

Table 1. Study Characteristics^a

First Author, Year	Location	Device	Study Design	No. of Patients	Patient	Race/	Indication for LVAD (%)	Duration of Support	Inclusion Criteria	Exclusion Criteria	
					Age, Years	% Men					Ethnicity (%)
Miller et al, 2007 ⁴⁶	Multi- center	HeartMate II	Prospect- tive, observa- tional	133	50.1	76.0	White (69) African American (23)	BTT (100) ICM (37)	126 d, median	End-stage heart failure	Severe renal, pulmonary, or hepatic dysfunction; active, uncontrolled infection; mechanical aortic valve; aortic insufficiency; other support device (except IABP)
Schulman et al, 2007 ²⁴	New York, USA	HeartMate II, DeBakey Micro- Med	Retro- spective, case series	27	55.1 (12.8)	81.5	NR	NR	NR	Implantation between October 2003 and April 2006	NR

Struber et al, 2008 ¹⁶	Hanover, Ger- many	HeartMate II	Retro- spective, case series	101	48 (13)	NR	NR	BTT (69.3) DT (30.7)	NR	12 European centers between March 2004 and January 2007	NR
Morshuis et al, 2009 ⁴⁷	Multi- center	DuraHeart	Prospec- tive, observa- tional	33	55.5 (12.5)	85.0	NR	BTT (100.0)	242 (243) d	Surgical contraindication to LVAD, high- risk cardiothoracic surgery within 30 days, aortic regurgitation, severe COPD, >1 week of ventilator support, active infection, end- stage renal or	NR

										liver disease, primary RV dysfunction	
Lahpor et al, 2010 ⁴⁸	Multi- center	HeartMate II	Registry review	411	51.0 (14.0)	81.0	NR	NR	236 (214) d	HeartMate II implanted in 1 of 64 European centers that contribute to the Thoratec data bank	Implantation <6 mo before study inception
Topkara et al, 2010 ³²	Missouri, USA	HeartMate II, Ventr- Assist	Retro- spective, case series	81	51.8 (13.7)	78.0	White (77) African American (23)	DT (29.6) BTT (70.4) ICM (46.7)	9.2 (9.2) mo	NR	NR
Wieselthaler et al, 2010 ⁴⁹	Multi- center	Heart- Ware HVAD	Nonran- domized control- led trial	23	48 (12.6)	87.0	NR	ICM (30.0)	167 (143) d	Refractory end- stage heart failure with optimal medical	Mechanical circulatory support (except IABP); cardiac transplant within 12

										therapy and inotropes. UNOS status 1A or 1B	mo; mortality within 14 days; >72 h mechanical ventilation; PE within 2 weeks; mechanical valve; aortic regurgitation; active, uncontrolled infection; thrombocytopenia; uncontrolled coagulopathy; dialysis; liver failure
Bogaev et al, 2011 ³⁹	Multi-center	HeartMate II	Secondary analysis of data from Heart-Mate II	465	51.8 (13.2)	77.6	NR	BTT (100.0) ICM (44.9)	338.9 (335.9) d	At least 18 mo follow-up	HeartMate II clinical trial

clinical
trial and
contin-
uous
access
protocol

Garbade et al, 2011 ⁵⁰	Leipzig, Ger- many	HeartMate II or Heart- Ware	Retro- spective, cohort	49	53 (12)	90.0	NR	DT (16.0) BTT (84.0)	138 (53) d	Implantation between 2006 and 2010	NR
John et al, 2011 ²⁵	Minne- sota, USA	HeartMate II	Retro- spective, cohort	102	52.6 (12.8)	74.5	NR	BTT (100.0)	327 (286) d	BTT	Exchange for device failure or destination therapy
John et al, 2011 ⁵¹	Multi- center	HeartMate II	Registry study	1982	NR	77.2	NR	BTT (100.0)	9.7 mo	CF LVAD as BTT, data as reported to INTERMACS and from the	NR

Author (Year)	Location	Device	Study Design	n	Mean Age (SD)	Mean EF (%)	Race	Primary Endpoint	Secondary Endpoint	Study Period	Notes
Schaffer et al, 2011 ¹⁵	Maryland, USA	HeartMate II	Retro-spective, case series	86	49.7, mean	70.9	NR	DT (33.7) BTT (66.3)	NR	Implantation between June 2000 and May 2009	NR
Starling et al, 2011 ²⁵	Multi-center	HeartMate II	Registry review	169	NR	78.0	White (74) African American (17)	BTT (100.0)	306 (173) d	INTERMACS registry for BTT between April and August 2008	NR
Aggarwal et al, 2012 ²⁰	Illinois, USA	HeartMate II	Retro-spective, cohort	87	62 (12.8)	86.0	White (36) African American (49)	NR ICM (57.4)	923.5 (567.3) d	Consecutive patients, between 2005 and 2009	Episode of transient bacteremia
Brewer et al, 2012 ⁵²	Multi-center	HeartMate II	Retro-spective,	896	56.8 (14.1)	76.1	White (71.9) African	NR	NR	Enrollment in HeartMate II	Exchange from HeartMate XVE to

Heart-
Mate II
BTT and
DT trials

American
(20.2)

clinical trials for
BTT or DT

HeartMate II

Bomholt et al, 2011 ⁵³	Copenhagen, Denmark	HeartMate II	Retro-spective, cohort	31	46 (24-55)	74.0	White (100.0)	BTT (81.0) DT (19.0) ICM (26.0)	317 (93-595) d	Consecutive patients	NR
Chamogeorgakis et al, 2012 ²⁷	Ohio, USA	HeartMate II	Retro-spective, case series	135	54 (14)	78.5	NR	BTT (40.0) BTD (39.0) DT (21.0)	NR	NR	NR
Donahey et al, 2012 ³¹	Georgia, USA	NR	Retro-spective, case series	57	NR	NR	NR	NR	NR	NR	NR
Eleuteri et al, 2012 ⁵⁴	Pennsylvania,	HeartMate II, Heart-	Retro-spective,	97	59 (10)	81.0	NR	BTT (33.0) BTC (21.6)	3359 (340) d	Implantation between 2006	NR

	USA	Ware HVAD	cohort					DT (47.4)		and 2011	
Fleissner et al, 2012 ²⁹	Hanover, Ger-many	Heart-Ware HVAD	Retro-spective, cohort	81	52 (16.1)	82.7	White (100.0)	ICM (45) NICM (55)	258 (531) d	Implantation in 2008, 2009, or 2011	NR
Goldstein et al, 2012 ³⁰	Multi-center	NR	INTERM ACS registry study	2006	NR, although younger age was a risk factor for percutaneous infection	NR, although older men were at increased risk for infection	NR	NR	NR	Implantation between 6/2006 and 9/2010	NR
Guerrero-Miranda et al, 2012 ⁵⁵	New Jersey, USA	HeartMate II, DeBakey	Retro-spective, cohort	120	NR	NR	NR	NR	NR	NR	NR

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Hozayen et al, 2012 ⁵⁶	Minne- sota, USA	Heart- Ware, Ventr- Assist, Heart- Mate II	Retro- spective, cohort	63	57.5 (17.4)	68.2	NR	ICM (52.4) NICM (47.6)	NR	NR	NR
Kamdar et al, 2015 ⁵⁷	Multi- center	NR	Registry study	2900	NR	NR	NR	NR	NR	All patients entered in	NR

