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Thoratec CentriMag for Temporary Treatment of Refractory Cardiogenic Shock or Severe Cardiopulmonary Insufficiency: A Systematic Literature Review and Meta-Analysis of Observational Studies

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The aim of the study was to systematically evaluate effect of CentriMag heart pump (Thoratec Corporation) as temporary ventricular assist device (VAD) and part of extracorporeal membrane oxygenation (ECMO) system on outcomes in patients with cardiac or cardiac-respiratory failure. A systematic search was conducted in five databases for the period 2003 to 2012. Fifty-three publications with data for 999 patients, supported with CentriMag, were included. In 72% studies, CentriMag was used as a VAD and in 25% as part of ECMO circuit. Mean duration of VAD support was 25.0 days in precardiotomy group, 10.9 days in postcardiac surgery cardiogenic shock group, 8.8 days in post-transplant graft failure and rejection group, and 16.0 days in post-LVAD placement right ventricular failure group. Survival on support was 82% (95% CI 70–92) for VAD support in precardiotomy cardiogenic shock indication, 63% (95% CI 46–78) in VAD support in postcardiac surgery cardiogenic shock indication, 62% (95% CI 46–76) in VAD support in post-transplant graft rejection or failure indication, and 83% (95% CI 73–92) in VAD support in post-LVAD placement right ventricular failure indication. CentriMag is an effective technology for temporary support of patients with cardiac and cardiorespiratory failure. *ASAIO Journal* 2014; 60:487–497.

Key Words: ventricular assist device, extracorporeal membrane oxygenation, mechanical circulatory support, cardiorespiratory failure, systematic literature review

Mechanical circulatory support was introduced to provide rescue treatment for patients with cardiac and cardiac-respiratory failure.[1–4] CentriMag Extracorporeal Blood Pumping System (pediatric version is named PediMag in the United States and PediVAS outside the United States; Thoratec Corporation, Pleasanton, CA) is one of the most commonly used devices to provide temporary cardiac or cardiac-respiratory support in critically ill patients. CentriMag is Conformite Europeenne marked for up to 30 days of use and also approved in number of other countries (United States, Canada, Argentina, Taiwan, Australia, Thailand, Saudi Arabia, Columbia, Turkey, Mexico, Indonesia, Singapore, Brazil, and Belarus). Since its introduction in 2003 it was extensively used for different indications, including precardiotomy and postcardiotomy cardiogenic shock in both ventricular assist device (VAD) and extracorporeal membrane oxygenation (ECMO) modes.

To facilitate informed decision making about survival and adverse events for temporary (<30 days) mechanical circulatory support, it is important to systematically evaluate current status of evidence in the field. As data from prospective randomized controlled trials are lacking, analysis need to rely on observational studies.

The aim of the study was to systematically review effect of CentriMag VAD and ECMO system on survival and adverse events in patients with cardiac or cardiac-respiratory failure.

Methods

Literature Searches

Systematic searches were performed in the following databases: Medline, Medline-in-Process, EMBASE, CENTRAL, and NHS EED. The search was conducted on February 8, 2012. The date span of the search was January 1, 2003, to February 8, 2012. Search strategy was refined to include all relevant ventricular assistance and ECMO publications to identify CentriMag data. Full details of the search strategy are provided in Supplemental Digital Content (http://links.lww.com/ASAIO/A49).

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Screening of abstracts and evaluation of full text publications was performed by two independent reviewers; disagreements were resolved by consensus. Excluded publications after evaluation of full text versions and reasons for exclusion are provided in Supplemental Digital Content (http://links.lww.com/ASAIO/A49).

Special attention was paid to identification and exclusion of duplicate publications which were reporting outcomes for the same patient groups. For this reason, all publications were grouped according to the institution where CentriMag was used in a patient sample, and the analysis of patient sample and outcomes was performed. Information about the grouping of studies is provided in Supplemental Digital Content (http://links.lww.com/ASAIO/A49). Studies were included if they reported different outcomes for the same sample of patients, or if a later publication reported an increased sample of patients. Studies that reported the same outcomes for the same sample of patients, or older publications that reported smaller sample sizes were excluded. Leading authors were contacted to validate decisions about exclusion of potential duplicates.

Data Extraction

Data from included publications were extracted by one reviewer. The second reviewer checked the quality and completeness of data extraction. Disagreements were resolved by consensus. Additional information about data extraction methods is provided in the Supplemental Digital Content (http://links.lww.com/ASAIO/A49).

Data Analysis

Survival rates and rate of adverse events were analyzed as dichotomous (binary) data. The following effectiveness outcomes were evaluated: survival on support, at discharge, at 30 days, at 90 days, at 6 months, at 1 year, at follow-up after 1 year; proportion of patients weaned from support or bridged to repeat heart transplant (for post–heart transplant graft failure indication); proportion of patients weaned from support or bridged to repeat heart transplant or bridged to long-term VAD (for post-LVAD placement right ventricular failure indication). The following

