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Role of Lithotripsy for Small Calcified Iliacs in the Era of Big Devices

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Abstract

Purpose of Review In recent years, transcatheter aortic valve replacement (TAVR) and percutaneous mechanical circulatory support (MCS) systems have seen a widespread diffusion. These devices require the insertion of large femoral sheaths in a population of patients often presenting with calcific peripheral artery disease. Small and severely calcified iliac vessels are associated with increased risk of vascular complications or strategy changes such as the use of an alternative subclavian or transapical approach for TAVR or a conversion to surgery. Intravascular lithotripsy (IVL) technology applies mechanical pressure waves to modify vessel calcifications. It has been applied both in coronary and peripheral calcific disease with promising results. The use in vessel preparation before the insertion of large sheaths is an emerging application of this device.

Recent Findings After case reports and presentations of isolated cases, two multicenter registries collected 42 and 12 patients treated with peripheral IVL before TAVR and MCS insertion. In most cases, the largest balloons were used in the iliac arteries with success achieved directly or using a separate insertion sheath in all cases. Low-pressure dilatation during energy delivery avoided dissections or vessel ruptures with no need of postprocedural stent implantation or emergency surgical repair.

Summary IVL can successfully modify the arterial compliance and facilitate transfemoral delivery of TAVR or MCS in patients with calcified iliofemoral vessels, reducing the need for alternative TAVR access routes and allowing to perform high-risk coronary procedures with adequate support.

Keywords Transcatheter aortic valve replacement · Mechanical circulatory support devices · Peripheral intravascular lithotripsy

Introduction

The last decade has seen a major expansion in indications to transfemoral aortic valve replacement (TAVR) and the diffusion of mechanical circulatory support (MCS) systems such as Impella (Abiomed, Inc., Danvers, MA) and veno-arterial extracorporeal membrane oxygenation (VA-ECMO). All these devices require the delivery of large arterial introducers, ranging from the 12 Fr of the Impella 2.5 to the 21 Fr required for the largest VA-ECMO arterial cannulas. Not infrequently, elderly patients proposed for TAVR and patients planned for periprocedural MCS in cases of high-risk percutaneous coronary revascularization present diffuse atherosclerotic disease, involving peripheral arteries. The presence of severe calcific

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iliofemoral disease can prevent the delivery of large sheaths and correlates with a high incidence of severe complications such as dissection, occlusion, or perforation. Conventional peripheral angioplasty has a limited efficacy when facing severe calcifications and requires high-pressure dilatations, with high risk of complications.

The application of intravascular lithotripsy (IVL) has recently emerged as a safe and effective option in the treatment of calcified vascular lesions, both in coronary and peripheral arteries. The aim of this technology is the development of controlled fractures of the arterial calcific sheets by means of acoustic waves, reducing the stiffness of vascular calcifications and allowing balloon dilatation with no need for high inflation pressures. In this manuscript, the use of IVL for facilitating the insertion of large-dimension sheaths in TAVR and MCS represents one possible field of application.

Mechanism of Action of Intravascular Lithotripsy

Lithotripsy was successfully applied in the treatment of kidney and gallbladder stones and of dysmorphic joint calcifications for over 30 years. Only recently, the application of the same physical principles to vessel wall calcifications was possible with the introduction of a dedicated intravascular emitter, which obtained CE mark in 2017. IVL mechanism of action consists in the delivery of pulsatile mechanical energy which does not affect the elastic normal segments of the vessel but fragments both superficial and deep vessel calcifications, with a "plaque modification" effect. Surrounding soft tissues are not affected by mechanical waves, minimizing the risk of vessel injury.

The Shockwave IVL system (Shockwave Medical, Santa Clara, CA, USA) consists of three different components: (a) a battery-powered rechargeable *generator*, capable of producing 3 KV of energy, preprogrammed to deliver a fixed number of pulses per balloon; (b) *a cable connector* that links the generator with the catheter and (c) a single-use sterile *catheter* with a semi-compliant balloon with miniaturized lithotripsy emitters distributed along its length. Specifically, peripheral IVL balloons present five emitters, each one converting electrical energy into transient acoustic pressure pulses (1 pulse/s for a maximum of 300 pulses divided into 10 cycles) (Fig. 1).

