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# Emergency transcatheter aortic valve implantation in patients with severe aortic regurgitation and a left ventricle assist device: A case report and systematic review

**Hindrik W van der Werf[1], Remco AJ Schurer[1], Ton E Vonck[1], Janny E Poelman[1], Aafke A Klungel[1], Vladimir Cernak[2], Ad FM van den Heuvel[1] and Pim van der Harst[1]**

## Abstract

**Background:** Cardiogenic shock due to severe aortic regurgitation in patients with left ventricle assist devices is a life threatening condition. Here, we consider transcatheter aortic valve implantation as a treatment option.

**Methods and results:** A patient with a left ventricle assist device was presented to us with cardiogenic shock due to severe aortic regurgitation. We successfully implanted a transcatheter aortic valve in emergency setting. The patient recovered and underwent cardiac transplantation three months afterwards. We performed a systematic literature review and identified 10 cases of patients with a left ventricle assist device undergoing transcatheter aortic valve implantation. In these cases, there was no procedural related mortality reported. In four (40%) patients, transcatheter aortic valve implantation resulted in significant paravalvular aortic regurgitation. In two of these cases it was due to migration of the valve towards the left ventricle.

**Conclusions:** Our case report and review of literature suggests that transcatheter aortic valve implantation is a feasible and lifesaving treatment option for left ventricle assist device patients presenting with severe aortic regurgitation.

## Keywords

Aortic regurgitation, transcatheter aortic valve implantations, left ventricle assist device

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## Introduction

Severe aortic regurgitation is a life threatening condition in patients with left ventricle assist devices (LVADs). In these patients severe aortic regurgitation results in recirculation of regurgitant blood causing inadequate circulation and refractory cardiogenic shock. Treatment for severe aortic regurgitation in patients treated with a LVAD is considered primarily surgical. However, in cardiogenic shock or other emergency situations this may not be deemed feasible by the surgical team. In these cases a percutaneous approach might be the only remaining life saving alternative. Currently, two percutaneous treatment options for aortic regurgitation in patients treated with LVAD can be considered: (1) the placement of an occluder device, and (2) a transcatheter aortic valve implantation (TAVI). Here, we report a case of emergency TAVI implantation for cardiogenic shock due to severe aortic regurgitation in a patient with a LVAD. We also review the available literature

[1]Department of Cardiology, University of Groningen, University Medical Centre Groningen, The Netherlands
[2]Department of Anaesthesiology, University of Groningen, University Medical Centre Groningen, The Netherlands

**Corresponding author:**
Hindrik W van der Werf, Department of Cardiology, University of Groningen, University Medical Centre Groningen, Hanzeplein 1, P.O. Box 30001, 9700 Groningen, The Netherlands.
Email: r.van.der.werf@umcg.nl

**Table 1.** Clinical and laboratory parameters pre- and post-TAVI and at discharge.

| parameter | Pre-TAVI | 24h post-TAVI | Discharge |
|---|---|---|---|
| **Mean arterial pressure** (mmHg) | 69 | 83 | 85 |
| **Systolic blood pressure** (mmHg) | 74 | 100 | 102 |
| **Diastolic blood pressure** (mmHg) | 67 | 75 | 76 |
| **Respiration rate** (/min) | 25 | Intubated | 18 |
| **Pulse (beats/min)** | 81 (paced) | 80 (paced) | 82 (paced) |
| **Saturation** | 96% (Ventimask, 50%) | 96% (tube) | 98% |
| **Haemoglobin** (mmol/l) | 6.8 | 6.0 | 6.7 |
| **Leukocytes** ($10^9$/l) | 30 | 11.2 | 7.0 |
| **Na** (mmol/l) | 129 | 137 | 142 |
| **K** (mmol/l) | 5.3 | 3.9 | 4.3 |
| **Ureum** (mmol/l) | 12.4 | 5.6 | 3.1 |
| **Creatinine** (µmol/l) | 254 | 81 | 96 |
| **LDH** (U/l) | 6545 | 780 | 334 |
| **ASAT** (U/l) | 5353 | 1410 | 28 |
| **ALAT** (U/l) | 3030 | 1867 | 23 |
| **GGT** (U/l) | 202 | 153 | 151 |
| **pH** (arterial) | 7.31 | 7.44 | |
| **Lactate** (mmol/l) | 6.6 | 1.1 | |
| **CK-total** (U/l) | 838 | 334 | |

TAVI: transcatheter aortic valve implantation; Na: sodium; K: potassium; LDH: lactate dehydrogenase; ASAT: aspartate aminotransferase; ALAT: alanine transaminase; GGT: gamma-glutamyl transpeptidase; CK-total: creatine kinase total.

reporting on TAVI implantation in patients with LVAD and summarize outcomes.