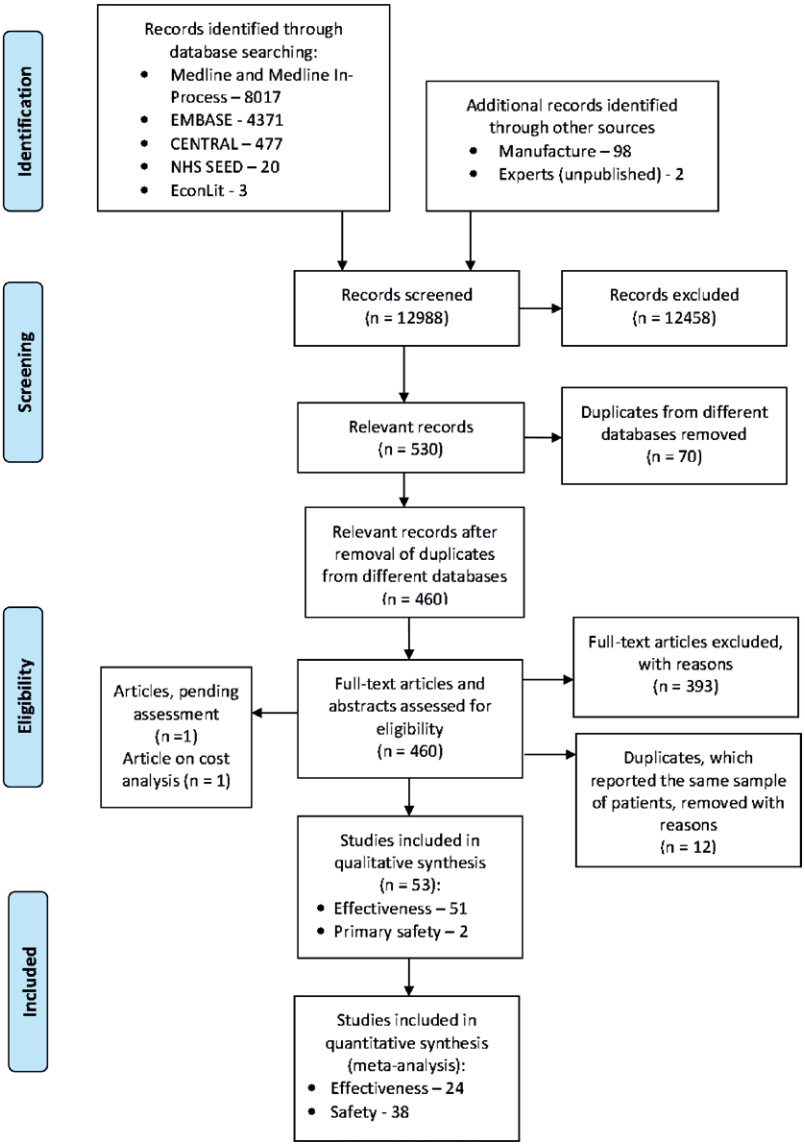

Figure 1. Study selection diagram. full color online

Table 1. Methodological Characteristics of Included Studies

First Author	Year	Study Period	Age	Population	Males, %	Indication	Country	Design	Sample Size	Mode of Support						Outcomes reported			
										% LVAD	% RVAD	% BiVAD	% VA ECMO	% VV ECMO	% VA + VV ECMO	Mort	Weaned	Bridged	Safety
Akay[12]	2011	2004–2009	65	A	59	VAD	USA	Cohort	22	100	0	0	0	0	0	Yes	Yes	No	Yes
Aziz[13]	2010	2008	45	A	50	ECMO	USA	Case series	10	0	0	0	100	0	0	Yes	No	Yes	Yes
Bhama[14]	2009	2005–2008	57	A	76	VAD	USA	Case series	29	0	100	0	0	0	0	Yes	Yes	Yes	Yes
Bindoff[15]	2009	NR	NR	NR	NR	VAD	UK	Case series	29	14	14	72	0	0	0	No	No	No	Yes
Bruschi[16]	2008	2005–2007	46	M	71	ECMO	IT	Case series	14	0	0	0	100	0	0	Yes	Yes	Yes	Yes
Byrnes[17]	2011	2007–2009	2	C	71	ECMO	USA	Cohort	7	0	0	0	100	0	0	Yes	No	No	Yes
Cassidy[18]	2009	1998–2007	13	C	NR	VAD	UK	Case series	3	0	0	0	0	0	0	Yes	No	Yes	Yes
Chen[19]	2012	2000–2010	NR	C	NR	VAD	USA	Case series	14	0	0	0	0	0	0	Yes	Yes	Yes	Yes
Chung[20]	2007	2004–2006	NR	NR	NR	ECMO	UK, DE	Case series	70	0	0	0	100	0	0	Yes	Yes	Yes	Yes
Clough[21]	2009	NR	NR	A	0	VAD	UK	Case series	2	50	0	50	0	0	0	Yes	Yes	No	No
De Robertis[11]	2008	2003–2007	32	A	88	VAD	UK	Case series	16	0	38	63	0	0	0	Yes	Yes	Yes	Yes
De Robertis[10]	2006	2003–2005	NR	M	NR	VAD	UK	Case series	12	75	25	50	0	0	0	Yes	Yes	Yes	Yes
den Uil[22]	2009	2008–2009	45	A	70	VAD	NL	Case series	2	0	100	0	0	0	0	Yes	Yes	No	Yes
DiBella[23]	2010	2007–2009	NR	A	67	ECMO	IT	Case series	6	0	0	0	100	0	0	No	Yes	Yes	No
Favaloro[24]	2008	2007–2008	47	M	50	VAD	AR	Case series	4	25	0	75	0	0	0	Yes	No	Yes	Yes
Garcia[25]	2011	2009	45	A	80	ECMO	USA	Case series	10	0	0	0	0	100	0	Yes	Yes	Yes	Yes
Gašparović[26]	2011	2008–2009	NR	A	83	VAD	HR	Case series	6	50	0	50	0	0	0	Yes	No	Yes	Yes
Haj-Yahia[27]	2009	2003–2008	39	A	75	VAD	UK	Case series	4	0	0	100	0	0	0	Yes	No	Yes	Yes
Horváth[28]	2011	2007–2010	46	A	85	VAD	CZ	Case series	20	55	10	35	0	0	0	Yes	Yes	Yes	Yes
Hosmane[9]	2012	2006–2011	NR	A	NR	ECMO	UK	Case series	10	0	0	0	100	20	0	Yes	Yes	No	No
John[29]	2007	2004–2006	57	A	100	VAD	USA	Case series	12	0	0	0	0	0	0	Yes	Yes	Yes	Yes
