



## Comprehensive Review

# Percutaneous Mechanical Aspiration for Infective Endocarditis: Proceedings From an Inaugural Multidisciplinary Summit and Comprehensive Review



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## ABSTRACT

The clinical presentation and epidemiology of infective endocarditis (IE) have evolved over time. While the cornerstones of IE treatment remain antimicrobial therapy and surgery, percutaneous mechanical aspiration (PMA) has emerged as an option for carefully selected patients as a complementary modality, based on retrospective data, case series, and expert experience. In this comprehensive review, we summarize the proceedings from an inaugural summit dedicated to the discussion of PMA in the global management of IE, consisting of experts across multiple disciplines from diverse geographic regions and care environments. After conceptualizing the 3 major roles of PMA as a bridge to decision, destination therapy, and adjunctive therapy, we then review the clinical scenarios in which PMA might be considered by IE subtype. We discuss patient selection, the rationale for intervention, and the most recent evidence for each. Next, we consider PMA for IE in the larger context of our health care system across 3 domains: clinical collaboration, financial considerations, and academic innovation, emphasizing the importance of interdisciplinary teams and cross-organizational partnerships, reimbursement models, and the need for high-quality research. Finally, we outline what we determined to be the most pressing outstanding questions in this space. In doing so, we propose a national consortium to help organize efforts to move this field forward and share our progress in these endeavors to date. PMA for IE has great promise, but significant work remains if we are to fully realize its potential to safely and effectively improve outcomes for modern endocarditis patients.

**Abbreviations:** CIED, cardiac implantable electronic device; CPT, Current Procedural Terminology; DUA-IE, drug use-associated infective endocarditis; IE, infective endocarditis; LSIE, left-sided infectious endocarditis; PFO, patent foramen ovale; PMA, percutaneous mechanical aspiration; RSIE, right-sided infectious endocarditis; SUD, substance use disorder; TV, tricuspid valve.

**Keywords:** cardiac catheterization; endocarditis; substance-related disorders; suction; thrombectomy.

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## Introduction

The clinical presentation and epidemiology of infective endocarditis (IE) have evolved over time. Two patient populations in particular are representative of the challenges of treating endocarditis in our current era. Both are commonly encountered in clinical practice, yet high-quality evidence to guide their management is often lacking.<sup>1,2</sup>

The first group includes elderly patients, often with chronic indwelling cardiac and vascular prosthetic material, a consequence of the increasing safety and expanding indications of chronic indwelling lines/ports, cardiac implantable electronic devices (CIED), and transcatheter valve interventions. More than 50% of elderly patients with IE have 1 or more chronic illnesses, nearly 20% have a CIED, and 20% to 40% have a valvular prosthesis.<sup>3,4</sup> Even with strong indications for surgery or extraction/removal, these patients may be deemed poor candidates due to their high risk of periprocedural mortality.<sup>5</sup> Without surgery or lead extraction, however, control of the infection or mitigation of their embolic risk may be difficult to achieve.

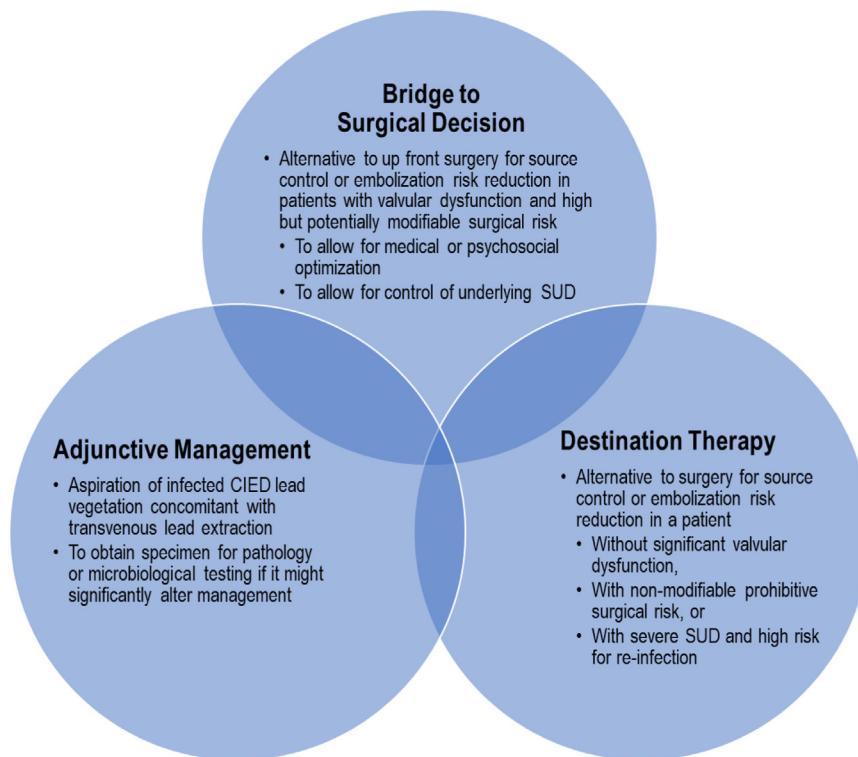
The second group includes younger persons who inject drugs with drug use-associated infective endocarditis (DUA-IE). Rates of DUA-IE have increased over time both in absolute terms as well as a proportion of overall endocarditis cases.<sup>6–10</sup> Patients with DUA-IE are at high risk for poor long-term surgical outcomes due to recurrent injection drug use, especially if the substance use disorder (SUD) is severe or undertreated.<sup>11</sup> Without a comprehensive, achievable, and evidence-based plan to manage their underlying SUD, surgical management for DUA-IE may be viewed as futile, in particular with recurrent disease.<sup>12</sup>