										INTERMACS registry between 6/2006 and 3/2011	
Krabatsch et al, 2012 ⁵⁸	Berlin, Germany	HeartWare HVAD	Retro-spective, case series	142	55.1 (15.9)	82.3	NR	NR	206 d, mean follow-up	Between 9/2009 and 10/2011	Children, patients with congenital heart disease
Maiani et al, 2012 ⁵⁹	Multisite, Italy	Jarvik 2000	Registry study	65	63.0 (8.0)	89.2	NR	DT (95) ICM (53)	320 d, mean	Between 2006 and 2011	NR
Mano et al, 2012 ⁶⁰	Pittsburgh, USA	CF LVAD	Retro-spective, cohort	78	NR	NR	NR	NR	260 (265) d	Between 12/2006 and 6/2011	NR
Menon et al, 2012 ⁶¹	Aachen, Germany	HeartMate II	Retro-spective, cohort	40	58.0 (11.0)	NR	NR	DT (22.5) BTT (62.5) BTC (15.0) ICM (72.5)	NR	NYHA IIIB or IV heart failure, between 2008 and 2011	NR
Park et al,	Multi-	HeartMate	Registry	281	63.3	76.0	NR	DT (100.0)	1.7 y, mean	≥2 y follow-up	Prior HeartMate XVE

2012 ⁶²	center trial	II	study		(12.6)			ICM (24.0)			
Popov et al, 2012 ⁶³	Hare- field, United King- dom	Heart- Ware HVAD	Retro- spective, case series	34	51.0 (10.0)	85.3	NR	NR	261 (264) d	Implantation between 2007 and 2011	NR
Schibilsky et al, 2012 ⁶⁴	Tubin- gen, Ger- many	HeartMate II or Ventr- Assist	Retro- spective, case series	43	55.7 (13.3)	83.7	NR	DT (25.6) BTT (74.4)	NR	Implantation between 2006 and 2010	NR
Tarzia et al, 2012 ⁶⁵	Multi- center, Italy	Jarvik 2000	Registry review	65	65, median	89.2	NR	ICM (53.0)	NR	Implantation between 2006 and 2011	NR
Aldeiri et al, 2013 ²¹	Texas, USA	HeartMate II	Retro- spective, cohort	149	55.5 (13)	75.8	NR	ICM (59.0)	NR	Implantation between 2008 and 2012	NR
Choudhary et	New	HeartMate	Prospec-	171	54.0	82.0	NR	NR	NR	Implantation	Death within 3 mo of

al, 2013 ²⁸	York, USA	II	tive, observational cohort		(12.4)					between 11/2006 and 1/2013	device explant
Forest et al, 2013 ²³	New York, USA	NR	Retro-spective, cohort	105	56 (14)	82.0	NR	DT (45.0) ICM (51.0)	NR	Implantation between 2006 and 2012	NR
Haj-Yahia et al, 2007 ⁶⁶	Minnesota, USA	HeartMate II	Registry study	115	62 [53-69]	83.0	NR	DT (64.0) BTT (36.0)	NR	Survival to discharge, between 2008 and 2011	NR
Lalonde et al, 2013 ⁶⁷	Toronto, Canada	HeartMate II and HeartWare HVAD	Retro-spective, case series	46	50.1 (12.6)	60.8	NR	BTT (76.2) BTC (19.5) DT (4.3) ICM (26.1)	NR	Implantation between 1/2006 and 4/2012	NR
Nienaber et al, 2013 ³⁶	Minnesota, USA	HeartMate II,	Retro-spective,	78	56.8 (14.9)	79.0	White (87.0) African	DT (62.0) BTT (38.0)	1.5 (1.0) y	Implantation between 2005	LVAD implanted elsewhere, RVAD

	USA	Jarvik 2000, Ventr- Assist	case series				American (7.0)			and 2011	
Slaughter et al, 2013 ⁶⁸	Ken- tucky, USA	Heart- Ware HVAD	Pro- spective, observa- tional	332	52.8 (11.9)	71.1	White (68.7) African American (25.9)	BTT (100.0) ICM (36.7)	NR	UNOS status 1A or 1B	Other mechanical circulatory device (except IABP)
Smedira et al, 2013 ¹⁷	Ohio, USA	HeartMate II	Retro- spective, case series	92	53 (14)	78.0	NR	DT (22.0) BTT (78.0)	NR	Implantation between 10/2004 and 1/2010	NR
Stulak et al, 2013 ⁶⁹	Minne- sota, USA	HeartMate II	Retro- spective, case series	285	54, mean	51.0	NR	DT (41.0) BTT (39.0) ICM (53.0)	NR	Primary VAD implantation	NR
Tong et al, 2013 ²⁶	Ohio, USA	HeartMate II	Retro- spective,	254	NR	NR	NR	NR	NR	Between 2004 and 2012	NR

Author (Year)	Location	Device	Study Design	n	Survival (%)	Stroke (%)	Quality of Life	Complications	Duration	Implantation Period	Notes
Wu et al, 2013 ⁷⁰	Berlin, Germany	HeartWare HVAD	Retro-spective, case series review	141	51.6 (16.2)	82.5	NR	DT (28.4) BTT (71.6) ICM (44.7)	NR	Between 8/2009 and 4/2011	NR
Baronetto et al, 2014 ⁴⁰	Turin, Italy	HeartWare HVAD	Prospective, observational cohort	23	57.5	100.0	White (100.0)	BTT (52.0) DT (48.0)	7 mo	Implant with HeartWare HVAD between 4/2013 and 11/2013	NR
Cagliostro et al, 2014 ⁴¹	New York, USA	HeartMate II (other devices unspecified)	Prospective, observational cohort	253	NR	NR	NR	NR	NR	Implantation between 2010 and 2013	NR
Chan et al, 2014 ⁷¹	Singapore,	HeartMate II or	Retro-spective,	40	41.0	NR	NR	NR	NR	Implantation between 5/2009	NR

	Singapore	HeartWare HVAD	cohort							and 9/2013	
Cogswell et al, 2014 ⁷²	Minnesota, USA	HeartMate II or HeartWare HVAD	Matched cohort	60	43 (14.6)	80.0	White (73.3) African American (16.6) Asian (1.6)	BTT (95.0) DT (5.0) ICM (30.0)	NR	Age >16 y; DSM, IV substance abuse (case arm) or documented lack thereof (matched cohort)	Death in hospital, contraindications to transplantation
Dean et al, 2014 ⁷³	Multi-center	HeartMate II	Secondary analysis of HeartMate II destination therapy	401	60, median	NR	NR	BTT (50.0) DT (50.0)	19 (7-46) mo	Inclusion in HeartMate II registry database	NR

O'Horo et al -16- (MM)

clinical
trial

Retro-
spective,
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series

Registry
study

Hieda et al, 2014 ⁷⁴	Osaka, Japan	NR	Retro- spective, case series	16	37.5 (11.9)	100.0	Asian (100.0)	BTT (100.0) ICM (18.8)	387 (228) d	BTT, between 2011 and 2013	NR
Jennings et al, 2014 ⁷⁵	Detroit, USA	NR	Retro- spective, case series	16	52, median	69.0	NR	DT (69.0) BTT (31.0)	NR	Between 1/2008 and 8/2011, with systemic antimicrobial agent therapy for suppression of confirmed LVAD infection	Superficial percutaneous driveline infection
John et al, 2014 ⁷⁶	Multi- center	Heart- Ware HVAD	Registry study	332	52.7 (11.9)	71.1	NR	BTT (100.0) ICM (36.7)	NR	Secondary analysis of ADVANCE BTT and CAP	NR

Author	Location	Device	Study Type	n	Survival (%)	Quality of Life (%)	Race	ICM (%)	BTT (%)	DT (%)	Notes	Previous Device
Jorde et al, 2014 ⁷⁷	Multi-center	HeartMate II	Registry study	380	NR	81.8	White (74.5) African American (18.7)	BTT (65.0) DT (35.0) ICM (60.0)	NR		trial with ≥6 mo follow-up First 247 patients who had a HeartMate II implant after FDA device approval and 133 patients in the original HeartMate II clinical trial	NR
Kimura et al, 2014 ³³	Tokyo, Japan	DuraHeart Evaheart	Retrospective, case series	31	39.7 (11.7)	84.0	NR	BTT (100.0) ICM (12.9)	NR		End-stage heart failure, BTT	HeartMate II device implantation
Koval et al, 2014 ⁷⁸	Ohio, USA	HeartMate II	Retro-spective, case	181	54 (13.8)	80.0	White (79.0) Other races unspecified	DT (29) BTT (71) ICM (46)	NR		Implantation between 10/2004 and	Previous LVAD

