouped by scope. The first are cross-sectional in scope, relating to topics as service organization (structure), quality assurance and improvement and clinical decision-making (processes). Recommendations regarding the three key indications then follow: first, those relating to the management of severe heart failure; second those for the management of severe respiratory failure; and finally, those that relate to supporting CPR following cardiac arrest. The order of the recommendations presented herein (R1 to R18) does not therefore reflect any order of priority.

Regarding the organization of ECMO services, INESSS recommends that:

R1. MSSS proceed with the designation of a limited number of ECMO centres on the basis of conformity with the structural, process and quality requirements set in R2 and R3.

R2. The designation of an ECMO centre be based on the following factors:

a. the distribution of academic-affiliated centres;

b. the population of the territory served by the centres;

c. the geographic distribution across the province;

d. the distribution of intensive care resources (e.g. access to a sufficient number of intensive care beds);

e. the particular mandates of certain centres (e.g. pulmonary or cardiac transplantation);

f. having the potential volume of annual ECMO cases likely required to develop and maintain expertise, being ideally a minimum of six patients per centre per year, as proposed by ELSO.

R3. Each centre offering ECMO complies with the requirements of a structured program, possessing the following organisational components and expertise:

a. a closed intensive care unit, supervised by an intensivist, having the appropriate level of care required for these patients;

b. a department of cardiac or vascular surgery;

c. appropriate monitoring modalities for the use of ECMO;

d. a multidisciplinary team with appropriate medical (minimally cardiac or vascular surgery, intensive care and emergency) and health professional (perfusionist) expertise with at least one physician and one health professional (perfusionist) having appropriate ECMO expertise;

e. sufficient human and material resources readily available for continuous operation of the service, that is:

    i. sufficient numbers of perfusionists, respiratory therapists, nurses and other health professionals (e.g. psychologists, social workers) to ensure availability of all hospital services normally required;

    ii. a minimum of two ECMO systems – fully functional, with backup components – readily available (24 h/7 d) and with the necessary compatibility to allow transfer of patients, in special circumstances (the notion of compatibility);

    iii. an intrahospital mobile team able to initiate ECMO treatment in various locations/departments within the hospital, and to support patient transfer

iv. outside the intensive care unit (e.g. from/to medical imaging, surgery, etc.);

f. standardized protocols and common tools specific to the following activities readily available (such tools to be developped collaboratively by all ECMO centres):

i. parameters for the use of ECMO (e.g. regarding initiation and termination of the treatment);

ii. clinical management of the ECMO patient;

iii. transfer and transport of patients being treated by ECMO (in exceptional circumstances) or potential ECMO patients;

iv. protocols for potential organ donation by ECMO patients.

R4. The designated centres be mandated to evaluate, in collaboration with referring centres, the pertinence of recourse to ECMO and to accept transfer requests when appropriate.

R5. Service corridors between ECMO centres and other hospitals be established to facilitate the transfer of critically-ill patients and possibly requiring ECMO. These service corridors wouldrequire:

a. the establishment of a province-wide coordinating system for the management of intensive care resources and the transfer of patients with severe respiratory failure or in severe cardiogenic shock for which ECMO is being considered;

b. the creation of out-of-hospital ECMO teams for patient transport between ECMO centres, in special circumstances;

c. the development of standardized procedures for patient transfers.

Regarding the development and maintenance of quality of the ECMO services, INESSS recommends that:

R6. All ECMO centres ensure that periods without exposure to the technique do not exceed three months, notably by considering running case simulations.

R7. All ECMO team members complete a training program, comprised of basic training and routine annual continuing education. The training program must consider the specific needs of the multidisciplinary team and include simulations when appropriate.

R8. All ECMO centres implement quality assessment and improvement activities for all processes of care related to using ECMO, including establishing a local multidisciplinary ECMO committee (or extending an existing committee) that is mandated to conduct regular, systematic review of all ECMO cases.

