NHS England

Clinical Commissioning Policy Proposition:

Extra corporeal membrane oxygenation (ECMO) service for adults with cardiac failure

Reference: NHS England D16X01/01

Information Reader Box (IRB) to be inserted on inside front cover for documents of 6 pages and over, with Publications Gateway reference number assigned after it has been cleared by the Publications Gateway Team. Publications Gateway guidance and the IRB can be found on the Intranet.

Clinical Commissioning Policy Proposition: Extra corporeal membrane oxygenation (ECMO) service for adults with cardiac failure

First published: February 2016

Prepared by NHS England Specialised Services Clinical Reference Group for
Adult critical care

Published by NHS England, in electronic format only.

Contents

Equality Statement

NHS England has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012. NHS England is committed to fulfilling this duty as to equality of access and to avoiding unlawful discrimination on the grounds of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, gender or sexual orientation. In carrying out its functions, NHS England will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which NHS England is responsible, including policy development, review and implementation.

Plain Language Summary

This policy proposition aims to define NHS England's commissioning position on extra corporeal membrane oxygenation (ECMO) as part of the treatment pathway for adult patients with acute heart failure.

Heart failure is a condition caused by the heart failing to pump enough blood around the body at the right pressure, causing breathlessness, tiredness and ankle swelling. Acute heart failure is when these symptoms develop quickly, and the patient will require urgent hospital treatment.

Acute heart failure may be treated with drugs and/or by mechanically supporting the circulatory system. Extracorporeal membrane oxygenation (ECMO) is a form of mechanical circulatory support, consisting of an artificial lung (membrane) located outside the body (extra corporeal) that puts oxygen into the blood (oxygenation) and continuously pumps this blood into and around the body, thus supporting or replacing the function of the heart.

In adult patients, ECMO is currently commissioned for patients with reversible acute lung injury or acute respiratory distress syndrome (see D16/S(HSS)/a). Development of ECMO technology over the last few years means that ECMO may now also be an option for adults with acute heart failure, albeit with potential greater risks.

NHS England has concluded that there is not sufficient evidence to support a proposal for the routine commissioning of extra corporeal membrane oxygenation (ECMO) for adults with acute heart failure.

1. Introduction

This document describes the evidence that has been considered by NHS England in formulating a proposal to not routinely commission extra corporeal membrane oxygenation (ECMO) for adults with acute heart failure.

For the purpose of consultation NHS England invites views on the evidence and other information that has been taken into account as described in this policy proposition.

A final decision as to whether extra corporeal membrane oxygenation (ECMO) for adults with acute cardiac failure will be routinely commissioned is planned to be made by NHS England by June 2016 following a recommendation from the Clinical Priorities Advisory Group.

2. The proposed intervention and clinical indication

Heart failure is a complex clinical syndrome of symptoms and signs that occurs when the efficiency of the heart as a pump is impaired. Acute heart failure is a rapid onset condition in which the heart fails to deliver oxygen at a rate that meets requirements of the metabolising tissues. When symptoms persist despite maximal medical therapy, the condition is defined as refractory cardiogenic shock and the prognosis is poor unless further therapeutic strategies are used, with mortality rates ranging from 50% to 80%.

Treatments for acute heart failure include pharmacological therapies and mechanical circulatory support. Pharmacological therapies include diuretics and inotropic agents. Invasive therapies include electrophysiological interventions such as pacemakers or implantable cardioverter-defibrillators, revascularisation procedures such as cardiomyopathy surgical revascularisation, percutaneous coronary intervention, valve replacement or repair, and temporary use of intra-aortic balloon pumps or ventricular assist devices (e.g. the Impella device).