Kretlow et al, 2014 ¹⁴	Texas, USA	CF LVAD	Retro- spective, case series	26	51.3 (15.7)	81.0	NR	DT (7.7) BTT (92.3)	NR	9/2011 All patients treated by the senior author for LVAD infection	NR
Masood et al, 2014 ³⁷	Michi- gan, USA	CF LVAD	Retro- spective, case series	328	56, median	77.0	NR	NR	NR	NR	NR
Moazami et al, 2014 ⁷⁹	Multi- center	DuraHeart	Prospec- tive, observa- tional study	63	54 (11.3)	84.0	NR	BTT (100.0) ICM (49.0)	NR	Advanced heart failure in patients listed for transplant at 1 of 40 investigator centers	NR
Nelson et al,	Pennsyl-	HeartMate	Retro-	12	54.3	75.0	White (86.0)	DT (42.0)	NR	Patients who	NR

2014 ⁸⁰	vania, USA	II and Heart- Ware HVAD	spective, case series		(19.3)		African American (14.0)	BTT (58.0) ICM (58.0) DCM (17.0) NICM (17.0) Familial (8.0)		required plastic surgery for complex wound management, between 2008 and 2013	
Nishi et al, 2014 ⁸¹	Osaka, Japan	Heart- Ware HVAD	Prospect- ive, cohort	9	33.5 (7.8)	66.7	NR	BTT (100.0) ICM (0)	245 (162) d	Patients eligible for cardiac transplantation, taking maximal medical therapy	NR
Raymer et al, 2014 ⁸²	Missouri, USA	HeartMate II Heart- Ware HVAD (35)	Retro- spective case series	316	NR	78.0	NR	NR	NR	Implantation between 6/2005 and 7/2013	NR
Sabashnikov et al, 2014 ⁸	Hare- field,	HeartMate II or	Retro- spective,	139	44 (13.7)	NR	NR	BTT (100.0) ICM (11.0)	514 (481) d	Implantation between 2007	NR

	United King- dom	Heart- Ware HVAD	cohort					DCM (83.0) PPM (1.0) HCM (5.0)		and 2013	
Singh et al, 2014 ⁸³	Wiscon- sin, USA	HeartMate II	Retro- spective, case series	125	NR	NR	NR	NR	628 (231.1) d	Implantation between 6/2008, and 10/2011	NR
Subbotina et al, 2014 ⁸⁴	Ham- burg, Ger- many	Heart- Ware HVAD	Retro- spective, case series	38	57 (12)	NR	NR	ICM 31.6	10 (7) mo	Implantation between 1/2010 and 8/2013	NR
Takeda et al, 2014 ⁸⁵	New York, USA	HeartMate II, Ventr- Assist, Dura- Heart, DeBakey Micro-	Retro- spective, case series	140	54.7 (14.4)	79.3	ICM (36.4)	DT (17.9) BTT (82.1)	NR	Implantation between 2004 and 2010	NR

Abou el ela et al, 2015 ⁸⁶	Missouri, USA	Med HeartMate II and HeartWare HVAD	Retro-spective, case series	363	NR	NR	NR	NR	NR	Implantation between 2009 and 2013	NR
Akhter et al, 2015 ³⁴	Wisconsin, USA	HeartMate II (120) HeartWare HVAD (1) DeBakey Micro-Med (1)	Retro-spective, case series	122	53 (12.9)	77.0	NR	ICM (43.6)	370 (336) d	Implantation between 2007 and 2013	NR
Birks et al, 2015 ⁸⁷	Multi-center	HeartWare HVAD	Registry study	332	52.7 (11.9)	71.1	White (68.7) African American	BTT (100) ICM (36.7)	NR	Secondary analysis of ADVANCE	NR

											(26.7)
											BTT and CAP trial, ≥ 6 mo follow-up
Fried et al, 2015 ¹¹	New York, USA	HeartMate II, HeartWare HVAD	Retro-spective, case series	298	NR	NR	NR	NR	NR	Implantation between 2008 and 2014	NR
Fudim et al, 2015 ⁸⁸	Tennessee, USA	HeartWare HVAD, HeartMate II	Retro-spective, case series	161	NR	NR	NR	NR	NR	Implantation between 2009 and 2014	NR
Haeck et al, 2015 ⁸⁹	Leiden, Netherlands	HeartWare HVAD	Retro-spective, case series	16	61 (8)	81.0	NR	DT (100.0) ICM (81.0)	NR	Consecutive LVAD implants	NR
Haglund et al, 2015 ⁴⁵	Tennessee,	HeartMate II, Heart-	Registry study	81	52.6 (10.6)	78.0	NR	BTT (100.0)	NR	Patients in the Vanderbilt	DT, died before the index hospitalization,

	USA	Ware HVAD								Advanced Heart Failure Registry	implantation with temporary or pulsatile LVAD, RVAD, or TAH
Harvey et al, 2015 ⁹⁰	Minnesota, USA	HeartMate II	Retrospective, cohort	230	57.0 (14.0)	80.4	NR	BTT (80.4) DT (19.6)	NR	Implantation between 2006 and 2013	NR
Henderson et al, 2015 ⁹¹	Illinois, USA	CF LVAD	Retrospective, cohort	56	52.4 (12.5)	NR	NR	NR	NR	Implantation between 2008 and 2014	NR
Imamura et al, 2015 ¹³	Japan	Evaheart, DuraHeart, Heart-Mate II, Jarvik 2000, Heart-	Retrospective, cohort	57	40.0 (12.0)	79.0	Asian (100.0)	BTB (9.0) ICM (5.0)	421 (325) d	NR	Driveline infection before first discharge

		Ware HVAD									
Krishna- moorthy et al, 2014 ⁹²	North Caro- lina, USA	HeartMate II	Retro- spective, case series	5	63.0 (12.2)	100.0	NR	DT (100.0) ICM (80.0)	NR	CIED lead removal after LVAD implant and ISHLT- defined LVAD infection	NR
Lushaj et al, 2015 ⁹³	Wiscon- sin, USA	HeartMate II, Heart- Ware HVAD	Retro- spective, case series	128	57.8	84.3	NR	DT (32.6) BTT (67.4) ICM (22.6)	NR	Between 1/2008 and 6/2014	NR
Majure et al, 2015 ⁹	District of Colum- bia, USA	HeartMate II, Heart- Ware HVAD	Retro- spective, case series	141	54.6 (13.6)	74.0	African American (61.7) Other races not specified	DT (36.1) BTT (63.9) ICM (35.0)	NR	Implantation between 2011 and 2014	Death before discharge

Maltais et al, 2015 ⁹⁴	Multi-center	HeartWare HVAD	Registry study	382	NR	NR	NR	NR	NR	Secondary analysis of ADVANCE BTT and CAP trial	NR
Matsumoto et al, 2015 ¹⁰	Osaka, Japan	Evaheart, HeartMate II	Retro-spective, cohort	39	NR	NR	NR	NR	NR	Implantation between 2007 and 2014	NR
McCandless et al, 2015 ⁹⁵	Utah, USA	HeartMate II	Retro-spective, cohort	57	56 (14.6)	87.7	NR	DT (25.0) BTT (75.0)	302 (302) d	Utah Artificial Heart Program Database, between 2008 and 2012	NR
McMenamy et al, 2015 ⁹⁶	Sydney, Australia	CF LVAD	Retro-spective, cohort	85	NR	NR	NR	NR	NR	Implantation between 2010 and 2014	NR
Nishinaka et al, 2015 ¹⁸	Japan	Evaheart	Registry review	108	42.0 (19)	NR	NR	NR	NR	Advanced heart failure, J-	NR

