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REVIEW

Artificial Lung / ECMO

A systematic review of effectiveness and economic evaluation of Cardiohelp and portable devices for extracorporeal membrane oxygenation (ECMO)

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Abstract

In recent years, there have been substantial advancements in the development of different technologies for extracorporeal membrane oxygenation (ECMO) for in-hospital and out of hospital applications. However the effectiveness of these devices is not clearly known. The objective of this study was to evaluate the cost-effectiveness of Cardiohelp compared to other portable ECMO devices. In this systematic review, we searched Medline (via Ovid), Embase, Pubmed, Cochrane Library, SCOPUS, CRD and NICE. Articles were assessed by two independent reviewers for eligibility and quality of the evidence. Studies which compared Cardiohelp to other ECMO devices were included. Seven out of 1316 publication were included in this review, three of them were clinical trials and four were observational studies. The majority of the studies had limited quality. According to the measures of safety, Cardiohelp had safer technological features, but on the other hand, was more complex to use. Considering the effectiveness, Cardiohelp was not statistically different from other technologies. Cardiohelp showed slightly better performance than Centrimag in terms of cost per patient and cost-effectiveness. However, when clinical criteria were used to select the patients with good prognosis to administer the ECMO, incremental cost utility ratios (ICURs) for both Cardiohelp and Centrimag were below the level of willingness-to-pay threshold. According to the measures of safety and effectiveness, ECMO with Cardiohelp was not considerably different from other evaluated technologies. Moreover, ECMO with Cardiohelp or Centrimag can be considered cost-effective, provided that the patients are selected carefully in terms of neurological outcomes.

Keywords Extracorporeal membrane oxygenation · Effectiveness · Cost-effectiveness · Extracorporeal life support

Introduction

Extracorporeal life support (ECLS) or extracorporeal membrane oxygenation (ECMO) is a technology to support cardiopulmonary system in critically ill patients who are refractory to conventional treatments [1, 2]. The ECMO circuit consists of a vascular access, connecting cannulas, a blood pump, a heater and cooler unit, and an oxygenator [1, 3]. This technology can be used for several hours to days to provide cardiopulmonary support [1]. Two most common types of ECMO administrations are the veno-venous (VV) and veno-arterial (VA). VA-ECMO predominantly supports the circulatory system in patients with cardiac failure and VV-ECMO is preferred in patients with pulmonary failure [1–4].

Application of ECMO is indicated in several medical conditions that can be divided into cardiac and respiratory

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failure. Most common indications for VA ECMO include cardiogenic shock, post-heart or heart–lung transplantation primary graft failure, refractory cardiac depression with drug overdose or toxicity, myocarditis, and sepsis. Most common conditions in which VV ECMO is indicated are acute respiratory distress syndrome (ARDS), post-lung transplantation primary graft failure, and severe bacterial or viral pneumonia [1–4].

Nowadays with rapid technology advances, devices for ECMO are available that are smaller in size, lighter, and portable or miniaturized which can be used in different situations such as patient transportation in addition to in-hospital use, including:

a. Centrimag™ ECMO system (Levitronix LLC, Waltham, MA, USA),
b. Cardiohelp™ (Maquet Cardiopulmonary AG, Hirrlingen, Germany),
c. Lifebox ™ (Sorin, Milan, Italy),
d. Lifebridge B2T ™ (Lifebridge Medizintechnik AG, Ampfing, Germany) [2, 4–6].

Previous studies have investigated the effectiveness of ECMO in comparison with conventional cardio-pulmonary resuscitation (CCPR) and shown positive effects on short-term survival and neurologic outcomes [7]. However, the evidence on the effectiveness and safety among these various technologies is mixed. So, the primary objective of this study was to evaluate the cost-effectiveness of Cardiohelp compared to other ECMO devices.

Methods

Study design

This systematic review was conducted and reported according to the preferred reporting items for systematic reviews and meta-analyses (PRISMA) statement [8]. This systematic review was registered at the National Institute for Health Research (NIHR) of Iran (24/M/95165) and the protocol is accessible there.