R9. All ECMO centres collect data specific to ECMO in a standardized manner. This initiative shouldbesupported by:

a. the development, by INESSS, and in collaboration with all centres, of a limited number of metrics and quality indicators in order to examine the use of ECMO as part of the global management of severe cardiac and respiratory failure;

b. adequate resources and the implementation of processes to collect prospective data for all ECMO patients;

c. an annual review of metrics and quality indicators;

d. participation in a provincial database, and potentially an international registry (e.g. the ELSO registry).

R10. A provincial ECMO committee be established to:

a. conduct the annual analysis of metrics and quality indicators in the common database;

b. conduct the annual review of all ECMO cases and establish a means to provide feedback to all participating centres;

c. plan and collaborate on the updating of common tools (selection criteria, procedures, etc.), based on new evidence.

Regarding decision-making on providing ECMO, INESSS recommends that:

R11. The decision-making process to consider offering ECMO relies on a consultation with a multidisciplinary team (ideally comprised of at least 2 medical specialists, one of whom having ECMO expertise) using a tool to be developed that provides common criteria to aid decision-making on ECMO in Quebec.

R12. Decisions to start or end ECMO therapy result, whenever possible, from a shared decision-making process and informed consent by the patient and/or the surrogate decision-maker, following transmission of information about the current level of evidence on efficacy, expected long-term quality of life and risks directly associated with ECMO treatment.

Regarding management of severe heart failure, INESSS recommends that:

R13. VA-ECMO be considered for certain patients with severe cardiac failure (e.g. those in cardiogenic shock), provided that:

a. VA-ECMO is considered only when the patient's condition continues to worsen despite optimal conventional cardiovascular support therapy;

b. the selection criteria for use of ECMO-VA include but are not limited to age, comorbidities and the quality of tissue perfusion;

c. the condition is considered potentially reversible and the prognostic is compatible with the patient's wishes;

d. a clear subsequent care plan has been established.

R14. Further to the recommendations specific to VA-ECMO, it is recommended that the global management of cardiogenic shock be optimized by establishing service corridors and methods of support for transfer of patients between referral centres and the various highly-specialized centres.

Regarding management of severe respiratory failure, INESSS recommends that:

R15. VV-ECMO be considered for certain patients with refractory acute respiratory failure, provided that:

a. VV-ECMO is considered only when the patient's condition continues to worsen despite use of advanced mechanical ventilation support (e.g. mechanical ventilation support in the prone position);

b. the selection criteria for use of ECMO-VV include but are not limited to age, comorbidities and duration of pre-ECMO mechanical ventilation support;

c. the condition is considered potentially reversible and the prognostic is compatible with the patient's wishes;

d. a clear subsequent care plan has been established.

R16. Further to the recommendations specific to VV-ECMO, it is recommended that the global management of ARDS be optimized by establishing service corridors and methods of support for transfer of patients between referral centres and the various highly-specialized centres.

Regarding resuscitation assistance following cardiac arrest, INESSS recommends that:

R17. ECPR be considered to assist resuscitation following cardiac arrest, provided that:

a. a witness of the cardiac arrest can provide information on timing;

b. continuous CPR was performed rapidly after the cardiac arrest;