Author	Country	Device	Study Type	n	Age (yr)	Female (%)	Race	Primary Endpoint	Secondary Endpoint	Notes	Ref
Ono et al, 2015 ⁹⁷	Japan	HeartMate II	Registry review	104	41.7	76.0	NR	BTT (100)	299.2 d	MACS registry J-MACS registry between 2013 and 2014	NR
Potapov et al, 2015 ⁹⁸	Europe	HeartMate II	Retro-spective, cohort	479	NR	NR	NR	ICM (46.6) DCM (49.5)	610 (592) d	Implant done at 1 of 3 high-volume European centers between 2006 and 2014	NR
Trachtenberg et al, 2014 ²²	Texas, USA	HeartMate II	Retro-spective, case series	149	55.4 (13)	76.0	NR	ICM (59.1)	642 (531) d	Implantation between 2008 and 2012	NR
Tsiouris et al, 2015 ⁹⁹	Connecticut, USA	HeartMate II (136) HeartWare	Retro-spective, cohort	149	53.7 (12.1)	74.0	White (59.0) African American (41.0)	BTT (54.3) DT (45.7) ICM (37.0) NICM (63.0)	435.7 (392.2) d	Implantation between 2006 and 2013	NR

HVAD
(13)

Van Meeteren et al, 2015 ¹²	USA	NR	Registry review	734	57, median	78.6	NR	NR	NR	Hospital in Mechanical Circulatory Support Registry Network, between 2004 and 2014	NR
Wus et al, 2015 ¹⁰⁰	Pennsylvania, USA	HeartMate II	Retro-spective, case series	68	57 (11.4)	80.9	White (60.3) Other races not specified	NR	NR	First implant	No ICU-intermediate care–discharge pathway, implant at outside hospital, OHT during index hospitalization, never left ICU, had pump exchange

Yoshioka et al, 2014 ¹⁰¹	Osaka, Japan	Jarvik 2000	Retro- spective, case series	9	57 (11.0)	77.8	NR	DT (22.8) BTT (77.2)	725 d, median	NR	NR
Yost et al, 2015 ¹⁹	Illinois, USA	NR	Retro- spective, case series	134	58 (13.1)	73.1	NR	NR	NR	Implantation between 2012 and 2014	NR

Abbreviations: ADVANCE, Ventricular Assist Device for the Treatment of Advanced Heart Failure; BTB, bridge to bridge; BTC, bridge to candidacy; BTD, bridge to destination therapy; BTT, bridge to transplant; CAP, continuous-access protocol; CF, continuous flow; CIED, cardiovascular implantable electronic device; COPD, chronic obstructive pulmonary disease; DCM, dilated cardiomyopathy; DSM, *Diagnostic and Statistical Manual of Mental Disorders*; DT, destination therapy; HCM, hypertrophic cardiomyopathy; IABP, intraaortic balloon pump; ICM, ischemic cardiomyopathy; ICU, intensive care unit; INTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support; ISHLT, International Society for Heart and Lung Transplant; IV, intravenous; J-MACS, Japanese Registry for Mechanically Assisted Circulatory Support; LVAD, left ventricular assist device; NICM, nonischemic cardiomyopathy; NR, not recorded; OHT, orthotopic heart transplant; PE, pulmonary embolus; PPM, peripartum cardiomyopathy; RV, right ventricular; RVAD, right ventricular assist device; TAH, total artificial heart.

^aData presented as mean (standard deviation) or median (interquartile range)

Table 2. Patients' Comorbidities^a

Study	BMI (kg/m ²)	INTERMACS Score	Cardiac Resynchronization	
			Device, %	Diabetes Mellitus, %
Miller et al, 2007 ⁴⁶	26.8 (5.9)	NR	NR	NR
Schulman et al, 2007 ²⁴	NR	NR	NR	37.0
Struber et al, 2008 ¹⁶	NR	NR	NR	NR
Morshuis et al, 2009 ⁴⁷	NR	NR	CRT, 82	NR
Lahpor et al, 2010 ⁴⁸	NR	NR	NR	NR
Topkara et al, 2010 ³²	28.0 (5.6)	NR	NR	33.3
Wieselthaler et al, 2010 ⁴⁹	27.6, mean	NR	69.6	NR
Bogaev et al, 2011 ³⁹	NR	NR	CRT, 49.4 ICD, 76.3	NR
Garbade et al, 2011 ⁵⁰	NR	1.7 (0.74)	NR	NR
John et al, 2011 ²⁵	28.7 (6.8)	3.6 (1.7)	NR	28.4
John et al, 2011 ⁵¹	28.4 (9.1)	2.5 (2.9)	NR	NR
Schaffer et al, 2011 ¹⁵	28.3 (7.0)	2.6 (1.0)	80.2	NR
Starling et al, 2011 ²⁵	NR	NR	NR	NR
Aggarwal et al, 2012 ²⁰	27.26 (6.4)	NR	NR	NR

Brewer et al, 2012 ⁵²	26.5 (5.9)	NR	53.1	NR
Bomholt et al, 2011 ⁵³	24.2 (21.1-27.3)	NR	CRT, 83.9 (ICD, 25/31; CRT-P, 1)	16.1
Chamo-georgakis et al, 2012 ²⁷	NR	NR	NR	NR
Donahey et al, 2012 ³¹	NR	NR	NR	NR
Eleuteri et al, 2012 ⁵⁴	NR	NR	NR	NR
Fleissner et al, 2012 ²⁹	26.9 (4.6)	NR	ICD, 100.0	14.8
Goldstein et al, 2012 ³⁰	NR	NR, although noted not to be a significant predictor of infection risk	NR	NR, although noted not to be a significant predictor of infection risk
Guerrero-Miranda et al, 2012 ⁵⁵	NR	NR	NR	NR
Hozayen et al, 2012 ⁵⁶	29.5 (6.1)	NR	NR	39.7
Kamdar et al, 2015 ⁵⁷	NR	NR	NR	NR
Krabatsch et al, 2012 ⁵⁸	NR	NR	NR	NR
Maiani et al, 2012 ⁵⁹	NR	NR	NR	NR

Mano et al, 2012 ⁶⁰	NR	NR	NR	NR
Menon et al, 2012 ⁶¹	NR	NR	NR	NR
Park et al, 2012 ⁶²	NR	NR	NR	NR
Popov et al, 2012 ⁶³	26.0 (6.0)	NR	NR	21.0
Schibilsky et al, 2012 ⁶⁴	NR	NR	NR	NR
Tarzia et al, 2012 ⁶⁵	NR	3.1	NR	NR
Aldeiri et al, 2013 ²¹	28.5 (7.0)	NR	NR	46.3
Choudhary et al, 2013 ²⁸	NR	NR	NR	NR
Forest et al, 2013 ²³	NR	NR	NR	NR
Haj-Yahia et al, 2007 ⁶⁶	NR	NR	NR	34.0
Lalonde et al, 2013 ⁶⁷	24.1 (5.1)	3.2 (0.7)	NR	23.9
Nienaber et al, 2013 ³⁶	29.4 (6.1)	NR	87.0	39.0
Slaughter et al, 2013 ⁶⁸	28.2 (6.1)	3 (2-3)	NR	NR
Smedira et al, 2013 ¹⁷	27 (6.0)	NR	NR	38.0
Stulak et al, 2013 ⁶⁹	NR	NR	NR	21.0
Tong et al, 2013 ²⁶	NR	NR	NR	NR
Wu et al, 2013 ⁷⁰	25.8 (5.1)	2 (1-3)	54.6	28.4
Baronetto et al, 2014 ⁴⁰	24.4	Median 3 (range, 2-4)	78.2	13.0