Available balloon measures range from 3.5 to 7.0 mm for peripheral IVL (unique length 60 mm). All balloons are compatible with 6-Fr introducers, with the exception of 6.5 mm and 7.0 mm, requiring a 7-Fr sheath. The crossing profile ranges from 0.054 to 0.073″. The balloons must be carefully prepared in order to eliminate air bubbles which could prevent optimal mechanical wave transmission. IVL therapy is delivered with balloon inflated to sub-nominal pressure of 4 Atm, followed by inflation to 6 Atm to reach nominal dimensions. Previous OCT studies on coronary IVL demonstrated lumen enlargement and calcium fractures after IVL treatment [1, 2]. With respect to other calcium modifying technologies, the risk of distal embolization appears to be lower and, in reason of the low inflation pressures required, the incidence of local complications such as dissection or vessel perforation is expected to be low.

Role of Lithotripsy for Facilitating Transfemoral Transcatheter Aortic Valve Replacement

Since the first in human TAVR in 2002, this minimally invasive technique has continuously gained popularity, becoming a standard of care for severe aortic stenosis patients presenting with increased surgical risk. Nowadays, international guidelines give a class IB indication to TAVR for patients at intermediate or high surgical risk (STS $\geq$4%) or with other risk factors not included in conventional risk scores, such as frailty, porcelain aorta, and previous chest radiation [3]. Recent publications in low-risk patients challenge these limited indications, demonstrating significant reduction in adverse events at 1 month and 1 year follow-up with TAVR with respect to surgical aortic valve replacement [4, 5].

In early TAVR experience, the transapical (TA) approach was frequently used, due to the high rate of vascular complications in transfemoral (TF) TAVR patients, due to the use of bulky introducers. Technological improvements and operator experience has made TF TAVR safer, with a major reduction in vascular complications. Recently, several studies have demonstrated that the clinical benefit related to TAVR is particularly evident for transfemoral procedures, with lower rates of stroke, acute kidney injury, and long-term rehospitalization in TF TAVR patients [6]. The 2017 ESC guidelines consider the feasibility of TF approach as a pivotal element in the decisional process between surgery and percutaneous treatment [3]. Alternative access routes, such as the TA, trans-subclavian, direct aortic or transcaval, are applied only to those patients with unapproachable prohibitively calcified or too small peripheral vessels.

At the beginning of the TAVR era, transcatheter valve delivery systems were 18 Fr for the CoreValve platform and 22 to 24 Fr (depending on valve size) for the Edwards Sapien valve. Among currently available self-expanding prostheses, CoreValve Evolut R InLine Sheath is a 14-Fr sheath (true outer diameter 18 Fr), requiring a minimal vessel diameter of 5.0 mm in absence of calcifications. The more recent EvolutPRO valve has a 16-Fr sheath (true outer diameter 20 Fr), requiring a minimal vessel diameter of 5.5 mm in the absence of calcifications, due to the addition of an external skirt aimed at improving valvular sealing on annular calcifications, reducing residual paravalvular leak. Other self-expanding valves require larger (18/19-Fr Portico, 19-Fr Lotus) or similar (14-Fr Accurate NEO, 14-Fr Portico when used sheathless) sheaths. The most widely used balloon

Fig. 1 Shockwave IVL system: generator and peripheral balloon (used with permission from Shockwave Medical)

expandable Edwards Sapien 3 valve is inserted through a highly hydrophilic introducer (eSheath), which is 14 Fr except for the 29-mm valve (16 Fr). This dimension is referred to the internal diameter and the expansion of the sheath during the introduction of the valve must be considered. The new Edwards Sapien 3 Ultra has recently become available, with a modified sheath that is 14 Fr for all prosthesis sizes Table 1.

Small vessel diameters, tortuosity, and calcifications prevent transfemoral access or lead to access failure in a proportion of TAVR patients, currently around 15% [7]. Moreover, peripheral atherosclerotic disease, vascular calcifications, and small vessels are associated with vascular complications and bleeding. The ratio between sheath outer dimensions and femoral artery diameter (SFAR) has been proposed as a predictor of vascular complications and has demonstrated a good correlation with VARC major vascular complications and with 30-day mortality [8].