Eligibility criteria

Types of studies

Eligible studies included randomized controlled trials (RCTs), non-randomized trials, historical (retrospective) or prospective cohort studies, case–control studies, and other retrospective studies in which Cardiohelp was compared to other portable ECMO devices. Yet, pure descriptive studies without making a comparison, studies that were investigated as a special part of the technology without evaluating the total effectiveness of the device, and traditional reviews as well as case series or case reports were not within the scope of this review.

Participants

Consecutive or randomly selected adult patients undergoing ECMO following refractory cardiac and/or pulmonary failure were eligible.

Outcome

Outcomes were included in three domains of clinical effectiveness, safety, and cost. Measures of clinical effectiveness were considered to be health-related quality of life (HR-QOL), QALY, all-cause mortality rate, survival rate during the time of supporting with the device, total survival rate, and survival rate after discharge.

Outcomes to assess the safety were reliable technical and safety certificates, flow alarms, power alarms, display of power supply status, alarms reactivation as well as measures of complications and side effects due to the technology including hemolysis, limb ischemia, stroke, renal failure, thrombosis, neurological complications, and bleeding.

Measures for cost analysis consisted of mean cost per patient, incremental cost-effectiveness ratio, and incremental cost–utility ratio.

Search strategy

The Medline (via Ovid), Embase, Pubmed, Cochrane Library, SCOPUS, CRD and NICE were searched. Our last search was performed in February 2016 and all articles published before were retrieved. For thesis and dissertations, Proquest Dissertations and Theses Database was searched. No language and date limitation was applied. Reference lists of relevant articles were searched for other potentially relevant studies.

Based on PICO, free-text and controlled vocabulary were selected and searched according to the following keywords: Cardiohelp; Extracorporeal Membrane Oxygenation [MeSH] OR Extracorporeal Membrane Oxygenation OR ECMO; Extracorporeal cardiopulmonary resuscitation OR ECPR; Ventricular assist device OR VAD; Extracorporeal Life Support OR ECLS; Miniaturized OR portable; Centrimag OR Lifebridge OR LifeBox; Cost-effectiveness OR effectiveness OR safety OR quality of life OR efficacy OR Complications.

Study selection process and data extraction

Two review authors (FH and AHA) independently screened titles and abstracts, according to the eligibility criteria and rated each article using a "relevant", "irrelevant" or "unsure" designation. Full-text articles were retrieved for citations that received a "relevant" or "unsure" decision from at least one of the two review authors. Records rated "irrelevant" by the two review authors were set aside for further review. All disagreements were resolved by discussion. The two review authors independently assessed full-text articles to decide if they met eligibility criteria and performed qualitative and quantitative data extraction, using a standardized form. The corresponding authors of the articles were contacted to obtain additional information about study eligibility, where necessary. The reasons for excluding study records were recorded. Because of few numbers of included studies and the heterogeneity of them, no pooling was conducted in this systematic review.

Data items

Extracted data were first author's last name, publication year, country, study design, type of the patients included, technology compared to Cardiohelp, and the language of the article.

Risk of bias assessment

The two review authors independently appraised the methodological quality of the studies using the critical appraisal skills program (CASP) checklists [9].

Results

Study selection

A total of 1316 articles were initially identified by the search strategy. Figure 1 presents the PRISMA flowchart. Fifteen full-text articles were investigated for eligibility [10–24]. After reviewers' assessment, seven studies were found eligible to be included in this systematic review [10–16].