Cagliostro et al, 2014 ⁴¹	NR	NR	NR	NR
Chan et al, 2014 ⁷¹	>25, 81% overweight	NR	NR	NR
Cogswell et al, 2014 ⁷²	30 (7.5)	3.6 (1.9)	NR	15.0
Dean et al, 2014 ⁷³	NR	NR	NR	NR
Hieda et al, 2014 ⁷⁴	NR	NR	0	NR
Jennings et al, 2014 ⁷⁵	NR	NR	NR	NR
John et al, 2014 ⁷⁶	28.2 (6.1)	NR	NR	NR
Jorde et al, 2014 ⁷⁷	NR	NR	NR	44.2
Kimura et al, 2014 ³³	NR	2.2 (0.8)	NR	NR
Koval et al, 2014 ⁷⁸	28 (5.9)	2.5 (3.3)	NR	NR
Kretlow et al, 2014 ¹⁴	NR	NR	NR	NR
Masood et al, 2014 ³⁷	NR	NR	NR	NR
Moazami et al, 2014 ⁷⁹	NR	NR	NR	NR
Nelson et al, 2014 ⁸⁰	29.3 (8.0)	NR	NR	58.3
Nishi et al, 2014 ⁸¹	NR	2.3 (0.5)	NR	NR
Raymer et al, 2014 ⁸²	NR	NR	NR	NR
Sabashnikov et al, 2014 ⁸	26.0 (5.0)	2.4 (1.1)	46.0	13.0

O'Horo et al -33- (MM)

Singh et al, 2014 ⁸³	NR	NR	NR	NR
Subbotina et al, 2014 ⁸⁴	NR	NR	NR	NR
Takeda et al, 2014 ⁸⁵	NR	NR	82.9	31.4
Abou el ela et al, 2015 ⁸⁶	NR	NR	NR	NR
Akhter et al, 2015 ³⁴	NR	3.0, median	NR	26.7
Birks et al, 2015 ⁸⁷	28.2 (6.1)	NR	NR	NR
Fried et al, 2015 ¹¹	NR	NR	NR	NR
Fudim et al, 2015 ⁸⁸	NR	NR	NR	NR
Haeck et al, 2015 ⁸⁹	NR	3.4 (1.3)	75.0	25.0
Haglund et al, 2015 ⁴⁵	28.8 (5.5)	2.9 (1.0)	NR	41
Harvey et al, 2015 ⁹⁰	NR	NR	NR	34.2
Henderson et al, 2015 ⁹¹	NR	NR	NR	NR
Imamura et al, 2015 ¹³	20.5 (2.9)	2.5 (0.6)	42.0	3.5
Krishna-moorthy et al, 2014 ⁹²	31 (6.3)	NR	100.0	60.0
Lushaj et al, 2015 ⁹³	28.2 (5.6)	2.7	81.3	40.6
Majure et al, 2015 ⁹	28.3 (5.9)	NR	NR	37.5
Maltais et al, 2015 ⁹⁴	NR	NR	NR	NR

Matsumoto et al, 2015 ¹⁰	NR	NR	NR	NR
McCandless et al, 2015 ⁹⁵	26.8 (5.0)	NR	NR	NR
McMenamy et al, 2015 ⁹⁶	NR	NR	NR	NR
Nishinaka et al, 2015 ¹⁸	NR	NR	NR	NR
Ono et al, 2015 ⁹⁷	NR	NR	NR	NR
Potapov et al, 2015 ⁹⁸	NR	2 (1-3)	NR	NR
Trachtenberg et al, 2014 ²²	28.4 (7.1)	NR	NR	46.3
Tsiouris et al, 2015 ⁹⁹	28.4 (5.6)	2.8 (1.1)	25.3	45.0
Van Meeteren et al, 2015 ¹²	NR	NR	NR	NR
Wus et al, 2015 ¹⁰⁰	28.6 (5.9)	NR	NR	39.0
Yoshioka et al, 2014 ¹⁰¹	NR	1.8 (0.35)	NR	NR
Yost et al, 2015 ¹⁹	NR	NR	NR	NR

Abbreviations: BMI, body mass index; CRT, cardiac resynchronization therapy; CRT-P, cardiac resynchronization therapy, with pacemaker; ICD, implantable cardioverter-defibrillator; INTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support; NR, not reported.

^aData presented as mean (standard deviation) or median (IQR).

Table 3. Infection and Outcome Data

Study	Incidence of Infection	Type of Infection	Outcome of			Comments/Limitations
			Infection	Outcome of Treatment	Microorganisms	
Miller et al, 2007 ⁴⁶	19 LVAD infections	DLI, 100.0%	NR	NR	NR	Pacemaker lead-related infections occurred later in the course of treatment
Schulman et al, 2007 ²⁴	11 LVAD infections	DLI, 18.8% BSI, 63.6% Endocardial infection, 9.1%	NR	NR	NR	NR
Struber et al, 2008 ¹⁶	24 LVAD infections	0.37 DLI/patient y	Of 21 DLI, 6 recurred; no mortality associated with DLI	NR	NR	NR
Morshuis et al, 2009 ⁴⁷	24 infections 18 LVAD infections	DLI, 72% PPI, 28%	NR	NR	NR	NR
Lahpor et al, 2010	NR	0.19-0.61 DLI/patient	0.13-0.62 deaths	NR	NR	Combined results of 3 studies

		y	attributable to			
		0.07-0.09 PPI/patient y	infection			
Topkara et al,	42 patients with at least	PPI, 78.0%	Sepsis (18.5%)	1 patient required	DLI:	Infection was associated with
2010 ³²	1 episode of infection	DLI, 22.0%	associated with	LVAD explantation	MRSA (27.2%)	greater length of hospital stay
	(number of infections	8.6% developed	decreased survival		<i>Pseudomonas aeruginosa</i>	and mortality
	not specified)	<i>Clostridium difficile</i>	Overall mortality		(18.1%)	
		infection	from LVAD		MSSA (9%)	
			infections, 19.7%		<i>Serratia marcescens</i> (9%)	
					<i>Citrobacter koseri</i> (9%)	
					<i>Enterobacter cloacae</i> (9%)	
					<i>Stenotrophomonas</i>	
					<i>maltophilia</i> (9%)	
					<i>Klebsiella pneumonia</i> (9%)	
					PPI:	
					MRSA, 1 (16.6%)	
					CoNS, 2 (33.3%)	
					<i>P aeruginosa</i> , 1 (16.6%)	
					<i>C koseri</i> , 1 (16.6%)	

N sicca, 1 (16.6%)

Wieselthaler et al, 2010 ⁴⁹	16 infections 8 LVAD infections	DLI, 100%	NR	7 treated with antimicrobial agents alone; 1 treatment failed and debridement required	NR	NR
Bogaev et al, 2011 ³⁹	89 patients with at least one infection (number of infections not specified)	20 LVAD infections; subtypes not specified	NR	NR	NR	Excluded transient bacteremia
Garbade et al, 2011 ⁵⁰	6 LVAD infections	Only DLI reported	NR	NR	NR	NR
John et al, 2011 ²⁵	22 LVAD infections	DLI, 100.0%	NR	NR	NR	Before FDA device approval, the rate of driveline infection was 26.3%, which decreased to 18.8% after FDA approval
John et al, 2011 ⁵¹	1,113 infections in 556 patients	303 LVAD infections: PPI, 33	NR	NR	NR	NR

		BSI, 233 Endocardial, 5 Line sepsis, 41 Other, 386					
Schaffer et al, 2011 ¹⁵	140 infections 68 LVAD infections	DLI, 30.0% PPI, 28.0% Sternal wound, 2%	NR	NR	NR	NR	
Starling et al, 2011 ²⁵	142 infections	DLI, 31.7% PPI, 2.8% BSI, 33.1% Line sepsis, 1.4% Other, 60.5%	NR	NR	NR	NR	
Aggarwal et al, 2012 ²⁰	30 infections	BSI only	BSI was associated with increased risk of hemorrhagic and ischemic stroke	NR	CoNS, 47.1% <i>Candida</i> spp, 8.8% <i>Enterococcus faecalis</i> , 8.8% <i>Achromobacter</i> <i>xylosoxidans</i> , 5.9%	The study aim was to show sex differences in LVAD complications; higher strokes and fewer infections were reported for women	

MRSA, 5.9%
 MSSA, 5.9%
Bacillus spp, 2.9%
Corynebacterium spp, 2.9%
E cloacae, 2.9%
P aeruginosa, 2.9%
Streptococcus mitis, 2.9%
 Other *Streptococcus* spp,
 2.9%