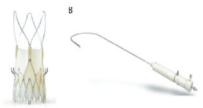
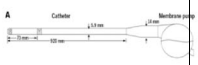
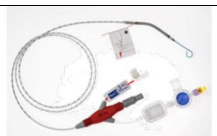
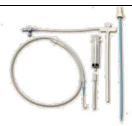
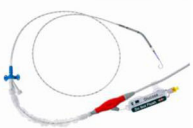
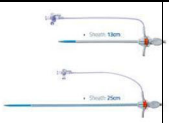
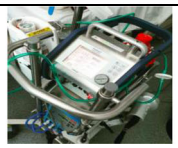
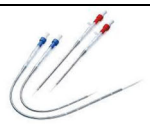
The location of vascular calcifications along the vascular axis is particularly important when planning a TAVR procedure. Common femoral artery calcifications most often prevent optimal deployment of vascular closure systems, leading to complications such as residual bleeding, vessel dissection, or occlusion, requiring surgical correction. These complications can be minimized with an accurate preprocedural planning: the less diseased side should be chosen for main vascular access, optimal puncture location should be identified, and, in extreme cases, elective surgical cut-down should be performed.

Significant calcifications located more cranial in the vascular bed, at common iliac artery or external iliac artery level, can make valve progression towards the abdominal aorta challenging, even with modern low-profile introducers. The use of excessive force to push a valve delivery system can lead to life-threatening complications such as iliac artery dissection and rupture or vascular avulsion. Possible solutions in cases of difficult progression across iliac arteries include the use of a more supportive guidewire or the use of dedicated introducers such as the recollapsible Solopath, a highly hydrophilic introducer, with an insertion profile of 13.5 to 15 Fr and an inflation system providing an increase in internal dimensions once positioned inside the vessel, reaching an inner diameter of 19 to 24 Fr. After valve positioning, a second port allows active deflation of the system with a reduction in sheath profile approaching initial dimensions. Major vascular damage has been described after the high-pressure sheath distension and collapse. Even with the applications of this modern technology, a proportion of the patient's peripheral vessels look so diseased at the initial evaluation as not to attempt transfemoral TAVR.

Intravascular lithotripsy application for peripheral artery disease treatment was first investigated in a premarket European study, the DISRUPT PAD I. In this single-arm study, IVL demonstrated a dramatic reduction in stenosis severity with high acute gain and minimal vessel injury, in 35 patients with severely calcified femoropopliteal lesions [9]. This study was followed by the DISRUPT PAD II trial, a non-randomized, multicenter trial, including 60 patients with complex calcified peripheral arteries stenosis. In this study, 73.3% of investigated lesions were located on superficial femoral artery and 26.7% on popliteal arteries. The study showed that treatment with IVL was associated with minimal vascular complications, large acute lumen gain, and minimal need for stent implantation [10]. Further information will be available after the publication of the DISRUPT PAD III trial, a prospective, multicenter, randomized trial comparing the use of IVL versus standard balloon angioplasty used in combination with drug coated balloons for the treatment of calcific femoropopliteal disease (ClinicalTrials.gov Identifier: NCT02923193).

Recently, the use of IVL for treating calcific common femoral artery stenoses has been described in a series of 21 patients across 3 sites. In all cases, the IVL system was successfully delivered to the target lesion, with consistent post-treatment lumen gain and minimal vascular complications, limited to a few cases of non-flow-limiting dissections [11].

Table 1 Commercially available (Europe) transcatheter aortic valves and mechanical circulatory support devices

Device	Device	Sheath	Producers labeled sheath diameter (F)	Minimum required vessel dimension (mm)
CoreValve Evolut R 23, 26, 29 mm *(Medtronic)*			14	5.0
CoreValve EvolutPRO 23, 26, 29 mm Evolut R 34 mm *(Medtronic)*			16	5.5
Sapien 3 Ultra 20, 23, 26 mm Sapien 3 29 mm *(Edwards Lifesciences)*			14	5.5 6.0
Acurate Neo S,M,L *(Boston Scientific Corporation)*			14	5.5
Lotus Edge 21, 23, 25, 27, 29 mm *(Boston Scientific Corporation)*			19	6.5
Portico 23,25,27,29 mm *(Abbott Vascular)*			14 (sheathless insertion) 18/19	5.5 6/6.5
iVAC2L *(Terumo)*			17	5.9
Impella 2.5 *(Abiomed)*			12	4.5
Impella CP			14	5.5
VA ECMO			14	5.5

Sheath dimensions indicate inner diameter. True outer diameters once the device is inserted can vary significantly; therefore, we indicate the minimum vessel diameter recommended

The application of IVL to facilitate transfemoral TAVR in patients with severe calcific iliofemoral disease has been reported in separate case reports by Di Mario et al. [12], Gorla et al. [13], and Cruz González et al. [14] Each case report described successful transfemoral TAVR in patients with calcific narrowed iliofemoral arteries, with no periprocedural complications and good procedural result (Fig. 2).