## Methods

We first describe our case of an emergency TAVI for the indication of a refractory cardiogenic shock due to inefficient LVAD function caused by severe aortic regurgitation. We searched the PubMed medical database for all articles published on TAVI in patients with a LVAD. We used the following search terms: (transcatheter aortic valve implantations OR Aortic regurgitation) AND left ventricular assist device. No limits or restrictions were applied. All abstracts were screened to determine whether the article concerned LVAD patients undergoing TAVI. Full text articles were retrieved to obtain detailed data on patient characteristics, indication, type of LVAD, valve type and size, access route, procedural complications and outcome. Due to the small sample size of the identified cases data were tabulated and summarized without further formal statistical testing.

## Results

### *Case*

An approximately 40 year old male patient is known in our centre with a dilated cardiomyopathy due to a phospholamban gene mutation. He had experienced incessant ventricular tachycardias in the last year that could not adequately be treated by medical therapy or catheter ablation and eventually he received a LVAD (HeartMate II, Thoratec Corp., Pleasanton, CA, USA) as a bridge to transplant. During the past year he had gradually developed aortic regurgitation of increasing severity. Sixteen months after LVAD implantation he presented at the emergency department with nausea and vomiting and elevated infection parameters. He was admitted to the clinic under the suspicion of a gastro-enteritis. During the clinical course our patient developed severe dyspnoea, liver and renal failure (Table 1). Echocardiography demonstrated a severe aortic regurgitation with systolic and diastolic backward flow over the aortic valve (Figure 1). We concluded a cardiogenic shock with multi organ failure due to recycling of regurgitant blood by the LVAD device. Treatment with inotropics (milrinon, noradrenaline in high dosage and levosimendan) was initiated. The pursued clinical effect was not achieved and the clinical and biochemical parameters deteriorated further (Table 1). He was transferred to our intensive care unit to receive continuous venovenous haemofiltration. The cardiothoracic surgeon was consulted but declined conventional aortic valve surgery due to the severe clinical condition and the estimated procedural mortality of 39% (logistic EuroSCORE 1). The authors considered, as a last resort therapy, an emergency TAVI. In our experienced centre (>300 elective procedures) this would be our first emergency TAVI procedure.

At 23.00 hours, under general anaesthesia, the TAVI procedure was performed using the trans-femoral route. An 18 Fr introducer sheath was inserted into the right femoral artery. The aortic annulus dimensions were measured with DynaCT