Brewer et al, 2012 52	230 LVAD infections	NR	NR	NR	NR	Sepsis and device-related infections increased as BMI increased to >35
Bomholt et al, 2011 ⁵³	55 infections in 12 patients	DLI, 55 No BSI, PPI, or others reported	All patients treated with antibiotics alone; no LVAD explantations	Patients had 1-8 relapses, but none required device explantation	<i>Staphylococcus aureus</i> (33%) <i>Corynebacterium</i> spp (15%) <i>E faecalis</i> (13%) <i>E coli</i> (14%)	Infection rates were low, and those that occurred were easily managed

					<i>Klebsiella</i> spp (7%)	
					<i>E cloacae</i> (3%)	
					<i>Proteus</i> spp (3%)	
Chamogeorgakis et al, 2012 ²⁷	34 infections	DLI, 26 (67.0%) PPI, 8 (21.0%)	2 deaths, both in patients with infections managed with medical therapy	5 patients had device exchange; 2, device removal; 1, recurrence; 6 infections required surgical débridement	<i>S aureus</i> (33%) CoNS (7%) <i>Pseudomonas</i> spp (27%) <i>Klebsiella</i> spp (7%) <i>Serratia</i> spp (7%) <i>Proteus</i> spp (7%) <i>Candida</i> spp (7%)	Major risk factor for recurrence was continued device need; recommended a workup to determine if device reimplantation was necessary after explantation in all cases
Donahey et al, 2012 ³¹	17 MDRO LVAD infections	NR	Infections were associated with longer length of stay but not mortality	NR	MRSA was the most common MDRO	Risk factors for MDRO included exposed driveline, hospital length of stay, and age
Eleuteri et al, 2012 ⁵⁴	23 infections	DLI, 100%	NR	NR	NR	Study included implementation of a driveline grading system–based approach to site care,

						with a significant drop in driveline infection rate (36.3% to 16.0%)
Fleissner et al, 2012 ²⁹	20 infections	DLI, 100%	No association was observed between LVAD infections and mortality	11 infections were treated medically, with 3 treatment failures requiring device explantation	37 isolates in 20 DLI <i>S aureus</i> (6/37) <i>Staphylococcus epidermidis</i> (7/37) <i>Staphylococcus warneri</i> (1/37) <i>Staphylococcus lugdunensis</i> (1/37) <i>Staphylococcus haemolyticus</i> (1/37) <i>S mitis</i> (1/37) <i>Staphylococcus dysgalactiae</i> (1/37) <i>Proteus mirabilis</i> (4/37) <i>Proteus vulgaris</i> (1/37)	Increased rates of infection associated with obesity, very low ejection fraction, use of fresh frozen plasma during surgery, and not double tunneling the driveline

Corynebacterium spp (8/37)

Granulicatella spp (1/37)

Enterococcus spp (3/37)

Pseudomonas spp (1/37)

Escherichia spp (1/37)

Goldstein et al, 2012 ³⁰	239 infections in 197 patients	DLI, 100% (percutaneous site)	23 deaths, 6 with sepsis In multivariate analysis, LVAD infection was associated with younger age and did negatively impact survival	20% of infections were associated with sepsis; pneumonia was the most common nondevice-associated infection	NR	Prolonged LVAD use was positively associated with infection, with 19% of patients developing an LVAD infection by 12 mo of support
Guerrero-Miranda et al, 2012 ⁵⁵	9 LVAD infections in patients with axial-flow LVADs; 0 in patients	NR	NR	NR	NR	Infections decreased (LVAD and non-LVAD-related) with the later generation of continuous-

	with centrifugal flow devices						flow devices (vs pulsatile and axial devices)
Hozayen et al, 2012 ⁵⁶	9 LVAD infections	DLI, 100.0%	NR	NR	NR		Foam dressing was noninferior to gauze for preventing infection and was associated with higher caregiver satisfaction
Kamdar et al, 2015 ⁵⁷	294 LVAD infections	DLI, 80.0% PPI, 6.8% BSI, 12.6%	NR	NR	NR		Younger age and prior bypass grafting were risk factors for infection
Krabatsch et al, 2012 ⁵⁸	37 LVAD infections	DLI, 75.7% BSI, 24.3%	5.3% of infections progressed to sepsis	NR	NR		NR
Maiani et al, 2012 ⁵⁹	3 episodes of sepsis in the first 12 mo after device implantation	NR	NR	NR	NR		INTERMACS score correlated with mortality and infection
Mano et al, 2012 ⁶⁰	Rates of infection varied from 19%-25% among groups (stratified by	NR	NR	NR	NR		Lower BMI was associated with more nondevice-related infections

	body surface area)					
Menon et al, 2012 ⁶¹	2 LVAD infections	DLI, 100%	1 death	1 successful débridement, device retained	<i>S aureus</i> 2 (100%)	NR
Park et al, 2012 ⁶²	383 infections 257 LVAD infections	DLI, 27% PPI, 7% BSI, 28% Other LVAD, 30% non-LVAD, 45%	NR	NR	NR	Risk of infection decreased midtrial vs early
Popov et al, 2012 ⁶³	5 infections	DLI, 100%	NR	NR	NR	NR
Schibilsky et al, 2012 ⁶⁴	7 LVAD infections	DLI, 100%	NR	NR	NR	Fewer superficial, late DLI in the double-tunnel group compared with the conventional group
Tarzia et al, 2012 ⁶⁵	NR	DLI, 5	NR	NR	NR	Postauricular gable and intraventricular pump appeared to be associated with reduced local and systemic infections

						compared with prior studies of LVAD infections
Aldeiri et al, 2013 ²¹	33 infections, 19 LVAD-related	NR	<i>P aeruginosa</i> BSI associated with stroke	NR	NR	NR
Choudhary et al, 2013 ²⁸	56 LVAD-related infections	DLI, 91% PPI, 5%	Survival not impacted by infection	NR	15 <i>Pseudomonas</i> organisms	<i>S aureus</i> infections tended to occur earlier than infections of other organisms, particularly <i>Pseudomonas</i> spp
Forest et al, 2013 ²³	27% of patients had at least 1 episode of infection (some recurrent)	DLI, 30% 43% of patients with DLI had bacteremia	Bacteremia did not impact long-term survival, but BSI was associated with longer hospital stay	NR	41% of organisms were <i>Staphylococcus</i> spp	NR
Haj-Yahia et al, 2007 ⁶⁶	32 infections, 6 LVAD-associated	DLI or PPI, 100%	Infection was a leading cause of readmission	NR	NR	NR

Lalonde et al, 2013 ⁶⁷	1.2 (1) infections/patient, including 16 episodes of pneumonia, 10 episodes of urinary tract infection	DLI, 11 episodes BSI, 5 episodes	30-day mortality from LVAD infections, 10.9%	NR	NR	Infection rates were comparable between HeartWare HVAD and HeartMate II
Nienaber et al, 2013 ³⁶	101 LVAD infections in 78 patients	DLI, 36.6% PPI, 4.0% BSI, 35.6% Cannula infection, 10.9% Mediastinitis, 5.0% CIED, 3.9%	NR	14% of infections required débridement; only 3 required device explant	NR	Candidemia was associated with poor outcome DLI was associated with prolonged therapy and destination therapy. Most superficial infections did not progress to deep infection Outcomes improved with CIED removal for concomitant LVAD/CIED infection
Slaughter et al, 2013 ⁶⁸	145 LVAD infections	DLI, 51.7% Sepsis, 48.3%	NR	NR	NR	NR
Smedira et al,	68 infections	DLI, 55.0%	Infection was the	NR	NR	NR