After the publication of first case reports, a prospective multicenter registry was started with the aim of investigating the potential role of IVL in facilitating transfemoral TAVR in patients deemed to have prohibitive iliofemoral calcified narrowing. The primary endpoint was the success rate of transfemoral delivery of a TAVR after IVL. The registry included 42 patients, with lesion minimum diameter of 4.3 mm, an average stenosis of 58.6%, and an average maximum calcium arc of 265.5°. In all cases, successful sheath passage and valve implantation was achieved, with no local complications at the site of IVL, including no need for bail-out stent implantation at the lithotripsy site. Two stents were implanted to stop bleeding at the puncture site, not treated with IVL. In the majority of cases, the IVL was performed with the largest balloon available (7 mm). Implanted valves were Edwards Sapien 3 (57.1%), CoreValve Evolut R (33.3%), and CoreValve EvolutPRO (9.5%) [15•], with good final results in terms of paravalvular regurgitation.

Potential Impact of the Application of Peripheral IVL to Increase the Success of Transfemoral TAVR: a Single-Center Experience

In our institution, Shockwave IVL was applied to facilitate transfemoral TAVR in 14 patients between January 2018 and May 2019. All patients presented severe symptomatic aortic stenosis and were given indication to TAVR after Heart Team discussion, based on comorbidities and surgical risk. Preprocedural evaluation included angio-CT scan in all patients; all patients presenting with iliofemoral calcifications and vessel dimensions unsuitable for transfemoral valve delivery were given indication to IVL vessel preparation. Data were collected in a dedicated database including demographics, baseline echocardiographic and CT data, procedural data, and results.

On basal angio-CT scan, average lesion length was 18.56 ± 7.92 mm, average minimum vessel diameter was 4.54 ± 0.97 mm, with an arc of calcium of 315.78 ± 53.43°, and a minimal cross-sectional area of 25.39 ± 9.66 mm^2. Target lesion was located on common iliac artery in 13 (92%) cases, with involvement of external iliac artery in 2 patients; in a single patient IVL was delivered to the common femoral artery. In 2 (14%) patients, predilatation with a conventional peripheral balloon was needed to allow IVL balloon positioning. IVL balloon dimension was 7.0 mm in 12 (85%) patients; 6.5 mm and 6.0 mm in one patient, respectively. In one patient with chronically occluded superficial femoral artery, a second treatment with a 5.0-mm balloon was performed to dilate the profunda femoris. Average number of delivered pulses was 231 ± 71.

Femoral access was achieved percutaneously in 11 (78%) patients; in 3 patients presenting with severe common femoral artery calcifications, elective surgical cut-down was performed.

In all cases, successful delivery of a TAVR system was possible after IVL treatment; in 3 patients, the use of an adjunctive sheath (recollapsible Solopath in 2 cases, hydrophilic Cook sheath in one case) was required to cross the stenotic lesion. Both self-expanding and balloon-expandable prostheses were implanted, with 9 (64%) CoreValve Evolut R, 1 (7%) CoreValve EvolutPRO, and 4 (28%) Edwards Sapien 3