John[30]	2011	2004–2009	58	A	61	VAD	USA	Case series	38	21	32	47	0	0	0	Yes	Yes	Yes	Yes
Khan[31]	2008	NR	NR	A	67	ECMO	UK	Case series	3	0	0	0	33	67	0	Yes	Yes	No	Yes
Kouretas[32]	2009	NR	13	C	50	VAD	USA	Case series	2	50	0	50	0	0	0	Yes	Yes	Yes	Yes
Loforte[33]	2010b	2004–2009	NR	NR	NR	VAD	NR	Case series	36	25	47	28	0	0	0	Yes	Yes	Yes	No
Loforte[34]	2009	2006–2008	50	A	67	VAD	DE	Case series	30	0	0	100	0	0	0	Yes	No	Yes	Yes
Loforte[35]	2011	2004–2010	62	A	76	VAD	IT	Case series	42	21	45	33	0	0	0	Yes	Yes	Yes	Yes
Loforte[36]	2010a	NR	NR	A	83	VAD	IT	Case series	6	0	100	0	0	0	0	Yes	Yes	No	Yes
Maat[37]	2008	NR	NR	C	67	VAD	NL	Case series	3	33	0	67	0	0	0	Yes	No	Yes	Yes
Marquez[38]	2009	NR	NR	A	50	VAD	USA	Case series	2	0	100	0	0	0	0	Yes	Yes	Yes	No
McCormick[39]	2010	2004–2009	NR	A	NR	VAD	USA	Case series	83	36	10	30	0	0	0	Yes	No	No	Yes
Meyer[40]	2009	2007	50	A	72	ECMO	DE	Case series	18	0	0	0	100	0	0	Yes	Yes	No	Yes
Morgan[41]	2009	2007	50	A	NR	VAD	USA	Case series	9	0	0	100	0	0	0	Yes	Yes	Yes	No
Nelson[42]	2006	NR	NR	A	NR	VAD	USA	Case series	6	0	100	0	0	0	0	Yes	Yes	Yes	Yes
Netuka[43]	2011	2007-?	51	A	50	VAD	CZ	Case series	16	0	100	0	0	0	0	Yes	Yes	No	Yes
Pawlak[44]	2009	2009-?	30	M	100	VAD	PL	Case series	2	0	50	50	0	0	0	Yes	Yes	No	Yes
Reckers[45]	NR	2005–2007	NR	C	NR	ECMO	DE	Case series	33	0	0	0	0	0	0	Yes	No	No	Yes
Russo[46]	2010	2005–2009	44	M	67	ECMO	IT	Case series	15	0	0	0	100	0	0	Yes	Yes	Yes	Yes
Santise[47]	2006	2003–2005	NR	M	50	VAD	UK	Case series	2	0	0	100	0	0	0	Yes	Yes	Yes	Yes
Shuhaiber[48]	2008	2004–2006	47	A	70	VAD	UK	Case series	27	26	22	52	0	0	0	Yes	Yes	Yes	Yes
Singh[49]	2009	NR	NR	M	50	VAD/ECMO	USA	Case series	2	0	50	0	50	0	0	Yes	Yes	No	No
Soleimani[50]	2011	2008-?	47	M	73	ECMO	USA	Case series	34	0	0	0	100	0	0	Yes	Yes	Yes	No
Stepanenko[51]	2010	2008–2009	NR	NR	NR	VAD	NR	Case series	6	0	100	0	0	0	0	Yes	Yes	No	Yes
Takayama[52]	2011	2007–2009	NR	NR	NR	VAD	USA	Case series	63	0	0	0	0	0	0	No	No	No	Yes
Takayama[53]	2012	2009–2010	37	M	38	VAD	USA	Case series	8	0	100	0	0	0	0	Yes	Yes	Yes	No
Thomas[8]	2011	2003–2008	49	A	71	VAD	UK	Case series	34	6	29	65	0	0	0	Yes	Yes	Yes	Yes

(*Continued*)

Table 1. (*Continued*)