Extracorporeal membrane oxygenation (ECMO) is a form of mechanical circulatory support that can sustain or replace cardiac function. It is a type of life support intended for short to mid-term support. There are two main types of ECMO – venovenous (VV) and venoarterial (VA). For acute heart failure in adults, the venoarterial (VA) method is used. Blood is withdrawn via the venous system (usually the femoral vein or right atrium) and pumped through an oxygenator, where gas exchange of oxygen and carbon dioxide takes place. It is then returned to the arterial system (usually the femoral artery or ascending aorta). VA ECMO provides both respiratory and haemodynamic support. Some forms of VA ECMO can be inserted percutaneously by experienced clinicians who don't need to be surgeons, but some forms of VA ECMO require cardiothoracic surgical interventions. Patients are given a continuous infusion of an anticoagulant, usually heparin, to prevent blood clotting in the external system.

The use of VA ECMO in acute heart failure in adults can be divided in 3 main categories:

1. Following heart surgery: in cases where the patient cannot be separated from the bypass machine at the end of the procedure, ECMO can be used to keep the patient stable and organs perfused for a few days, in order to allow time for the heart to recover or to institute further treatment (bridge to recovery or bridge to decision).

2. Acute heart failure: in cases of rapid decline of heart function, such as in cases of infection or toxicity presented in the emergency department, ECMO can be used to stabilise the patient, allow time to transfer the patient to a specialist cardiac centre and institute appropriate therapy (bridge to recovery, transplantation or implantation of a long term mechanical assist device). This situation can also arise in patients with a chronic heart failure suffering from an acute exacerbation.

3. Augmented CPR: if a patient in cardiac arrest does not recover after regular CPR, ECMO can be used to stabilise the patient and keep the organs perfused while the heart recovers and/or assessment of neurological recovery is performed. This may be used in in-hospital cardiac arrest, emergencies in the catheterisation catheter laboratory (sometimes for impeding arrest, allowing stability while revascularisation of the myocardium is attempted). Some have reported its use in the out-of-hospital setting (bridge to decision, recovery, transplantation, implantation of a long term mechanical assist device).

ECMO is currently commissioned in the context of stabilising, transferring and supporting adults with reversible acute lung injury or acute respiratory distress syndrome (see D16/S(HSS)/a). Veno-venous ECMO is usually used in these indications. The development of ECMO technology over the last few years now renders this mode of support potentially suitable to also stabilise and transport safely patients with acute cardiac or cardiopulmonary failure, albeit with potential greater risks. NICE issued guidance on ECMO for acute heart failure in adults in March 2014 (IPG482), and concluded that the evidence on the efficacy of ECMO for acute heart failure in adults is adequate but there is uncertainty about which patients are likely to benefit from this procedure, and the evidence on safety shows a high incidence of serious complications. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, audit or research. The Extracorporeal Life Support Organization (ELSO) produced a 2013 guideline for the use of prolonged extracorporeal life support (ECLS) in adult cardiac failure, presented as describing 'useful and safe practice' but 'not necessarily consensus recommendations'.

3. Definitions

Extracorporeal membrane oxygenation (ECMO): a supportive measure that uses a pump to circulate blood through an artificial lung back into the bloodstream.

Inotropes: various drugs that affect the strength of contraction of heart muscle.

Cardiopulmonary bypass (CPB): a supportive measure used during cardiac surgery that uses a pump to circulate blood through an artificial lung back into the bloodstream. This allows the heart to be stopped to facilitate surgery.

Cardiopulmonary resuscitation (CPR): an emergency lifesaving procedure that is done when someone's breathing or heartbeat has stopped, and combines rescue breathing and chest compressions.

Cardioverter-defibrillator: a device implantable inside the body, able to perform cardioversion, defibrillation and pacing of the heart. The device is therefore capable of correcting most life-threatening cardiac arrhythmias.

A catheterization laboratory (Cath lab): an examination room in a hospital or clinic with diagnostic imaging equipment used to visualize the arteries of the heart and the chambers of the heart and treat any stenosis or abnormality found.

Acute myocarditis: an inflammatory disease of the heart muscle (myocardium) that can result from a variety of causes.