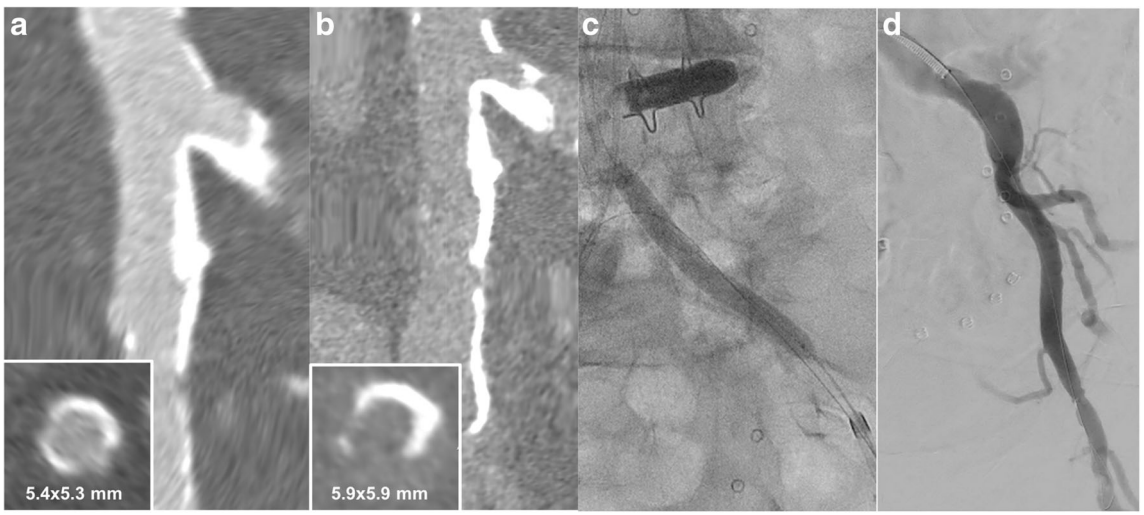


Fig. 2 Intravascular lithotripsy (IVL) before transfemoral TAVR. **a** Angio-CT scan demonstrating almost circumferential iliac calcifications and small vessel dimensions. **b** Non-contrast CT scan after IVL, showing calcium fractures and significant luminal gain. **c** Iliac IVL with a 7-mm balloon. **d** Final angiography demonstrating absence of local complications

valves. No major complications were observed on the site of IVL treatment, with only two non-flow-limiting type B dissections that did not require stent implantation. In two patients, a covered stent was placed on the access site due to residual bleeding. Predischarge echocardiography confirmed good procedural result in all cases, with moderate paravalvular leak in 2 patients and mild or trivial in all others.

This preliminary experience shows the effectiveness and safety of IVL vessel preparation to facilitate transfemoral TAVR in patients with severe calcific iliofemoral disease, traditionally considered a poor candidate for this approach.

In our experience, the introduction of this technology in the field of TAVR preparation, has markedly reduced the need for alternative access routes such as the transapical one. In 2018, the percentage of transapical TAVR was 0.8% versus 13% in 2016, while transfemoral TAVR increased from 85% in 2016 to 94% in 2018.

Role of Lithotripsy for Facilitating Access for Mechanical Circulatory Support

Percutaneous MCS include traditional intra-aortic balloon pump (IABP), TandemHeart (Cardiac Assist, Inc., Pittsburgh, PA), Impella, VA-ECMO and other recently introduced devices such as iVAC2 (PulseCath BV, Amsterdam, the Netherlands). Other devices are in development with the promise to deliver very high flows, but large sheaths (14 Fr) are still expected. These devices can be used during high-risk cardiological procedures to achieve adequate cardiac output, to increase mean pressure, and consequently maintain vital organ perfusion; therefore, they are useful tools to decrease periprocedural complications during complex interventional procedures [16, 17]

No single or univocal definition exists to define complex high-risk procedures but more variables contribute: (a) patient specific (age, sex, comorbidities such as diabetes mellitus, renal kidney disease, peripheral arterial disease, prior myocardial infarction), (b) clinical presentation specific (EF < 35%, hemodynamic instability), and (c) lesion specific (left main, bifurcation, chronic total occlusion). In a recent expert consensus, clinical and anatomical settings to use MCS are better characterized. The use of MCS is considered appropriate in some particular scenarios of high-risk coronary PCI: left main with Syntax score > 22, complete revascularization in multivessel coronary disease, complex chronic total occlusion with retrograde approach through the last remaining vessel, or a LIMA, treatment of the last remaining vessel, diffuse calcified lesions, PCI on degenerated vein graft, complex PCI in patients with severe systolic dysfunction (EF < 35%), or concomitant severe heart valve disease [18] In acute myocardial infarction complicated by shock or recurrent life-threatening arrhythmias, the preliminary insertion of MCS before primary angioplasty has been advocated and shown to improve prognosis compared with historical findings. Emerging indications for periprocedural MCS are critically ill patients undergoing percutaneous aortic valvuloplasty, TAVR, percutaneous mitral repair, or complex electrophysiological ablation procedures [17, 18]. MCS have different structural features (Impella and HeartMate PHP are intracorporeal microaxial pump, ECMO is an extracorporeal centrifugal circuit), different mechanism of action and hemodynamic effect on pressure-volume loops of cardiac cycle and different peak output flow were provided [19]. MCS are not interchangeable but each device is more appropriate in a specific clinical setting. A heart team approach should be encouraged to select the most suitable device [20]. With the exception of some surgical MCS such as the 18-Fr surgical Impella inserted transaxillary or transubclavian, most MCS are inserted percutaneously or surgically through the femoral artery.