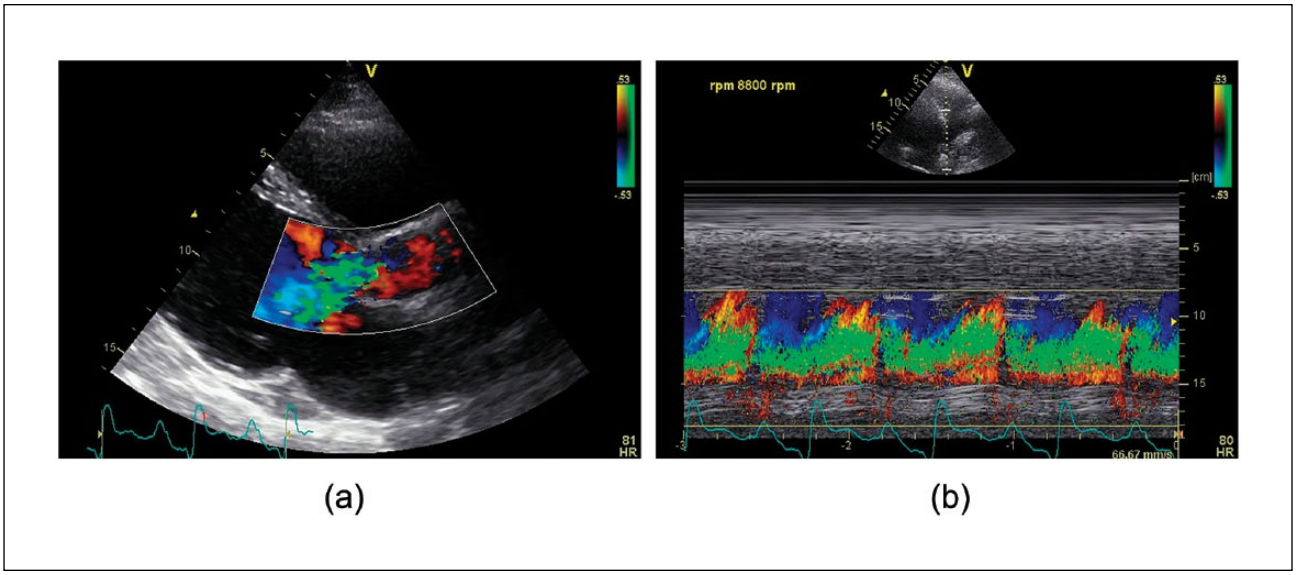


**Figure 1.** (a) Severe aortic regurgitation in left parasternal long axis transection. (b) Continous aortic regurgitation in systole and diastole in M-mode.

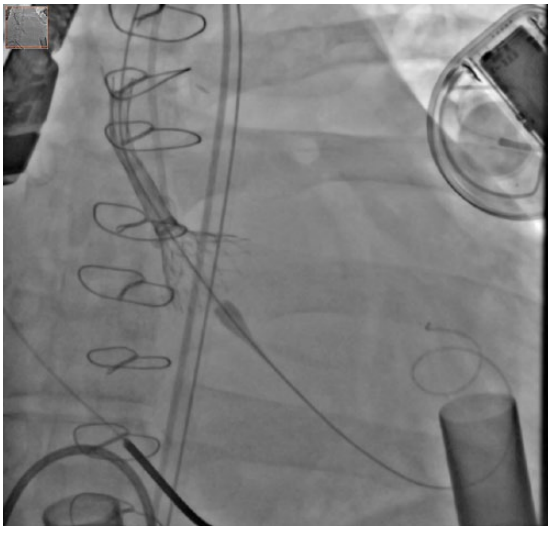

**Figure 2.** Deployment of the Medtronic CoreValve.

(Siemens AG, Medical Solutions, Germany). Based on a mean annulus diameter of 24 mm and a perimeter of 76 mm a CoreValve 29 mm valve (Medtronic, Minneapolis, MN, USA) was selected for implantation. There were no visible calcifications in the native aortic valve on the transthoracic echocardiography. Considering the risk of entrapment of a guidewire in the LVAD we used a diagnostic pigtail catheter to cross the native aortic valve. The pigtail catheter was manoeuvred into a safe position, distant from the LVAD inlet (Figure 2), and then used to introduce an Amplatz super stiff flex-tip guidewire (Boston Scientific, Marlborough, MA, USA). Pre-dilatation was not performed. By guidance of transoesophageal echocardiography, fluoroscopy and overlay images of the DynaCT, the CoreValve was manoeuvred into the optimal position (Figure 2). The placement of the valve was challenging because of the extreme tendency to migrate towards the left ventricle due to the suction of the LVAD. While pulling on the delivery system with considerable force the valve was deployed. After placement only grade 1 paravalvular aortic regurgitation was visible on transoesophageal echocardiography. Haemodynamic parameters improved instantly after valve deployment (Figure 3). Systolic ventricular pressure was below mean aortic pressure suggesting efficient LVAD functioning and no opening of the bioprosthetic valve due to severe left ventricular (LV) failure. These observations were considered satisfying and no further interventions were performed. The femoral artery was closed using a Prostar XL closure device (Abbott Laboratories, Abbott Park, IL, USA). After the procedure the patient's clinical and biochemical condition improved markedly. Renal and liver function completely recovered (Table 1) and the patient was placed back on the transplantation list the next day. As per local protocol, clopidogrel was initiated in addition to vitamin K antagonist (VKA), which the patient already received to prevent LVAD thrombosis. Three months later the patient successfully underwent heart transplantation. During transplantation a cardiotomy was performed, in which the TAVI device was removed together with the aortic root.