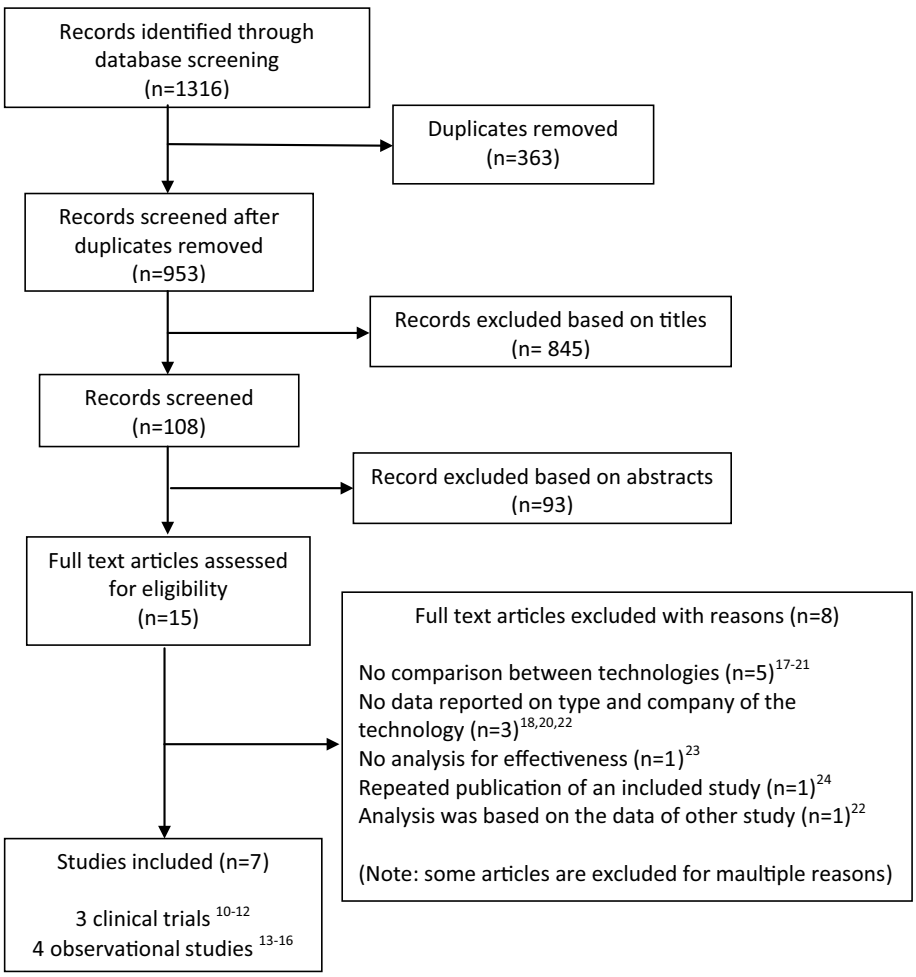

Fig. 1 The PRISMA flowchart of study selection

Study characteristics

Three of the included studies were clinical trials [10–12] and 4 were retrospective observational studies [13–16]. Two of the trials were at phase III and their results were not published [10, 11]. In one of them, Combes et al. planned to evaluate the mortality rate of patients with severe ARDS under Cardiohelp compared to conventional treatments [10]. Schober et al. in the other trial investigated the effectiveness of Cardiohelp and Lifebridge in patients with cardiac arrest [11]. The third randomized trial had evaluated the complications of ECMO procedure among three technologies of Cardiohelp, the Dideco ECC. O5 (Sorin Group, Italy), and the Deltastream system with Hilite 7000 LT + DP3 pumphead (Medos, Stolberg, Germany) and no measure of effectiveness was assessed. So, the results of this study were included only for comparing the safety of devices [12]. The characteristics of the included studies are summarized in Table 1.

All of the observational studies included in this systematic review were retrospective. In one of them, to compare Cardiohelp to Centrimag in patients with cardiogenic shock, only the abstract represented in the Resuscitation Science Symposium was accessible and after contacting the author the full article was not obtained. Therefore, the results reported in the summary were used in our work [13]. The second observational study had evaluated the safety of Cardiohelp to Centrifugal pump of Rotaflow (Maquet, Germany) and portable centrifugal pump of Centrimag [14]. The third study evaluated the efficacy of gas transfer in Cardiohelp compared to three other systems including PLS (Permanent Life Support; Maquet, Germany), Hilite 7000 LT, and Dideco ECC.O5 system [15]. The fourth study assessed the health-related quality of life in Cardiohep and Centrimag [16].