First Author	Year	Study Period	Age	Population	Males, %	Indication	Country	Design	Sample Size	Mode of Support						Outcomes reported			
										% LVAD	% RVAD	% BiVAD	% VA ECMO	% VV ECMO	% VA + VV ECMO	Mort	Weaned	Bridged	Safety
Westaby[54]	2007	NR	NR	A	80	VAD	UK	Case series	5	100	0	0	0	0	0	Yes	Yes	No	Yes
Worku[55]	2011	2001–2009	53	M	NR	VAD	USA	Case series	56	0	0	0	0	0	0	No	No	No	No
Yang[56]	2010	2007–2009	44	A	69	VAD/ECMO	USA	Case series	16	0	100	0	100	0	0	Yes	Yes	No	No
Zych[57]	2011	2001–2010	37	A	63	VAD	UK	Case series	24	0	100	0	0	0	0	Yes	Yes	Yes	No
UK ECMO Service Evaluation[7]	2013	1997–2012	NR	M	58	ECMO	UK	Cohort	67	0	0	0	81	16	3	Yes	No	No	Yes
Velik-Salchner[58]	2009	NR	47	A	50	VAD	AT	Case series	2	0	100	0	0	0	0	Yes	No	No	Yes
Sims[59]	2011	NR	51	A	100	VAD	USA	Case report	1	0	0	100	0	0	0	Yes	No	No	Yes

Population: A, adults; C, children; M, mixed. Indication: ECMO, extracorporeal membrane oxygenation; VAD, ventricular assist device. Country: AR, Argentina; AT, Austria; CZ, Czech Republic; DE, Germany; HR, Croatia; IT, Italy; NL, Netherlands; PL, Poland; UK, United Kingdom; USA, United States. Mode of support: LVAD, left ventricular assist device; RVAD, right ventricular assist device; BiVAD, biventricular assist device, VA, veno-arterial; VV, venovenous. Outcomes: mort, mortality; weaned, weaning from device support; bridged, bridging to heart transplant or long-term VAD support. All columns: NR, not reported.

safety outcomes were evaluated: rate of bleeding, thrombosis and thromboembolism, hemolysis, neurological complications, infection, renal complications, and device failure.

Data were presented for each included study in the table format. For effectiveness and safety outcomes pooling of the data from multiple studies (meta-analysis) was performed. Meta-analysis was performed using R package (program code is provided in the Supplemental Digital Content; http://links.lww.com/ASAIO/A49). As analysis of raw proportions using inverse variance method may bias results,[5] Arcsine transformation of data was used and analysis was performed using fixed-effect model using inverse variance method.[6] When possible, separate analysis for adult and pediatric populations was performed.

Results

Literature Search and Citation Screening

In total, from 12,988 records, identified in the initial search, 65 eligible publications were identified for inclusion. However, 12 publications were at risk of reporting outcomes for the same patients already reported in other included publications and were therefore excluded from analysis. There is a potential overlap between two largest UK studies[7,8] and other UK publications, although overlap was not possible to determine. References and reasons for exclusions are provided in the Supplemental Digital Content (http://links.lww.com/ASAIO/A49).

Figure 1 presents the number of studies retrieved by the searches and the records selected and rejected following the searches. Two unpublished studies were included.[7,9]

In the study by De Robertis *et al.*,[10] data on six patients in whom CentriMag VAD was used as a bridge-to-decision are not included in the analysis, since there is a high probability of reporting outcomes for the same patients in a later study.[11] However, data on adverse events are included in the analysis since the whole cohort of patients is represented in the 2006 study.

Description of Identified Studies

Table 1 summarizes the methodology of included studies. In the absence of randomized controlled trials, which is common in the field of critical care, evidence is constituted by a number of small- and medium-sized observational studies. There was wide variation and inconsistency in the reporting of included studies, and details were often sparse.

The included studies comprise three cohort studies,[7,12,17] 49 case series studies and one case report.[59] Six (11%) studies[14,15,22,30,40,42] report prospective data collection and in 13 (25%) publications[8,13,16,18,25,39,43,46,48,53,55,56] data was collected retrospectively. Studies were conducted in the United States (n = 20, 37%), the United Kingdom (n = 14, 26%), Italy (n = 5, 9%), the Netherlands (n = 4, 8%), Germany (n = 3, 6%), the Czech Republic (n = 2, 4%), the United Kingdom/Germany (n = 1, 2%), Argentina (n = 1, 2%), Austria (n = 1, 2%), Croatia (n = 1, 2%), and Poland (n = 1, 2%).

In total, the 53 publications included report clinical effectiveness outcomes for 999 patients receiving support with the CentriMag pump. The median number of patients included was 12 (IQR 4–29). Thirty-one (59%) publications included adult patients only, six (11%) publications included pediatric

patients only, 11 (21%) publications included both pediatric and adult patients, and five (9%) publications did not report the age of the participants.

In 38 (72%) publications, CentriMag was used as a VAD and in 13 (25%) publications it was used as a part of the ECMO circuit; two (3%) publications combined both indications. Mode of support was reported in 26 (65%) VAD studies and 14 (93%) ECMO studies. Left ventricular support was used in 93 (20%) patients, right ventricular support—in 198 (42%) patients, biventricular support—in 179 (38%) patients. In