## *Transcatheter aortic valve implantation for aortic regurgitation in patients with LVAD: systematic review of the literature*

Our search, performed on 7 November 2014, resulted in 189 articles reporting data on patients treated with LVAD

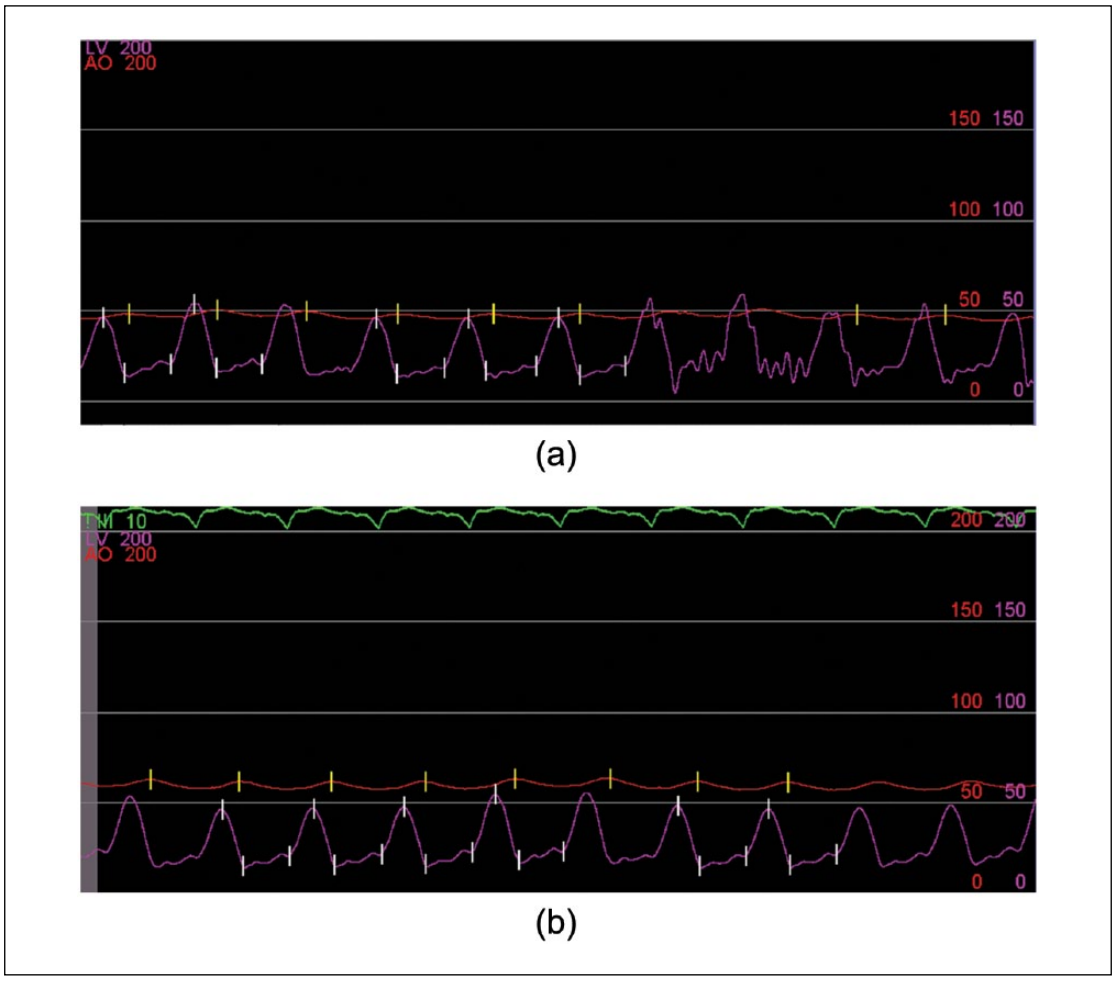


**Figure 3.** (a) Left ventricular (LV) and aortic (AO) pressure before implantation of the Medtronic CoreValve. (b) LV and AO pressure after implantation of the Medtronic CoreValve.

(Figure 4). Our case and two additional cases were retrieved using other sources than the described search results in PubMed. These three cases were not (currently) indexed in PubMed. After removing eight duplicates 181 articles remained. After reviewing the abstracts of these articles we excluded 160 articles because these did not concern implantation of TAVI in patients with a LVAD. Of the 21 remaining abstract, full text articles were obtained and an additional 11 were excluded (Figure 4).