Quality of the included studies

Two of the trials were at phase III and their results are not reported in this study [10, 11]. The only trial that the results are used in this systematic review was a single-center prospective randomized study to compare the laboratory markers of haemostatic complications in three technologies. The method of randomization was reported completely in this article. However, it should be considered that no information about blinding was reported in this research, and assessment was focused on laboratory markers with no measure of clinical outcomes of the patients, and there is potential conflict of interest of the authors, because three companies of Maquet Cardiopulmonary AG, Sorin Group, and Medos had supported this work [12]. So, it can be concluded that the quality of this study was limited.

For one of the included retrospective observational studies, the full text was not accessible [13]. Therefore, the quality of the study was unclear to our team. In another included retrospective study conducted by Palanzo et al., the outcomes of comparison were restricted to technical features of technologies. Besides, the characteristics of study patients and their health situation were not reported and clinical outcomes were not assessed [14]. According to critical appraisal, the quality of this study was rated as limited. In the study done by Lehle et al., one of the authors was the advisor of Maquet Company [15].

In total, the quality of the four studies which are included in this systematic review was rated as limited. Only one of the included studies was rated to have moderate quality [16]. However, this study investigated only in-hospital cases; therefore, the results cannot be extrapolated to out of hospital and transferred patients. Additionally, no information about the type of oxygenator used along with the Centrimag has been reported in the article. Moreover, the

Table 1 Summary of the characteristics of the included studies

Author	Year	Location	Study design	Patients	Technologies compared to Cardiohelp	Language
Combes [10]	–	–	RCT III	ARDS	Conventional	French
Schober [11]	–	–	RCT III	Cardiac arrest	Lifebridge Conventional	English
Malfertheiner [12]	2016	Germany	RCT	ARDS	Dideco ECC.O5 Deltastream with Hilite 7000 LT + DP3 pumphead	English
Shah [13]	2012	U.S	Retrospective	Cardiac shock	Centrimag	English
Palanzo [14]	2014	U.S	Retrospective	–	Centrimag Rotaflow	English
Lehle [15]	2014	Germany		Respiratory failure	PLS Hilite 7000 LT Dideco ECC.O5	English
Burišková [16]	2014	Czech	Retrospective	Cardiac shock	Centrimag	English

RCT randomized controlled trial, *ARDS* acute respiratory distress syndrome

comparison of two technologies in this study (Cardiohelp and Centrimag) was limited to cost analysis with no clinical outcomes compared [16].

Safety

Considering the complications resulting from the ECMO devices, Shah et al. retrospectively compared eight patients on Cardiohelp to three patients on Centrimag and reported that no cases of limb ischemia or stroke were seen in the study participants [13].

Palanzo et al. had retrospectively studied the safety options of three technologies for patients who were on ECMO for at least 3 days, including Centrimag centrifugal pump with Quadrox-D membrane oxygenator (Maquet), Rotaflow centrifugal pump with Quadrox-D membrane oxygenator (Maquet), and Cardiohelp. This study reported that flow alarms, power alarms, and power supply status were available in all of the three devices. However, reactivation of the alarms after being silenced by the operator was available in Cardiohelp and Centrimag, but not in Rotaflow. According to the ease of setup and using the device, Cardiohelp allows the user to set the interventions but these features add to the complexity and so more training is needed for the user. Centrimag and Rotaflow are equally easy to use. Additionally, Cardiohelp has more safety benefits than the other two devices such as a built-in pressure monitoring and bubble detector [14].

Malfertheiner et al. in a single-center prospective randomized trial compared the haemostatic complications among three vv-ECMO technologies of Cardiohelp, the Dideco ECC.O5, and the Deltastream system with Hilite 7000 LT + DP3 pump head (Medos). All of these three devices had oxygenator membranes of polymethylpentene (PMP) fibers. In Medos, an axial blood pump is used but in the other two systems the pump is centrifugal. Laboratory markers were used to investigate the complications in three categories of coagulation, hemolysis, and inflammation [12]. The results of the analysis are summarized in Table 2. The majority of the analyzed markers showed statistically significant changes after 5 days on ECMO; however, there was no statistically significant difference among the ECMO systems. So, the results of this study suggest that all three ECMO systems are equally recommendable for long-term use if the blood flow is similar to that in this study (< 3.5 L/min). It is crucial to consider that changes in plasmatic coagulation had been stabilized within 1 day after termination of ECMO therapy [12].