Table 2. Effectiveness Outcomes in the Included Studies

		Duration of Support		Survival, % of Patients							Clinical Outcomes, % of Patients		
Study	Sample Size	Mean (SD)	Range	On Support	At Discharge	30 day	90 day	6 month	1 year	After 1 year	Weaned	Bridged HTx	Bridged VAD
VAD support in precardiotomy indication													
De Robertis[11]	16	46.9 (32.3)	6–111	81	–	81	69	69	69	–	13	19	38
Haj-Yahia[27]	4	87.7	26–105	–	100	100	100	100	100	100	–	100	–
Maat[37]	3	NR	6	67	–	–	–	-	-	–	–	–	66
Morgan[41]	9	NR	–	100	–	–	56	56	56	–	78	–	22
John[29]	12	8	4–22	83	–	75	–	75	63	–	17	–	66
Loforte[34]	14	NR	–	–	–	64	–	–	–	–	–	–	–
Loforte[35]	5	8.6 (4.3)	–	20	–	–	–	–	–	–	–	20	–
John[30]	14	17	1–29	–	50	50	–	43	–	–	–	–	–
Gašparović[26]	5	21 (23)	–	–	60	–	–	–	–	–	–	60	–
Shuhaiber[48]	9	15.3 (16)	1–51	–	–	22	–	–	–	–	–	–	–
VAD support in postcardiac surgery cardiogenic shock indication													
Akay[12]	22	5 (3)	1–12	81	–	81	69	69	69	–	13	19	38
Clough[21]	2	14.5	12–17	100	100	–	–	–	–	–	100	–	–
Marquez[38]	2	NR	–	100	100	–	–	–	–	–	50	–	50
Westaby[54]	5	4.2	2–6	80	80	–	–	–	–	–	80	–	–
Bhama[14]	7	3 (2)	–	–	43	–	–	–	–	–	43	–	–
Loforte[34]	16	NR	–	–	–	38	–	–	–	–	-	–	–
Loforte[35]	23	8.8 (2.8)	–	52	–	–	–	–	–	–	48	4	–
Netuka[43]	5	14.2 (15.4)	–	60	–	–	–	–	–	–	60	–	–
John[30]	12	8	1–60	–	33	33	–	17	–	–	–	–	–
Gašparović[26]	1	1	–	–	0	–	–	–	–	–	–	–	–
Shuhaiber[48]	7	8 (5.2)	1–14	–	–	42	–	–	–	–	–	–	–
McCormick[39]	8	7	–	–	63	63		63	63	–	–	–	–
VAD support in post-transplant graft rejection or failure indication													
Santise[47]	2	4.5	2–7	100	100	–	–	–	–	–	50	50	–
Thomas[8]	34	8*	0–45	50	–	50	–	–	32		35	15	–
Bhama[14]	10	8 (11)	–	–	60	–	–	–	–	–	70	–	–
Loforte[35]	4	7.7 (0.9)	–	100	–	–	–	–	–	–	100	–	–
Netuka[43]	5	15.6 (5.9)	–	–	–	80	–	–	–	–	80	–	–
Shuhaiber[48]	6	8.6 (2.6)	7–14	–	–	50	–	–	–	–	–	–	–
VAD support in post-LVAD placement right ventricular failure indication													
Nelson[42]	6	15.7	2–28	67	–	67	50	–	–	–	50	–	17
Stepanenko[51]	6	15*	3–33	100	–	–		–	–	–	100	–	–
Zych[57]	24	28	5–146	71	63	79	71	-	60	–	59	13	–
Bhama[14]	12	9 (2)	–	–	50	–	–	–	–	–	58	–	25
Loforte[35]	10	18.6 (9.2)	–	80	–	–	–	–	–	–	80	–	–
Netuka[43]	6	7.7 (5)	–	84	–	–	–	–	–	–	83	–	–
John[30]	12	14	1–29	–	42	58	–	33	–	–	50	–	8
Loforte[36]	6	17.5 (2.4)	13–20	100	100	–	–	–	–	–	100	–	–
Shuhaiber[48]	5	17.8 (17.6)	4–40	–	–	0	–	–	–	–	–	–	–
ECMO support in precardiotomy indication													
Russo[46]	9	NR	–	–	56	–	–	–	–	–	22	44	22
ECMO support in postcardiac surgery indication													
Russo[46]	4	NR	–	–	25	–	–	–	–	–	50	25	0
ECMO support in post-transplant graft rejection or failure indication													
Russo[46]	1	NR	–	–	0	–	–	–	–	–	0	0	0
Hosmane[9]	10	5.4 (2.4)	–	–	–	82	–	–	–	–	90	–	–
ECMO support in respiratory failure indication													
Garcia[25]	10	20 (15)	9–36	52	–	–	–	–	–	–	40	20 (lung transplant)	

BiVAD, biventricular assist device; ECMO, extracorporeal membrane oxygenation; HTx, heart transplant; LVAD, left ventricular assist device; NR, not reported; RVAD, right ventricular assist device; VAD, ventricular assist device.

*Median duration of support.

publications discussing ECMO, veno-arterious mode was used in 246 (91%) patients, venovenous mode in 23 (8%), and both modes in two (1%) patients. In one publication, patients initially received support with CentriMag BiVAD, but after several days an oxygenator was added to the circuit.[56]

Majority of the patients (n = 517, 94% for whom clinical indication was reported) had cardiac indication for support, while remaining 6% (n = 35) respiratory indication. Among patients with cardiac indication, 68% (n = 353) of the patients had postcardiotomy condition and 32% (n = 164) precardiotomy condition. Patients with postcardiotomy cardiogenic shock were distributed into three subgroups: postcardiac surgery cardiogenic shock (n = 158, 45%), post-transplant graft failure or rejection (n = 99, 28%), and post-LVAD placement right ventricular failure (n = 92, 26%). In all clinical groups, CentriMag was used as a bridge-to-recovery, bridge-to-decision, or bridge-to-transplant solution.