Including our case as described above, nine cases have been published reporting TAVI treatment for severe aortic regurgitation in LVAD patients.[1–5,7–9] One TAVI was performed in a patient with aortic valve stenosis due to fusion of the leaflets in a failing LVAD.[6,10] In nine of the 10 cases the implanted LVAD was a Heartmate-2 and in one case a Heartware (Heartware, Framingham, MA, USA). In Table 2 data on patient characteristics and in Table 3 data on procedural details are presented. The age of patients ranged from 40 to 65 years and four (40%) were female. Four patients had undergone interventions on the aortic valve previously: two patients previously received an aortic homograft, one patient a bioprosthetic aortic valve and one patient suture closing of the aortic valve during LVAD implantation. Indications for performing a TAVI were acute refractory cardiogenic shock ($n$=4), end stage heart failure ($n$=4) or episodes of syncope ($n$=1). One patient received a TAVI for severe aortic regurgitation during exchange of the LVAD (due to LVAD thrombosis). Three patients underwent emergency interventions, all for acute refractory cardiogenic shock.

Access was obtained by a transfemoral, transapical, direct aortic approach and in one case the inflow cannula of the LVAD was used. In seven (70%) of the cases a Medtronic CoreValve was implanted. There was no procedural related mortality reported in these 10 cases. Of one reported case[6] an additional case[10] report was published reporting the death of the successfully TAVI treated patient after an attempt to explant the LVAD (due to recovery of the left ventricular function). During the operation the implanted valve was not functional due to complete fusion of the leaflets. The patient died a few days later due to a cerebral vascular accident. In all other cases no thrombo-embolic complications were mentioned. In four (40%) cases, significant post-procedural paravalvular aortic regurgitation was reported. In two cases this was due to migration of the