Effectiveness and cost-effectiveness

In a retrospective study, Lehle et al. studied the capacity of oxygen (O_2) transfer and carbon dioxide (CO_2) elimination in adults with severe respiratory failure with four different veno-venous ECMO devices including Cardiohelp, PLS, Hilite 7000 LT, and ECC.O5 system. The oxygenators in all of these three devices were of polymethylpentene (PMP) membrane. This study suggests that CO_2 elimination capacity was highest with the PLS system than others. However, the other three technologies (ECC.O5 system, Cardiohelp, Hilite) were equally effective in CO_2 removal. The ECC.O5 system was least effective in O_2 transfer with a statistically significant difference, maybe due to the surface of the oxygenator; however, the other three (PLS, Cardiohelp, Hilite) ensured a maximum O_2 transfer [15].

Table 2 Results of comparing markers of hemostatic complications among Cardiohelp system, the Dideco ECC.O5, and the Deltastream system with Hilite 7000 LT + DP3 pumphead

Category of complication	Laboratory marker	Total change after ECMO	Difference between ECMO systems
Coagulation	D-dimer	↑ SS	NS
	Fibrinogen	↓ SS	NS
	Antithrombin	↑ SS	NS
	Thrombin–antithrombin complex	↑ SS	NS
	Prothrombin fragment1.2	↑ SS	NS
	Platelet count	↓ SS	NS
	FXIII	↓ SS	NS
Hemolysis	Lactate dehydrogenase (LDH)	↑ NS	NS
	Free hemoglobin (fHb)	↓ SS	NS
Inflammation	C-reactive protein (CRP)	↓ SS	NS
	Interleukin (IL)-6	↓ SS	NS
	Interleukin (IL)-8	↓ SS	NS
	Polymorphonuclear-elastase	↓ SS	NS

SS statistically significant, *NS* not significant, ↑ increase, ↓ decrease

Buriskova et al. conducted a cost-effectiveness analysis comparing Cardiohelp or Centrimag to conventional cardiopulmonary resuscitation (CPR) in patients with refractory cardiac arrest. The outcomes considered in this study were survival time and health-related quality of life determined for individual cerebral performance categories (CPC). The results of this study showed that all patients in the non-ECMO group (35 subjects) died (the neurologic deficit value was CPC 5). For the ECMO group, 8 out of 16 patients survived; four of them (25%) had CPC 1–2 with the average survival time of 20 months, and the other four patients (25%) had CPC 3–4 with the average survival time of 5 months. The other 8 participants of the ECMO group (50%) died on average within 10 days (CPC 5). In total, the average survival time in the ECMO group was 8.3 months compared to 12 h in the non-ECMO group. QALY for patients with ECMO was 0.200 years compared to zero in non-ECMO group [16].

In another retrospective study in patients with cardiac arrest, Shah et al. showed that 30-day survival in Cardiohelp was similar to that with Centrimag [13].

Economic evaluation

According to the systematic search of related literature, we found only one study for cost-effectiveness analysis of ECMO with conventional CPR [16]. ECMO procedure was conducted via Cardiohelp or Centrimag in patients with refractory cardiac arrest. Reportedly, the mean unit cost of treating one patient through ECMO (including cost of materials, medications, personnel, bed in different wards, ECMO system and its consumable materials) was higher for Centrimag compared to Cardiohelp and a similar result was found when considering only the patients with CPC1-2 based on a 5-year period of ECMO depreciation. Cost-effectiveness analysis using total survival time showed that incremental cost-effectiveness ratio (ICER) of ECMO compared to the non-ECMO group was 1163593 (CZK/year) for Centrimag and 1023778 (CZK/year) for Cardiohelp. In both the ECMO devices, the ICER was below the level of willingness-to-pay threshold (CZK 1,116,292). Similarly, cost–utility analysis using the QALY showed that the cost per QALY was higher in Centrimag than Cardiohelp in all patients and also in patients with CPC 1–2. The incremental cost–utility ratio (ICUR) for all patients was 40202015 (CZK/QALY) in Centrimag and 3537155 (CZK/QALY) in Cardiohelp. For patients with CPC1-2, the ICUR was slightly higher in Centrimag than Cardiohelp. ICUR for all of the patients was higher than the level of willingness-to-pay threshold which proposes against the intervention via ECMO, but for patients with CPC1-2 the ICUR for both of the devices dropped below the level of willingness-to-pay threshold. So, to increase the cost-effectiveness of the intervention (either by Centrimag or Cardiohelp), it is recommended to adopt strategies to predict the neurological outcomes of the patients and to maintain this type of intervention as the last choice for patients with good prognosis and potential reversible vital signs [16]. The authors of this study concluded that ECMO intervention is an effective and cost-effective modality for patients with refractory cardiac arrest, and between the two compared technologies, Cardiohelp worked a little better in terms of cost and cost-effectiveness than Centrimag.