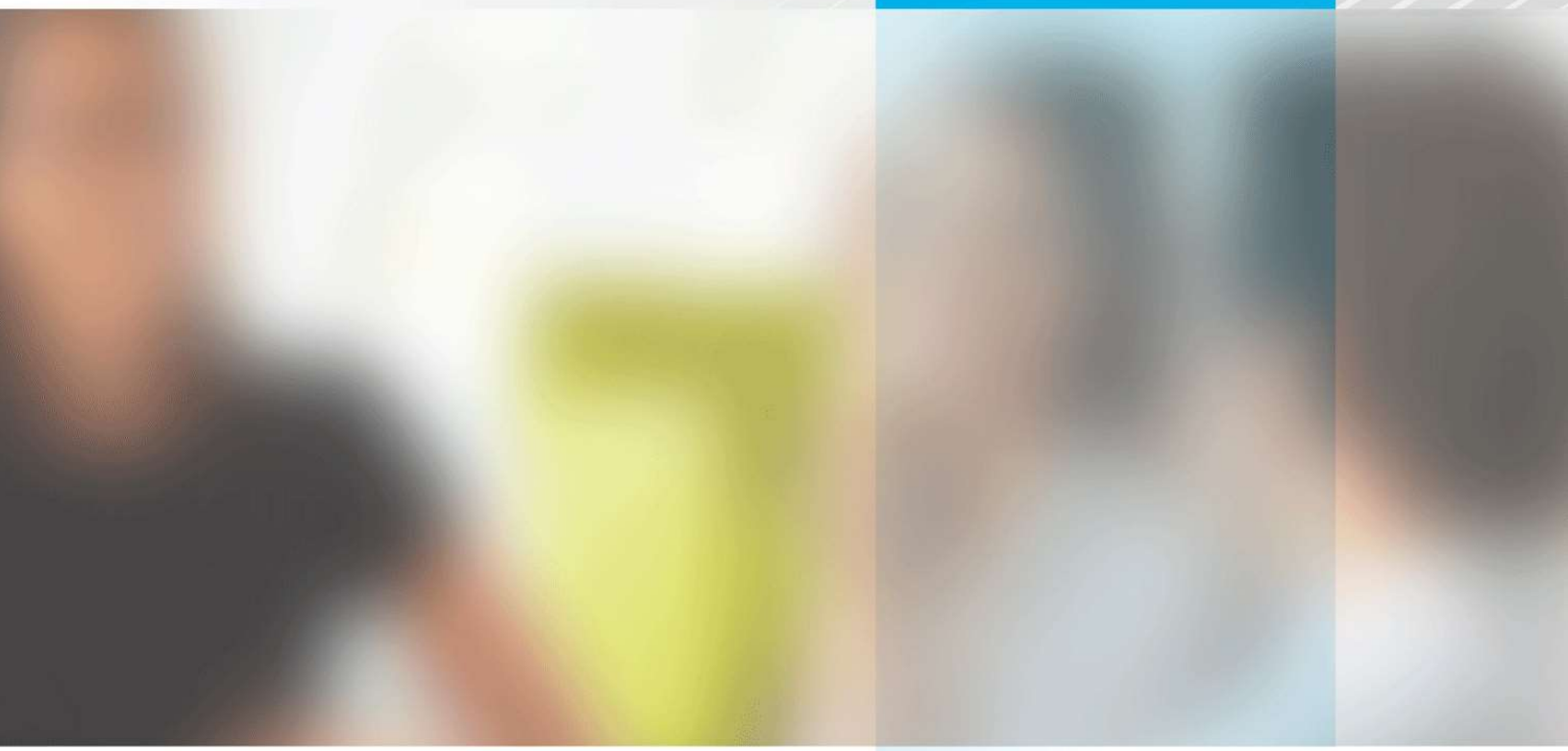
c. there has been no return to spontaneous circulation despite CPR;

d. the suspected etiology of the cardiac arrest is reversible and the prognostic is compatible with the patient's wishes;

e. ECPR can be initiated rapidly (ideally within one hour of the cardiac arrest);

f. the selection criteria for use of ECPR include but not limited to age, comorbidities, time since cardiac arrest, initial rhythm, quality of the resuscitation and quality of tissue perfusion.

R18. Regarding out-of-hospital cardiac arrests or cardiac arrest in non-ECMO centres, it is not currently recommended to establish designated services or corridors for the transfer of patients to ECMO centres. This issue should however be re-evaluated if new evidence becomes available.



Siège social

2535, boulevard Laurier, 5e étage
Québec (Québec) G1V 4M3
418 643-1339

Bureau de Montréal

2021, avenue Union, 12e étage, bureau 1200
Montréal (Québec) H3A 2S9
514 873-2563
inesss.qc.ca

Institut national d'excellence en santé et en services sociaux
Québec