2013 ¹⁷	51 LVAD infections	PPI, 19.6% Septic emboli (device), 7.8% BSI, 5.8%	leading cause of readmission				
Stulak et al, 2013 ⁶⁹	NR	DLI, 41 infections 7 infections required device exchange	NR	NR	NR	NR	Study compared prophylactic antibiotics to reduce DLI; no effect noted
Tong et al, 2013 ²⁶	47 LVAD infections	PPI ± DLI, 23.4% DLI, 76.6%	NR	8 pump exchanges, 11 irrigation and debridement of the driveline or pump	10 patients had isolated bacteremia of no clinical significance; 90% were GPC; 43% of infections were gram positive, 43% gram negative, and 15% anaerobic	NR	Study of late onset infection; late infections occurred in 20% of patients and were associated with worse survival
Wu et al, 2013 ⁷⁰	66 infections	DLI, 27.3%	NR	NR	NR	NR	NR
Baronetto et al, 2014 ⁴⁰	None	NR	NR	NR	NR	NR	Primary purpose was to evaluate the use of a stat-lock and chlorhexidine disc to prevent

Author	Infections	DLI	Mortality	Treatment	Microbiology	Notes
Cagliostro et al, 2014 ⁴¹	NR	NR	NR	NR	NR	infection 76.3% of patients with a standard dressing did not have a driveline infection vs 88.6% with silver dressing
Chan et al, 2014 ⁷¹	11 infections	DLI, 100%	NR	All patients treated medically, 4 relapses	MSSA (27.6%) CoNS (20.7%)	Pus or discharge was present in 89% of patients
Cogswell et al, 2014 ⁷²	11 infections	DLI, 100%	Mortality was higher in patients who abused substances	NR	NR	Odds ratio was 5.4 for driveline infection in patients who were substance abusers
Dean et al, 2014 ⁷³	39 infections	DLI, 100%	NR	NR	NR	Leaving the velour portion of the driveline was associated with fewer infections compared with data from the original HeartMate II DT trial
Hieda et al, 2014 ⁷⁴	27 LVAD-associated infections	DLI, 55.6% BSI, 44.4%	No deaths	No medical therapy failed; no transplants	MRSA, 48 (11.9%) MSSA, 39 (9.7%)	Gram-negative bacilli were rarely isolated from the exit site

required

Staphylococcus anginosus,

5 (1.2%)

Staphylococcus capitis, 10

(2.5%)

Staphylococcus caprae, 5

(1.2%)

S epidermidis, 45 (11.1%)

S haemolyticus, 4 (1.0%)

S lugdunensis, 26 (6.4%)

α -*Streptococcus* spp 9

(2.2%)

Staphylococcus spp 14

(3.5%)

Corynebacterium spp 28

(6.9%)

K pneumonia, 39 (9.7%)

E coli, 38 (9.4%)

E aerogenes, 16 (4.0%)

S maltophilia, 7 (1.7%)

E faecalis, 22 (5.4%)

M morganii, 18 (4.5%)

C freundii, 18 (4.5)

P fluorescens, 4 (1.0%)

S marcescens, 9 (2.2%)

Jennings et al,
2014⁷⁵

17 infections in 16
patients

DLI, 13
PPI, 1
BSI, 3

NR

Chronic suppression
with antibiotics failed
in 5 patients; 3 devices
had to be explanted

MRSA, 3 (12%)

MSSA, 5 (20%)

S marcescens, 3 (12%)

P mirabilis, 1 (4%)

P aeruginosa, 1 (4%)

Staphylococcus maltophilia,
2 (8%)

Klebsiella spp, 4 (16%)

Acinetobacter spp, 1 (4%)

Achromobacter spp, 2 (8%)

Citrobacter spp, 1 (4%)

Actinomyces spp, 1 (4%)

C difficile infection, 2 patients

						<i>Corynebacterium</i> spp, 1 (4%)	
John et al, 2014 ⁷⁶	113 infections	DLI, 49.6%	NR	NR		<i>S aureus</i> was the most common microorganism in DLI	DLI was associated with diabetes mellitus and higher BMI. Sepsis was associated with decreased survival
Jorde et al, 2014 ⁷⁷	192 LVAD infections	Before FDA approval, 35%; after approval, 19%	NR	NR	NR	NR	NR
Kimura et al, 2014 ³³	17 LVAD infections	DLI, 94.1% BSI, 5.9%	34% of readmissions were attributed to infection; 8 episodes progressed to sepsis	NR		<i>S aureus</i> predominated (6 of 8 culture-positive sepsis episodes)	NR
Koval et al, 2014 ⁷⁸	89 LVAD infections	DLI, 100% (study was of DLI only)	DLI was associated with a decreased	1/3 of superficial infections progressed		<i>S aureus</i> and <i>Pseudomonas</i> spp were responsible for	When there was recurrent infection with a new organism,

			rate of survival	despite conservative therapy	1/3 of infections	gram-positive infections occurred after gram-negative infections and vice versa
Kretlow et al, 2014 ¹⁴	26 patients with at least 1 LVAD infection	DLI, 42.3% PPI, 50.0% Endocardium, 8.0%	Successfully treated infections had 29% mortality compared with 67% mortality of treatment failures	1 device was explanted; the patient survived	<i>P aeruginosa</i> , 9 (19.6%) <i>E coli</i> , 5 (10.9%) VRE, 4 (8.7%) <i>S marcescens</i> , 4 (8.7%) <i>S maltophilia</i> , 4 (8.7%) CoNS, 3 (6.5%) <i>E cloacae</i> , 2 (4.3%) MSSA, 2 (4.3%) MRSA, 1 (1.0%) <i>Acinetobacter baumannii</i> , 1 (2.2%) <i>Actinomyces</i> spp, 1 (2.2%) <i>Candida albicans</i> , 1 (2.2%) <i>C koseri</i> , 1 (2.2%) <i>Eikenella corrodens</i> , 1	Antibiotic bead and repeat debridement was associated with infection clearance in most patients (65.3%)

(2.2%)

K pneumonia, 1 (2.2%)

M morgani, 1 (2.2%)

N sicca, 1 (2.2%)

P mirabilis, 1 (2.2%)

GBS, 1 (2.2%)

Viridans group

streptococci, 1 (2.2%)

No growth, 1 (2.2%)

Masood et al, 2014 ³⁷	59 LVAD infections	Exclusively DLI and PPI	NR	0% mortality with pump exchange	NR	Pump exchange with omental transposition for confirmed PPI; had a 75% (21%) freedom from recurrence of device-related infections
Moazami et al, 2014 ⁷⁹	33 LVAD infections	DLI, 30.0% PPI, 6.0% BSI, 13.0%	NR	NR	NR	NR
Nelson et al, 2014	12 patients with at least	DLI, 50.0%	Multidisciplinary	50% mortality noted at	MSSA, 1	Complex wounds were associated

80	1 LVAD infection	Mediastinitis and LVAD exposure/erosion, 50.0%	surgical approach achieved salvage achieved in all cases		follow-up (post hospital discharge)	MRSA, 1 <i>Pseudomonas</i> spp, 4 <i>Parvimonas</i> spp, 1	with greater mortality, even after attempted surgical salvage
Nishi et al, 2014 ⁸¹	2 LVAD infections	DLI, 1 BSI, 1	NR		NR	NR	NR
Raymer et al, 2014 ⁸²	NR	NR	NR		NR	NR	BMI >35 was associated with increased risk of infection
Sabashnikov et al, 2014 ⁸	73 infections 37 LVAD infections	DLI, 95.0% PPI, 5%	NR		NR	27 organisms isolated <i>S aureus</i> (70%) <i>Enterobacter</i> spp (15%) Coliform spp (44%) <i>Pseudomonas</i> spp (48%) <i>Enterococcus</i> spp (15%) <i>Klebsiella</i> spp (22%) <i>S maltophilia</i> (19%) <i>Proteus</i> spp (19%) <i>Bacteroides</i> spp (7%)	Double tunnel was not associated with fewer driveline infections HeartMate II was associated with more infections than the HeartWare HVAD

Citrobacter spp (15%)

S marcescens (4%)

A baumannii and

calcoaceticus (4%)

Pantoea spp (4%)

Chryseobacterium

indologenes (4%)

VRE, 1/27 (4%)