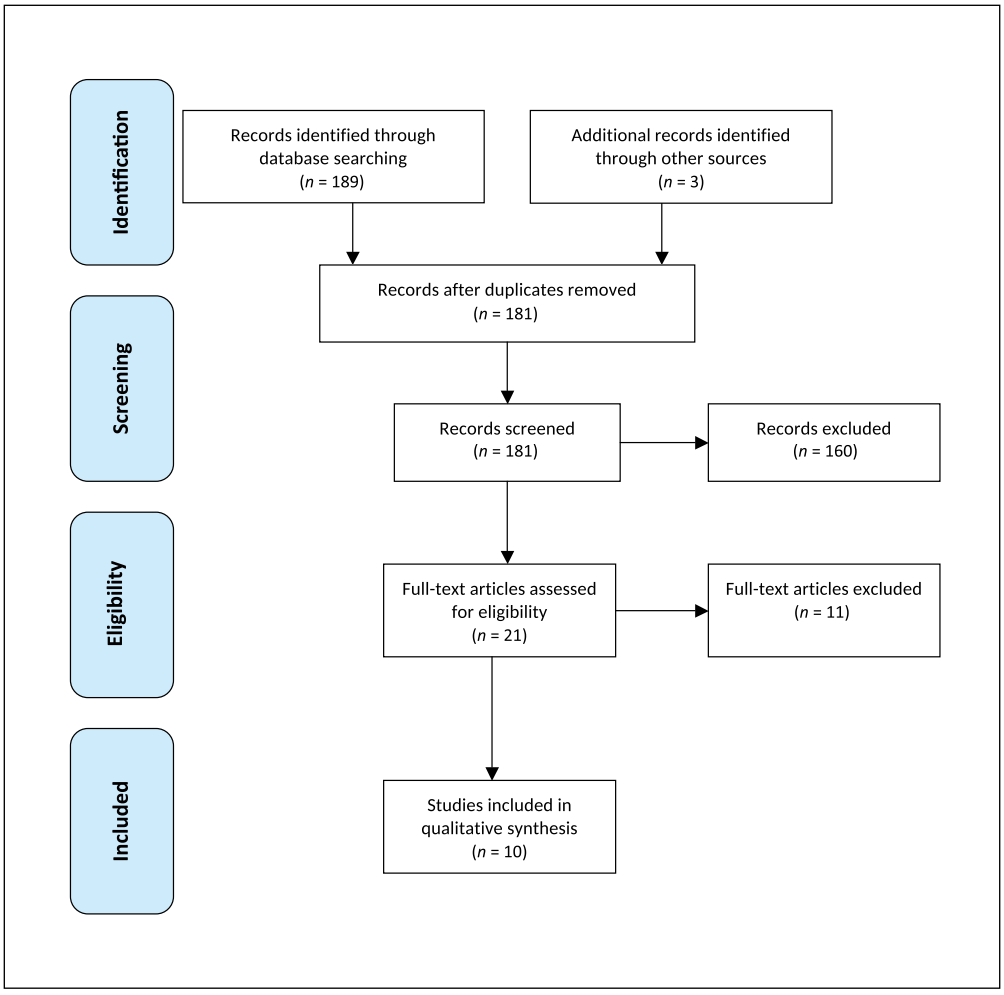


**Figure 4.** Flow diagram.

**Table 2.** List of all case reports of transcatheter aortic valve implantation in patients with severe aortic regurgitation a left ventricle assist device. Patient characteristics.

| First author and year of publication | Patient | Age (years) | Diagnosis | LVAD | Previous aortic valve interventions | Presentation | Emergency or urgent procedure[a] |
|---|---|---|---|---|---|---|---|
| d'Ancona 2012[1] | Male | 63 | iCM | HW | None | End stage heart failure | Urgent |
| Santini 2012[2] | Male | 53 | DCM | HM2 | None | Acute Cardiogenic shock | Emergency |
| Lavee 2013[3] | Female | 55 | DCM | HM2 | None | End stage heart failure | Urgent |
| Ong 2013[4] | Male | 49 | DCM | HM2 | None | End stage heart failure | Urgent |
| Khan 2013[5] | Male | 61 | NA | HM2 | Homograft | Acute Cardiogenic shock | Emergency |
| Wilson 2014[6] | Female | 64 | DCM, due to anthracycline | HM2 | Suture closure during LVAD implantation | Syncopal episodes | Urgent |
| Krause 2014[7] | Female | 65 | iCM | HM2 | None | End stage heart failure | Urgent |
| Ribichini 2014[8] | Male | 51 | DCM | HM2 | Homograft | Cardiogenic shock | Urgent |
| Vavalle 2014[9] | Female | 62 | Non-ICM | HM2 | 23mm Hancock bioprosthesis | Haemolytic anaemia | Urgent |
| Van der Werf 2014 | Male | 40 | DCM due to PLN gene mutation | HM2 | None | Acute cardiogenic shock | Emergency |

[a]Emergency = acute procedure; urgent = planned procedure.
iCM: ischaemic cardiomyopathy; DCM: dilated cardiomyopathy; non-ICM: non ischaemic cardiomyopathy; LVAD: left ventricle assist device; HW: Heartware; HM2: Heartmate 2; PLN: phospholamban

**Table 3.** List of all case reports of TAVI in patients with severe aortic regurgitation and LVAD. Periprocedural data.

| First author and year of publication | Valve type | Annulus sizing | Access route | Valve size (mm) | Significant paravalvular leakage post procedure requiring intervention | Procedural survival | Follow-up |
|---|---|---|---|---|---|---|---|
| d'Ancona 2012[1] | Edwards Sapien | MSCT | Transapical | 29 | No | Yes | One day |
| Santini 2012[2] | Medtronic, CoreValve | NA | Transfemoral | 29 | Yes due to moderate paravalvular leakage second valve implanted. | Yes | Until discharge |
| Lavee 2013[3] | Medtronic CoreValve | NA | Transfemoral | 29 | No | Yes | Three months |
| Ong 2013[4] | Medtronic, CoreValve | MSCT | Transfemoral | 31 | Yes due to migration of the valve towards the left ventricle, emergency surgery necessary | Yes | Until discharge |
| Khan 2013[5] | Medtronic, Melody | TTE and balloon sizing | Transfemoral | 22 | No | Yes | 10 months |
| Wilson 2014[6] | Medtronic, CoreValve | MSCT | Transfemoral | 29 | No | Yes | NA |
| Krause 2014[7] | Medtronic, CoreValve | TEE and MSCT | Direct aortic | 31 | Yes due to migration of the valve towards the left ventricle, second valve implanted | Yes | 12 months |
| Ribichini 2014[8] | Medtronic, CoreValve | TEE and MSCT | Transfemoral | 31 | Yes post-dilation with 30mm balloon | Yes | NA |
| Valvalle[9] | Edwards, Sapien | NA, valve in valve procedure | LVAD inlet | 23 | No | Yes | Until discharge |
| Van der Werf 2014 | Medtronic, CoreValve | DynaCT | Transfemoral | 29 | No | Yes | 12 months |