Three studies reporting outcomes for CentriMag as a part of the ECMO circuit included 35 patients with respiratory failure.[7,25,31] Methodological quality of studies varied. Inclusion criteria in many publications were not clearly stated, although most publications presented all available experience with ventricular assistance or ECMO support in the centers using a CentriMag pump. Only 11% of the studies report prospective data collection. However, as the main outcomes in the majority of publications are survival, weaning from support or bridging to transplant/long-term VAD, these outcomes can easily be identified in medical records. Definition and measurement of adverse events were described only in 16 (39%) studies. Selective safety outcome reporting was not possible to evaluate in majority of included publications. Relevance of observed adverse events to use of CentriMag was also not possible to evaluate in the studies, except the prospective multicentre case series study of John *et al*.[30] The method of follow-up after discharge from hospital was not reported in the majority of publications, although patients receiving temporary mechanical circulatory support, heart transplantation or long-term VAD remain under the close surveillance of the transplant centre. Fourteen papers were published as conference abstracts with no full text available. All abstracts provided limited information about clinical population, treatment, methodology aspects, outcomes, and statistical analysis. Although this may significantly decrease the value of the results and the extent to which they can be generalized, abstracts and conference proceedings remain an important source of information in the intensive care specialists' clinical community. In addition to the reporting issues, this is an opportunity for bias given observational uncontrolled design of the majority of the studies.

Effectiveness Outcomes

Data from studies which explicitly reported outcomes are provided in **Table 2**. Outcomes data for studies, which reported outcomes for mixed group of patients, are provided in the Supplemental Digital Content (http://links.lww.com/ASAIO/A49).

Duration of Support

Naïvely pooled mean duration of VAD support was 25.0 days in the precardiotomy group, 10.9 days in postcardiac

Table 3. Meta-Analysis of Effectiveness Outcomes in the Included Studies, Survival (Fixed-Effect Model)

		Survival, Percentage (95% Confidence Interval)										
Indication	N Studies (n pts)	On Support	N Studies (n pts)	At Discharge	N Studies (n pts)	30-day	N Studies (n pts)	90-day	N Studies (n pts)	6-month	N Studies (n pts)	1-year
VAD support in precardiotomy cardiogenic shock indication	5 (45)	82% (70–92%)	3 (23)	66% (45–83%)	6 (69)	66% (54–76%)	3 (29)	72% (55–87%)	4 (46)	68% (54–80%)	3 (32)	72% (55–86%)
VAD support in postcardiac surgery cardiogenic shock indication	4 (32)	63% (46–78%)	6 (32)	53% (35–69%)	5 (65)	41% (30–54%)	—	—	2 (20)	33% (15–55%)	—	—
VAD support in post-transplant graft rejection or failure indication	3 (40)	62% (46–76%)	2 (12)	71% (43–92%)	3 (45)	54% (39–68%)	—	—	—	—	—	—
VAD support in post-LVAD placement right ventricular failure indication	6 (58)	83% (73–92%)	4 (54)	62% (49–75%)	3 (41)	61% (46–75%)	—	—	—	—	—	—

Pts, patients; VAD, ventricular assist device.

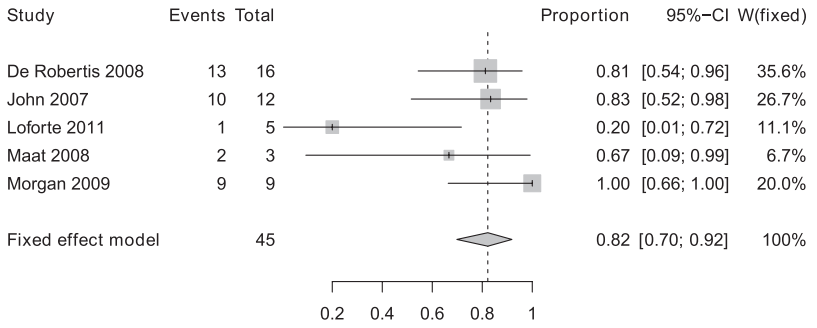

Figure 2. Survival on support in precardiotomy cardiogenic shock indication.

surgery cardiogenic shock group, 8.8 days in post-transplant graft failure and rejection group, and 16.0 days in post-LVAD placement right ventricular failure group. Mean duration of ECMO support for post–heart transplant graft failure was 5.4±2.4 days[9] and 20±15 days in respiratory failure indication group.[25] Weighted pooling (meta-analysis) of duration of support outcome was not possible due to insufficient reporting of summary statistics in included studies.

Effectiveness Outcomes

Survival and other effectiveness outcomes (proportion of patients weaned from support or bridged to heart transplant of long-term VAD) were evaluated for five major indications in 28 studies (**Table 2**).

Pooled Effectiveness Outcomes

Results of meta-analysis of effectiveness outcomes for patients supported with CentriMag VAD at different time periods are provided in **Table 3**. Results of meta-analysis showed that CentriMag offers significant benefits to patients with cardiorespiratory failure. Survival on support was 82% (95% CI 70–92) for VAD support in pre-cardiotomy cardiogenic shock indication (**Figure 2**), 63% (95% CI 46–78) in VAD support in postcardiac surgery cardiogenic shock indication (**Figure 3**), 62% (95% CI 46–76) in VAD support in post-transplant graft rejection or failure indication (**Figure 4**), and 83% (95% CI 73–92) in VAD support in post-LVAD placement right ventricular failure indication (**Figure 5**).

The outcomes of overall (beyond CentriMag support) treatment of cardiorespiratory indication up to follow-up of 1 year are provided in the Supplemental Digital Content (http://links.lww.com/ASAIO/A49). Due to limited number of ECMO studies meta-analysis was not possible.