Discussion

The aim of this systematic review was to evaluate the effectiveness and cost-effectiveness of Cardiohelp compared to other ECMO devices. Our literature search yielded relatively few studies. Most of the included studies were of limited quality. This study provides important insight into the cost-effectiveness of ECMO devices, especially for Cardiohelp.

In terms of technical features and safety characteristics, the Cardiohelp has some advanced options that makes it safer but at the same time more complex to use in a user-friendly manner. However, according to laboratory and clinical measures of complications after intervention, Cardiohelp was similar to other ECMO technologies including Centrimag, Rotaflow, Dideco ECC.O5, and the Deltastream system with Hilite 7000 LT + DP3 pumphead [12–14].

The results of effectiveness analysis in this systematic review showed that CO_2 elimination capacity in Cardiohelp was comparable to the ECC.O5 system and Hilite, but lower than that of PLS. The capacity of O_2 transfer by Cardiohelp was comparable to PLS and Hilite and higher than that of the ECC.O5 system [15]. Considering the clinical outcomes, the 30-day survival rate of Cardiohelp was comparable to Centrimag [13]. So, available studies suggest no discrepancy for effectiveness of Cardiohelp with other ECMO devices. However, only one paper was found, addressing our study's question about the cost-effectiveness of the Cardiohelp device compared to Centrimag. Therefore, it can be concluded that the paucity of evidence about cost-effectiveness of Cardiohelp compared to other ECMO devices still remains. The study conducted by Buriskova et al. had moderate quality in terms of the design and sample size which poses the possibility of bias and threatens the generalizability and transferability of the study findings. Another vital issue is the source of the study population's preferences, used for the cost–utility analysis. As mentioned by researchers, the data for quality of life were not elicited for the study population, but adopted from another study [16]. In sum, more caution should be exerted while interpreting the estimated ICUR and the final conclusion about the cost-effectiveness of the study's intervention. Another important finding of this study is that, without precise selection of patients to whom

ECMO is offered, the measures of ICUR and ICER would be higher than the level of willingness-to-pay threshold, which is opposed to the cost-effectiveness of this intervention, although for subjects with good neurological scores, the ICUR and ICER fall well below the willingness-to-pay threshold. Therefore, it is vital to predict the neurological outcomes of the indicated patients and keep this last life-saving option for patients with probable good outcomes. In conclusion, further structured criteria are needed to estimate the likelihood of prognosis for each individual patient.

Limitations

This review has limitations, in addition to the previously presented sources of bias within the individual studies included in this review. First of all, we found insufficient number of studies to pool the results. In addition, our search revealed no studies on the effectiveness of Lifebox and Lifebridge to completely fulfill the PICO of the research.

Conclusions

There were no substantially different outcomes of safety and survival for ECMO with Cardiohelp in comparison with other evaluated technologies. ECMO with Cardiohelp or Centrimag can be considered effective interventions relative to conventional CPR, but to the best of our findings the quantity and quality of related literature are not able to prove the cost-effectiveness of Cardiohelp to other miniaturized ECMO devices.

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Conflict of interest None of the authors have any conflicts of interest to declare.

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