Impella 2.5 was used in high-risk PCI in the randomized trials PROTECT I and II showing hemodynamic advantages compared with IABP but neutral effect on clinical outcomes [21, 22]. The EUROPella and USPella real-world registries confirmed safety and feasibility of this device [23, 24]. Impella CP can be used as a temporary ventricular support device during complex high-risk procedures and it is approved by the Food and Drug Administration (FDA) with a recommended activation time of < 6 h. It provides 3–4 l/min of flow and is inserted in the femoral artery through a 14-Fr sheath. In some preliminary experiences, Impella 2.5 and Impella CP have been used during emergency balloon aortic valvuloplasty in patients with cardiogenic shock [25] or in patients percutaneously treated with complex PCI and balloon aortic valvuloplasty [26]. The VA-ECMO system is an extracorporeal circuit composed by inflow cannula, centrifugal pump, heat exchanger, membrane oxygenator, and outflow cannula. In the peripheral percutaneous VA-ECMO, the inflow cannula (18–21 Fr) is inserted into the right atrium via a jugular or femoral vein and the outflow cannula (14–21 Fr) is inserted in the descending aorta via a femoral artery and it provides 4–6 l/min of flow rate, ensuring a fully respiratory and circulatory support. During VA-ECMO support, bleeding and limb ischemia occurred in high rate due to large vascular access; therefore, the use of this device is severely limited in emergency setting (cardiac arrest, electrical storm, severe respiratory failure, and severe biventricular dysfunction). Conversely, in the last year, a single case report or case series reported VA-ECMO support during TAVI [27] or during catheter ablation of ventricular tachycardia, as shown by Virk et al.; in fact VA-ECMO is the unique MCS able to allow fully circulatory support and organ perfusion during complex electrophysiologic procedures [28]. In this specific scenario, PAAINESD score should be used for predicting acute hemodynamic decompensation during VT ablation and for selecting patients needing MCS [29].

Peripheral artery disease is a common contraindication for MCS implantation due to large sheath dimensions, making MCS often unable to cross severe calcified stenoses of femoroiliac arteries [30]. In a specific clinical setting, IVL could be a valid therapeutic option to facilitate transfemoral passage of delivery systems for MCS during planned procedures in patients with severe iliofemoral vascular disease. Riley et al. described the first case of IVL to facilitate Impella CP passage prior to high-risk percutaneous coronary intervention [31]. In our preliminary experience, IVL was performed in 2 patients prior to Impella CP implantation as hemodynamic support during high-risk PCI [32]. A retrospective registry of peripheral IVL application before Impella delivery has been recently published. Data have been collected from 6 medical centers, for a total number of 12 patients. In 92% of cases, the implanted device was an Impella CP, with successful delivery of the device in all cases and no post-IVL peripheral complications. Interestingly, besides the planned use of Impella for high-risk PCI in the majority of cases, there was a 25% of unplanned Impella implantation, with cardiogenic shock as indication [33•].

Conclusions

Vascular calcifications represent a challenge in interventional cardiology, and peripheral calcific disease is gaining increasing attention with the expansion of transcatheter techniques requiring large-dimension introducers. Although the experience is still limited, IVL appears to be a safe and effective solution in patients scheduled for TAVR presenting with iliofemoral calcifications, with the potential of reducing the need for alternative access routes. Data coming from case reports and one multicenter registry show a high rate of success with limited complications. Data describing the application of IVL prior to MCS devices introduction are limited to a low number of elective cases; nonetheless, the ease of use and efficacy of this methodology will probably lead to a future expansion in its applications.

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Compliance with Ethical Standards

Conflict of Interest Francesca Ristalli, Carlotta Sorini Dini, Miroslava Stolcova, Giulia Nardi, Serafina Valente, Francesco Meucci, and Carlo Di Mario declare that they have no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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