Postcardiotomy myocardial dysfunction: a type of acute heart failure that occurs when a patient cannot be weaned from cardiopulmonary bypass.

4. Aim and objectives

This policy proposition aims to define NHS England's commissioning position on extra corporeal membrane oxygenation (ECMO) as part of the treatment pathway for adult patients with acute cardiac failure.

The objective is to ensure evidence based commissioning with the aim of improving outcomes for adults with acute cardiac failure.

5. Epidemiology and needs assessment

About 900,000 people in the UK have heart failure. About 30% to 49% of patients diagnosed with heart failure die within a year, but beyond one year the mortality is less than 10% per year (https://www.nice.org.uk/guidance/ipg482/evidence/overview-497170189).

The use of VA ECMO in acute heart failure in adults can be divided in 3 main categories: following heart surgery, acute heart failure, and augmented CPR:

1. Following heart surgery (bridge to recovery or bridge to decision)
A UK national audit of adult cardiac surgery for 2010/11 reported 30,231 procedures in 2010/11 with a UK mortality rate for all cardiac surgery of 3.1% (NICOR, 2011). The incidence of postcardiotomy myocardial dysfunction is as high as 3% to 5% among patients receiving routine cardiac surgical procedures. Approximately 1% of these require prolonged postoperative circulatory support owing to refractory cardiac and or pulmonary dysfunction (Doll, et al, 2004).

The incidence of refractory postcardiotomy cardiogenic shock in adult cardiac patients ranges from 0.5% to 1.5% (Rastan et al, 2010). A telephone survey of cardiac surgical units in the UK and Ireland in 2007/08 found that ventricular assist devices for postcardiotomy cardiogenic shock were required in 0.24% of patients undergoing coronary artery bypass grafting and/or valve surgery (Borishenko et al, 2014).

2. Acute heart failure (bridge to recovery, transplantation or implantation of a long term mechanical assist device)
This category describes the patients with rapid decline of heart function, often in cases of infection or toxicity presented in the emergency department. Clinical practice indicates that only a small number of patients fall into this category.

3. Augmented CPR (bridge to decision, recovery, transplantation, implantation of a long term mechanical assist device)
A UK national heart failure audit for 2012/13 reported 44,000 hospital admissions for acute heart failure with an in-hospital mortality rate of 9.4% and a 30-day mortality rate of 14.9% (NICOR, 2013).
In 2013 in England, there were 28,000 out of hospital cardiac arrests where the emergency medical services attempted resuscitation. The survival rate of these patients was 8.6% (NHS England statistics).

In total, the number of adults receiving ECMO for acute heart failure has been estimated to be 200 per year and increasing.

6. Evidence base

NHS England has concluded that there is not sufficient evidence to support a proposal for the routine commissioning of extra corporeal membrane oxygenation (ECMO) for adults with acute cardiac failure.

ECMO has been used and studied among patients who have developed common symptoms acute of heart failure but arising from a range of different causes (e.g. fulminant myocarditis, following myocardial infarction, etc). These various underlying conditions have different prognoses – making it hard to assess the effectiveness of ECMO as a treatment in a heterogeneous population. In addition, most patient subgroups have poor prognoses regardless of the treatment modality, so it is more difficult to assess the benefits and risks of the therapy.

The questions considered in this review are addressed in turn below:

1. Is ECMO clinically effective in adult patients with acute heart failure compared to conventional (including pharmacological and invasive) therapies?

The evidence identified in the literature search does not support a clear answer to this question. Only one study comparing ECMO to another treatment was identified, which did not demonstrate any significant difference between ECMO and miniaturised percutaneous ventricular assist devices. No studies comparing ECMO to specific conventional therapies were identified. However it should be noted that most of the included studies specified that the population receiving ECMO were patients with cardiogenic shock that was refractory (resistant) to other interventions. The ELSO guideline for the use of prolonged extracorporeal life support in adult cardiac failure states that the indication for ECMO is cardiogenic shock. The only included study that did not specify cardiogenic shock in the patient inclusion criteria found that the presence of cardiogenic shock was associated with reduced risk of hospital death in a multivariate analysis. If ECMO is primarily used in patients with cardiogenic shock refractory to other interventions, this will impact on the interventions that ECMO can usefully be compared to.