MSCT: multi-slice computed tomography; NA: not available; TTE: transthoracic echocardiography; TEE: transoesophageal echocardiography; LVAD: left ventricle assist device

valve towards the left ventricle. In one case, post dilatation was performed and paravalvular leakage was successfully reduced. In two cases, a second valve was required during the same setting and in one case emergency surgery was required. During the reported follow-up, varying from one day to 12 months, no major events were reported.

## Discussion

### *Mechanism of development of aortic regurgitation in LVAD patients*

All cases with severe aortic regurgitation in the presence of LVAD had LVAD devices based on continuous flow. From observational data it has also been suggested that the progression of aortic regurgitation might be more likely to occur in patients treated with continuous flow devices as compared with pulsatile flow devices.[11] Moderate to severe aortic regurgitation develops (or deteriorates) after implantation of a LVAD in more than 50% of the patients treated for 18 months or longer.[1] The proposed hypothesis is that in continuous flow LVAD there is a constant and more complete LV unloading, resulting in a continuously closed or minimally mobile native AV. The lack of normal AV motion might result in leaflet fibrosis causing or deteriorating regurgitation. The mechanism of the aortic valve degeneration and development of aortic regurgitation in LVAD patients is not entirely clear. Factors that play a role in this process are thought to involve commissural fusion of the valve leaflets which is associated with decreased valve opening and an increasing prevalence of aortic regurgitation,[14–16] and altered flow patterns leading to aortic incompetence and subsequently aortic regurgitation.[17] Other factors associated with the development of aortic regurgitation after LVAD implantation are closed aortic valves, female sex, higher age, higher LVAD flows and longer duration of LVAD therapy.[12,13]

However, the pre-operative grade of aortic regurgitation does not correlate well with the development of aortic regurgitation post LVAD implantation.[11,13]

### *Treatment of aortic regurgitation in LVAD patients*

The primary treatment option for aortic valve dysfunction is usually considered surgical, also in LVAD patients. However, due to co-morbidities, complex previous cardiac surgery and emergency setting characterized with end stage heart failure or cardiogenic shock, surgery might not always be deemed feasible by the surgical team. In this setting, the only remaining alternative to

treat aortic valve dysfunction might be a percutaneous approach. For the percutaneous treatment of aortic regurgitation in LVAD patients two treatment strategies can be considered. Both the percutaneous implantation of an aortic valve or the placement of an Amplatzer Cribiform Septal Occluder to completely occlude the native aortic outflow have been performed successfully. However, for both options there are only anecdotal reports available.[18–20] The major limitations of an Amplatzer device is the limited length of the delivery sheath (80 cm), which, depending on the height of the patient, complicates the femoral approach. A subclavian approach might be the only feasible route for these patients. Another limitation for the use of an Amplatzer device is the risk of embolization of the device especially in non degenerative native valves.[18,19] Here, we report a case of percutaneous implantation of an aortic valve. The conceptual advantage is the presence of a functional valve in the setting of LVAD failure.

However, this theory does not always stand in real life, as there have been reports of fusion of the cusps and formation of a pseudomembrane.[10]

### *Percutaneous valve replacement to treat aortic regurgitation in LVAD patients*

Currently, there exists an increasing number of devices designed to replace the aortic valve via the percutaneous route. The data supporting the use of TAVI in aortic regurgitation are limited. Many, if not all, devices have their inherited limitations for the use in aortic regurgitation. The majority of available data on TAVI in aortic regurgitation are reporting on devices based on self expanding frames. Due to the high risk of dislocation in patients with aortic regurgitation treated with a LVAD, newer retrievable self-expanding devices and devices like the Engager (Medtronic, Minneapolis, MN, USA), Lotus valve (Boston Scientific, Marlborough, MA, USA) or Jenavalve (Jenavalve Technologies, München, Germany) seem to have important theoretical benefits over the earlier generation valves in native aortic valve regurgitation. However, only anecdotal data are available supporting the use of these newer devices.