Meta-regression, subgroup analysis, and evaluation of publication bias were not possible to perform due to low number of studies included for each indication.[6] As majority of the studies, which reported survival, included only adult population, separate analysis for adult and pediatric populations was not possible.

Adverse Events Reported in Clinical Studies

Summary statistics were not calculated for two studies (case series and case study) which were selected primarily because of safety outcomes, as their primary focus was on reporting adverse events in selected patients but not in the cohort of patients.[58,59] Meta-analysis of event rate using fixed-effect model indicated that mean occurrence of bleeding on device support was 28% (95% CI 23–32), thrombosis 7% (95% CI 5–11), hemolysis 3% (95% CI 1–6), neurological complications 7% (95% CI 4–11), infections 24% (95% CI 19–30), renal complications 28% (95% CI 22–36), and device failure 0.08% (95% CI 0.0–0.5). Device failure was reported only in two studies, whereas other 19 studies reported no device malfunction (three cases in total from 512 patients; naïvely pooled mean 0.58%).

Meta-analysis of event rate in adult compared with pediatric population showed that the mean occurrence of bleeding was 23% (95% CI 18–28%) *versus* 46% (95% CI 35–57%); thrombosis 4% (95% CI 1–9%) *versus* 22% (95% CI 14–31%); hemolysis 3% (95% CI 0–8%) *versus* 5% (95% CI 1–14%); neurological complications 6% (95% CI 3–11%) *versus* 12% (95% CI 6–20%); infections 24% (95% CI 18–30%) *versus* 26% (95% CI 16–39%); renal complications 22% (95% CI 15–31%) *versus* 39% (95% CI 27–53%); and device failure 0% *versus* 0% (95% CI 0–1%) consequently. Only incidence of bleeding and thrombosis differed statistically significant between adult and pediatric populations. Data for incidence of hemolysis,

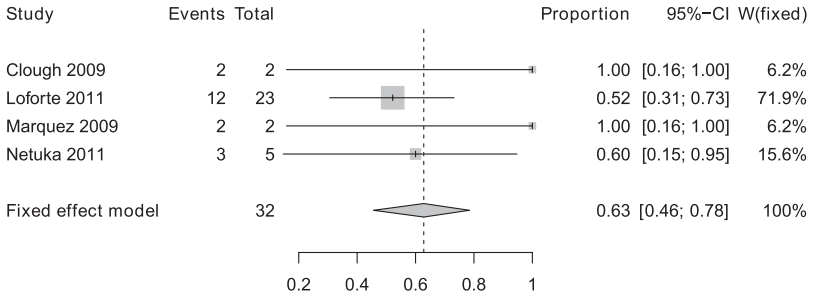

Figure 3. Survival on support in post-cardiac surgery cardiogenic shock indication.

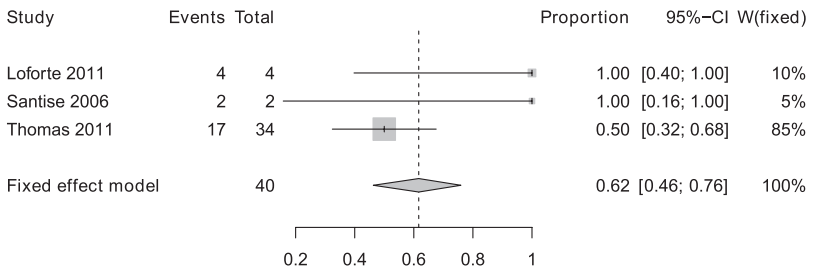

Figure 4. Survival on support in post-transplant graft rejection or failure indication.

infection, and renal complications in pediatric population were available only in a single study.[7]

Discussion

Evidence from 53 observational studies suggests that CentriMag is a versatile device for temporary mechanical circulatory support, which can be used as a VAD for all types of support (right-, left-, and biventricular) or as a part of the ECMO circuit. CentriMag provides good support in different patient groups. Average survival on VAD support varied from 61% in post-transplant graft rejection or failure indication to 83% in post-LVAD placement right ventricular failure indication. Prognosis in patients with cardiorespiratory failure remains good also beyond support with temporary VAD. Thus in the present meta-analysis 30-day survival was 66% in precardiotomy cardiogenic shock indication, 41% in postcardiac surgery cardiogenic shock indication, 54% in post-transplant graft rejection or failure indication, and 61% in post-LVAD placement right ventricular failure indication.

In the majority of publications, CentriMag was used as an urgent, immediate solution, since it can easily be utilized in both the VAD and the ECMO modes. It provides effective and inexpensive support until recovery of cardiac/respiratory function or until a decision about heart/lung transplantation or placement of a temporary, expensive ventricular assist has been made. The majority of patients present with multisystem organ failure and an often unclear neurological status, which may preclude immediate heart transplantation or implantation of a long-term VAD. Evidence suggests that immediate introduction of CentriMag support leads to recovery of heart function and weaning from device in a significant proportion of patients. In patients who are stable but not showing an improved cardiac function and in whom multisystem organ failure has been resolved, a decision about heart transplantation or placement of a permanent VAD can be made. By salvaging with CentriMag support, physicians have time to assess the dynamic of the clinical condition and make informed decisions about referring the patient to a heart transplant or permanent VAD implantation. Historical data shows, that without modern treatment, including temporary VADs, patients with cardiorespiratory shock have very poor prognosis. Analysis of incidence and mortality after cardiogenic shock, complicating acute myocardial infarction, in the United States showed that hospital survival in these patients ranged between 18.3% and 49.4% for the period of 1975–1999 years.[60] In SHOCK prestudy Registry hospital survival for post-AMI cardiogenic shock patients was 37% for the period of 1992–1997 years.[61] In our analysis, survival on support was 82.2% and 30-day survival was 66% in patients with pre-cardiotomy indication.