The only other study identified with a comparative element compared outcomes for patients before and after ECMO became available at one centre. This demonstrated an absolute risk reduction in 30-day survival of 33% after ECMO became available, which suggests that ECMO may be more effective than the treatments available in this centre before ECMO became available. However, the conclusions that can be drawn from one small non-randomised study are limited and the improved survival associated with ECMO may be due to confounding by other factors such as changes in patient management other than the availability of ECMO.

In this review, due to the large number of studies identified, only studies in which more than 100 adult patients received ECMO for acute heart failure were included, unless a smaller study had a comparative element or addressed an outcome of interest that was not considered in the larger studies, such as quality of life. Studies excluded due to their small sample size were similar in design to the included studies. For example, they involved reviews of patients at one institution and indications for the use of ECMO were also similar. Other reasons for exclusion of studies from this review included not distinguishing between ECMO for heart failure and respiratory failure in the analysis and not distinguishing between ECMO and other forms of support in the analysis.

The outcomes of interest listed in the brief (PICOS) for this review included optimal timing, patient selection, survival (to any point post-intervention), morbidity, quality of life and functional capacity.

Rates of survival to discharge following ECMO varied considerably between the different studies identified with no obvious factor to account for that difference. As the majority of published studies were single centre reviews, the possibility that centres with more favourable outcomes may be more likely to publish their results should be considered.

Two studies provided information on the longer-term survival of patients, reporting one-year survival rates of 17% and 25% respectively. In one study the three-year survival rate was reported as 8%; however, in another study the five-year survival rate was reported as 14%.

Studies addressing the issue of patient selection were identified. However, the results reported varied in the predictors of mortality identified in multivariate analysis and did not lend themselves to any strong conclusions.

Three small studies on quality of life following ECMO were identified. Whilst, perhaps unsurprisingly, some statistically significant differences were seen between ECMO patients and healthy controls and non-ECMO cardiac surgery patients, there were also several domains of the SF-36 where there was no statistically significant difference between ECMO patients and the controls. The precise impact of ECMO on quality of life is difficult to judge from this limited data but the evidence available suggests that ECMO is unlikely to have a particularly negative impact on quality of life.

A meta-analysis on the safety of venoarterial ECMO for the treatment of cardiogenic shock and cardiac arrest in adult patients suggests that high rates of serious complications are associated with ECMO.

2. Is ECMO cost effective in adult patients with acute heart failure compared to conventional therapies?

No studies assessing the cost-effectiveness of ECMO for adult acute heart failure were identified.

A figure for the annual use of ECMO for adult acute heart failure in England was not identified. Only 4,042 ECMO procedures were reported internationally in 2013, representing 7% of total ECMO procedures. The number of adults receiving ECMO for acute heart failure in England has been estimated to be 200 per year and increasing. A UK modelling study assumed an average annual device usage of ten usages per year, based on clinical consensus. The same UK modelling study calculated costs per patient ranging from £8,616 to £28,829 for four devices and three different cardiac indications for ECMO. However, the purpose of this study was to compare the costs of different devices and additional costs relating to, for example, routine staffing, medications or complications were not included.

7. Documents which have informed this policy proposition

NICE IPG 482: Extracorporeal membrane oxygenation (ECMO) for acute heart failure in adults
NHS contract for extra corporeal membrane oxygenation service for adults with respiratory failure D16/S(HSS)/a

8. Date of review

This document will lapse upon publication by NHS England of a clinical commissioning policy for the proposed intervention that confirms whether it is routinely or non-routinely commissioned (expected by June 2016).