The decision of which access route is preferable for a LVAD patient requiring TAVI might not be different from the decision making in regular transcatheter valve implantations. Due to its less invasive nature and lower short and mid term mortality, the transfemoral route might also be considered the first choice in this setting.[21] When peripheral artery disease limits the feasibility of the transfemoral route, alternative delivery routes can be preferred. The transapical route is probably the least advantageous, due to the presence of the LVAD inlet, but even this delivery route has been reported previously.[1] In one case, the inlet of the LVAD has even been used successfully to deliver the aortic valve prothesis.[9]

Theoretically, there is a high risk of valve thrombosis and thromboembolic complications after TAVI in LVAD patients. This might be due to a low flow state over the implanted valve. Maintaining the flow over the TAVI device as high as possible to favour adequate valve motion might prevent these complications. In LVAD patients with severely impaired LV-function this is not always feasible. All patients treated with a LVAD already receive oral anticoagulation to prevent LVAD thrombosis. In our patient we added the P2Y12 inhibitor clopidogrel, in addition to a VKA, as per local protocol. The combination of VKA, P2Y12 inhibitor and aspirin can be considered but is probably associated with an increased bleeding risk.

### *Delivery of a percutaneous valve in LVAD patients*

The delivery of a percutaneous valve for aortic regurgitation in a patient treated with a LVAD is a challenging intervention. In aortic regurgitation of a native aortic valve of the relatively young LVAD patient calcification is either absent or minimal in comparison with the typical elderly TAVI patient. The absence of calcification of the native valve reduces proper anchoring of the percutaneous valve and increases the risk of dislocation of the valve. Oversizing of 10–20% is generally recommended in TAVI with self-expanding frames. We do not recommend to oversize more than this general recommendation because of the increasing risk of annulus rupture. In all cases reported in the literature (Tables 2 and 3), no valve migration occurred when there was a prior intervention of the aortic valve. These patients with a fixed annulus probably provide better support for the percutaneous valve.

If serious paravalvular leakage develops due to valve migration, post-dilation might not be efficacious. Placement of a second valve, as demonstrated in the cases of Santini[2] and Krause,[7] might be the only feasible option to adequately reduce the paravalvular aortic regurgitation. Another option can be to snare the frame and pull it antegradely in the direction of the aorta. This latter option is only possible with self expanding valves and has a risk of dislocating the valve above the aortic annulus. Valve migration might be a serious risk in this population, even hours after the initial procedure, an example being the case in Ong.[4]

In LVAD patients presenting with cardiogenic shock due to severe aortic regurgitation there is a continuous reverse flow and negative pressure gradient over the aortic valve. When the rotations of the LVAD are increased this will result in even more recirculating volume and more suction of the LVAD inlet. These forces probably increase the already existing tendency of the valve to migrate in the direction of the left ventricle. Rapid pacing is often advised in the placement of percutaneous valves in aortic regurgitation for pressure and volume reduction to prevent dislocation. However, in the case of LVAD, especially when a patient is completely dependent on LVAD function, rapid pacing is less effective, because the left ventricle might not contribute to cardiac output and the pressure gradient and flow over the aortic valve is

already low or even negative. Reducing the rotation speed of the LVAD during valve deployment and thereby reducing the regurgitating flow over the aortic valve and suction of the apical LVAD inlet could theoretically provide a time-window for a more stable valve deployment as shown in our case. However, the evidence is limited and we also identified a case that shows successful valve placement is also possible without reducing the rotation speed.[3]

### *Limitations*

Our case and the cases previously reported treating LVAD patients with TAVI were successful. However, there are important limitations to consider when interpreting these successes. First, the data available to date are only based on case reports and do not concern prospectively designed trials with prospectively included patients and prospectively defined outcome parameters. Second, the duration of follow-up among the reported cases varies considerably and no systematic data on long-term outcomes are available. Finally, a publication bias of only successful cases might exist and influence the correct interpretation of the odds of successful treatment. Nevertheless, even considering these limitations, the reported data demonstrate that TAVI can be a successful and lifesaving intervention in severe aortic regurgitation in at least some of the LVAD patients.

## Conclusion

We presented a case and provide an overview of the literature to illustrate that TAVI treatment, although challenging, can be a feasible and lifesaving treatment option for LVAD patients in cardiogenic shock due to severe aortic regurgitation.

### Conflict of interest

The authors declare that there is no conflict of interest.

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