The important aspect of the CentriMag pump is the ability to work both in the VAD mode and as part of the ECMO circuit. Several studies report the versatility of adding an oxygenator to CentriMag VAD in situations of deterioration of respiratory function.[37,46,49,56] This may allow effective and less complex support in clinical scenarios where the clinical condition is changing.

CentriMag is used in extremely ill patients in intensive care settings and the complication rate by definition is substantial. However, since these patients will most likely die without support, the complication rate may be considered acceptable. By definition, life-saving technologies used in patients with multiorgan failure due to cardiogenic shock are very invasive. The CentriMag pump is designed to decrease hemolysis and thrombus formation by employing magnetic levitation and bearing-less technology. This allows minimal friction and thermal energy generation during operation. One cohort study (Byrnes *et al.*[17]) found a nonsignificant trend toward a lower rate of ECMO circuit change with the CentriMag pump compared with the roller pump (Stockert-Shiley Sill) (15% and 50%, respectively). Unpublished study from the UK confirmed, that centrifugal (CentriMag) pump has significantly better safety profile in comparison with roller pump for

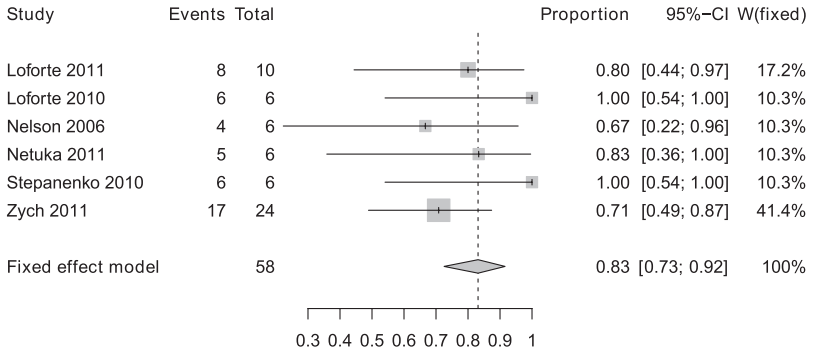

Figure 5. Survival on support in post-LVAD placement right ventricular failure indication.

ECMO support.[7] The CentriMag system has only three reported pump failures in 21 studies of 512 patients. In our analysis, adult patients experienced less complications compared with pediatric population. Incidence of thrombosis and neurological complications in pediatric population was in general in line with data reported for Berlin Heart EXCOR (Berlin Heart AG, Berlin, Germany) in the recent study from the UK.[62]

Evidence is based predominantly on case series studies with three cohort studies and one case report. No prospective controlled trials were identified in the search. The majority of the studies collected data retrospectively, which may introduce bias in the evaluation of adverse events. Some publications were presented in the format of conference abstracts which limits the validity of results and extent to which they can be generalized. Some inconsistencies and variations in reporting were observed which limits the extent to which results may be generalized.

Despite the above-mentioned limitations, the clinical-evidence base has several significant strengths. The publications included in this study present a significant proportion of the worldwide experience with the CentriMag pump. The population eligible for VAD is limited to the most critically ill patients, who will most likely die without mechanical circulatory support. As it is difficult to conduct prospective randomized controlled trials in the area of urgent, rescuing ventricular assistance, evidence from a range of observational studies may be considered as appropriate. In most studies, hard and objectively measured endpoints (survival, weaning from support or bridging to transplant/long-term VAD) are reported which do not require special measurement and can easily be captured with retrospective analysis of data. In a majority of the included publications, the centers report their total CentriMag experience at the time for publication. This increases the extent to which results can be generalized. In the case of CentriMag support for acute cardiac graft failure, an audit of all adult heart transplants was reported.

Mean duration of support varied from 8.8 days for post-transplant graft failure indication to 25.0 days in precardiotomy indication. Range of support varied from 1 to 146 days. Although CentriMag is approved for 30-day support in the EU, many studies report its use beyond 30-day time frame, when required. Recently published study of CentriMag support at Royal Brompton and Harefield NHS Foundation Trust revealed that from 2003 154 CentriMag devices were used for support of which 46 (30%) devices were used for more the 30 days.[63] Mean support time was 59 days (range 31–167 days) with major indication of refractory heart failure (85% of the patients). Overall, 74% patients were recovered or bridged, with a 1-year survival of 54%.

To the best of our knowledge, this study presents the first analysis of pooled efficacy and safety data for technology used for short-term bridge-to-decision or bridge-to-recovery indications in patients with cardiac and cardiorespiratory failure. Pooled estimates can be used as a benchmark for evaluation of efficacy and safety of other heart pumps in similar clinical situations and quality control of outcomes for short-term mechanical circulatory programs in real-world settings.

Conclusions

Results of comprehensive systematic literature review and meta-analysis showed that CentriMag is an effective technology for temporary support of patients with cardiac and cardiorespiratory failure. Evidence supports its use in different patient groups, including pre-cardiotomy, post-cardiac surgery cardiogenic shock, post-transplant graft failure or rejection, post-LVAD placement right ventricular failure.

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