Anaerobic spp, 1/27 (4%)

MRSA, 1/27 (4%)

Prevotella spp, 1/27 (4%)

Peptostreptococcus spp,

1/27 (4%)

Group B β -hemolytic

Streptococcus, 1/27 (4%)

Morganella morganii, 1/27

(4%)

Singh et al, 2014⁸³ NR

NR

NR

NR

MRSA and MSSA were the DLI decreased with exposure of

						most commonly isolated organisms	only the silicone velour portion of the driveline
Subbotina et al, 2014 ⁸⁴	6 infections 2 LVAD infections	NR	Infection was associated with 33% mortality	NR	NR	NR	NR
Takeda et al, 2014 ⁸⁵	NR	DLI, 21	NR	NR	NR	NR	NR
Abou el ela et al, 2015 ⁸⁶	98 infections	DLI, 100%	NR	22% of those with a primary revision needed a second revision	<i>Pseudomonas aeruginosa</i> , 26% MSSA, 19% MRSA, 22%	The combination of driveline relocation into the rectus muscle, velour removal, and wound- vacuum therapy had better outcomes	
Akhter et al, 2015 ³⁴	32 readmissions for infection; 21 were LVAD infections	DLI, 100%	NR	NR	NR	Infection was a leading cause of readmission in this cohort	
Birks et al, 2015 ⁸⁷	113 infections	DLI, 49.6%	NR	NR	<i>S aureus</i> was the most common organism isolated in DLI	DLI rates in white vs nonwhites were similar	

Fried et al, 2015 ¹¹	38 LVAD infections	DLI, 100%	NR	NR	NR	DLI was not associated with an increased risk of stroke or device thrombosis
Fudim et al, 2015 ⁸⁸	18 infections	DLI, 100%	NR	NR	NR	DLI was more common in those with external anchoring sutures, but this was not statistically significant after multivariate adjustment
Haeck et al, 2015 ⁸⁹	2 LVAD infections	DLI, 100%	NR	NR	NR	Both patients with DLI required hospitalization
Haglund et al, 2015 ⁴⁵	11 infections 5 LVAD infections	Sternal wound infection, 60% DLI/pump pocket infection, 40%	NR	NR	NR	More infections occurred in HeartMate II patients than in HeartWare HVAD patients (0.49 [0.70] vs 0.17 [0.68]; $P=.001$) Infection was the second most common cause of readmission after cardiac causes

Harvey et al, 2015 ⁹⁰	60 infections	DLI, 100%	NR	NR	NR	Risk of stroke was increased with infection and with postoperative sepsis
Henderson et al, 2015 ⁹¹	27 infections	DLI, 100%	NR	NR	NR	Higher BMI was associated with an increased risk of infection
Imamura et al, 2015 ¹³	24 LVAD infections	DLI, 23 PPI, 3	NR	1 pump exchanged (HeartMate II to Jarvik 2000) due to PPI	NR	Higher BMI was a predictor of readmission for infection
Krishnamoorthy et al, 2014 ⁹²	5 LVAD infections	BSI, 80%	NR	After lead extraction, 4 patients had a relapse of the BSI	<i>S aureus</i> , 20% <i>Enterococcus</i> spp, 40% <i>Pseudomonas</i> spp, 20% <i>Klebsiella</i> spp, 20% 40% were MDRO	CIED removal for LVAD infection is still associated with high rates of relapse of the infection and patient mortality
Lushaj et al, 2015 ⁹³	4 LVAD infections	NR	NR	NR	NR	BTT vs DT did not show a significant difference in infection rates
Majure et al, 2015 ⁹	66 infection-related readmissions	DLI, 39 infections	NR	NR	NR	Patients with an HVAD had a significantly higher rate of

	27 LVAD-infection– related readmissions						hospitalization than patients with a HeartMate II for LVAD- related infections (HR, 2.90 (95% CI, 1.03-8.13, <i>P</i> =.04)
Maltais et al, 2015 ⁹⁴	NR	NR	NR	NR	NR	NR	Infection overall decreased after 30 days, with 4.23 events/patient y in the first 30 d, and 1.06 events from 30-180 d, 0.97 events from 180-365 d. DLI did not change significantly over time
Matsumoto et al, 2015 ¹⁰	NR	NR	NR	NR	NR	NR	Freedom from infection at 12 mo was better with the HeartMate II (85%) than the Evaheart (46.2%)
McCandless et al, 2015 ⁹⁵	4 LVAD infections	DLI, 100%	NR	NR	NR	<i>S aureus</i> , 2 <i>Achromobacter</i> spp, 1 <i>S marcescens</i> , 1	Fewer infections with silicone than with velour

McMenamy et al, 2015 ⁹⁶	No LVAD infections	N/A	N/A	N/A	N/A	No DLIs, even in patients with a BMI >35
Nishinaka et al, 2015 ¹⁸	NR	0.36 DLI/patient year 0.04 PPI/patient year	NR	NR	NR	NR
Ono et al, 2015 ⁹⁷	NR	43% of those with BSA <1.5 and 16% of those with ≥1.5 BSA had DLI	NR	NR	NR	Smaller BSA was associated with more DLI
Potapov et al, 2015 ⁹⁸	NR	0.08 DLI/patient year	NR	NR	NR	Authors concluded that the HeartMate II has an acceptable associated complication and infection rate
Trachtenberg et al, 2014 ²²	45 infections	22 BSI originated from DLI 4, catheter-related BSI 4, UTI-related BSI	Persistent bacteremia, particularly <i>Pseudomonas</i> , was associated with all- cause	62% of BSI persisted after treatment with appropriate antibiotics and required chronic, lifelong oral suppression	<i>Pseudomonas</i> spp, 12 <i>S aureus</i> , 11 <i>E faecalis</i> , 5 <i>Candida</i> spp, 3 <i>E coli</i> , 1 <i>K pneumoniae</i> , 1	NR

			mortality and stroke		Other, 12	
Tsiouris et al, 2015 99	41 LVAD infections	DLI, 9 PPI, 1 BSI, 31	NR	1 patient required a device exchange; all others treated with 6 wk of antibiotics without need for chronic suppression	DLI: <i>S aureus</i> , 5 CoNS, 2 <i>Pseudomonas</i> spp, 1 <i>Serratia</i> spp, 1 PPI: CoNS, 1 BSI: CoNS, 16 <i>S aureus</i> , 5 <i>Enterobacter</i> spp, 3 <i>Klebsiella</i> spp, 2 <i>Serratia</i> spp, 1 <i>Candida</i> spp, 2 Viridans group streptococci, 2	DLI infection did not alter risk of death

Van Meeteren et al, 2015 ¹²	81 LVAD infections	DLI, 100% (other infections not included)	NR	DLI did not adversely affect survival or increase risk of pump thrombosis or stroke	NR	NR
Wus et al, 2015 ¹⁰⁰	NR	DLI, 0	NR	NR	NR	Driveline dressing changes varied from daily to weekly without any significant impact on DLI
Yoshioka et al, 2014 ¹⁰¹	1 LVAD infection	DLI, 100%	NR	NR	NR	DLI was late onset (2 y post implant)
Yost et al, 2015 ¹⁹	34 LVAD infections	DLI, 32.3% PPI, 8.8% BSI, 39.1%	NR	NR	NR	Infection rates in patients with and without delayed sternal closure were not statistically different

Abbreviations: BMI, body mass index; BSI, bloodstream infection; CIED, cardiovascular implantable electronic device; CoNS, coagulase-negative *Staphylococcus*; CRI, cardiac resynchronization device; DLI, driveline infection; DT, destination therapy; GPC, gram-positive cocci; MDRO, multidrug resistant organisms; MRSA, methicillin-resistant *Staphylococcus aureus*; MSSA, methicillin-susceptible *Staphylococcus aureus*; NA, not applicable; NR, not reported; PPI, pump pocket infection; UTI, urinary tract infection; VRE, vancomycin-resistant enterococcus; ±, with or without.

^a Study reported both incidents.