Therefore, for these and similar patients, there is often hesitancy to offer surgery despite otherwise compelling indications. Traditional indications for surgical management of IE are based on historical observational data that do not necessarily reflect the modern demographics of IE or the interval advances in diagnostic technologies and

interventional techniques.<sup>13,14</sup> As the disease state evolves, our management paradigms must evolve with it.

While the cornerstones of IE treatment remain antimicrobial therapy and surgery, transcatheter-based interventions have emerged as an option for carefully selected patients as a complementary modality, based on retrospective data, case series, and expert experience.<sup>15</sup> This is especially true for the patient populations described above. Specifically, by debulking infective vegetations via a transcutaneous approach, percutaneous mechanical aspiration (PMA) may assist in achieving infectious source control, reducing the risk of embolization, and in some cases, relieving valvular obstruction and functional stenosis caused by large vegetations.<sup>16–20</sup> PMA has the advantage of avoiding the upfront risks of cardiac surgery in frail, elderly populations as well as the downstream consequences of an infected prosthetic valve or potential repeat sternotomy in the younger, DUA-IE populations. Furthermore, using PMA to remove infected material from intracardiac leads may help lower the risk of septic embolization during a lead extraction procedure, reduce bacterial load, and eliminate potential sources in pulmonary circulation for ongoing or recurrent infection. In rare cases, PMA may act as an alternative to extraction in conjunction with medical therapy when the procedural risks are prohibitive.

Therefore, PMA has the potential to fill 3 important clinical needs, as outlined in Figure 1. The first is as a “bridge to decision” regarding future definitive surgery by stabilizing patients with IE who were otherwise failing medical therapy to allow time for optimization of their underlying medical or SUD.<sup>21</sup> The second is as a “destination therapy” in conjunction with medical management for selected patients with IE who have surgical disease but have unusually high perioperative risk due to unmodifiable risk factors. The third is as an “adjunctive therapy” for certain patients with intracardiac lead infections, either as a means to reduce septic embolization burden during transvenous lead extraction or as an alternative to medical therapy alone for those at prohibitive risk



**Figure 1.**

**Indication framework for percutaneous mechanical aspiration in infective endocarditis.** This figure demonstrates when to consider and when to exercise caution in using percutaneous mechanical aspiration for infectious endocarditis based on clinical scenarios. CIED, cardiac implantable electronic device; SUD, substance use disorder.

of morbidity or expected mortality from an extraction procedure. In addition, aspiration allows for nonsurgical sample acquisition for analysis, which may be useful for cases in which diagnosis is difficult and histological or microbiological data would alter management. These indication categories are not exclusive and may overlap in a single patient. As the evidence base grows and we gain more familiarity across different clinical scenarios, PMA may gain a more prominent position in the care of IE beyond the higher-risk populations described above.

The role of PMA is being increasingly recognized by major societies, such as in the 2022 American Heart Association scientific statement on the management of IE in people who inject drugs as well as the 2023 European Society of Cardiology guidelines on the management of endocarditis, which gives a class IIb, level of evidence C recommendation for aspiration of right intraatrial septic masses for selected patients who are at high risk for surgery.<sup>22-24</sup>

Yet despite its potential, PMA for IE remains understudied as a potential treatment option. Mortality and complications following PMA appear to be low based on observational data and published experiences, but our current knowledge of the true safety and efficacy is limited by inconsistent reporting, publication bias, and low-quality evidence.<sup>15</sup> Furthermore, there are no large prospective or randomized evaluations of PMA for IE.

While there is a dearth of high-quality data, descriptions of PMA for IE have existed in the literature for over a decade.<sup>25</sup> Despite this, national trends on procedure volumes and geographic variation in uptake are also lacking. In addition to well-designed, rigorous studies to establish indications and outcomes, it is also important to track who is receiving this procedure, who is performing it, and where it is being performed, in order to identify and address any geographic or demographic disparities that may exist. Once an evidence base is established, raising awareness and providing education about PMA to the many specialties and care roles involved in the interdisciplinary management of endocarditis patients will be key to ensuring equitable access. This is especially vital because those who stand to benefit the most, including frail elderly and those with SUD, are also among the most socially vulnerable.<sup>26,27</sup>

## Purpose

A summit organized by K.R., S.S.S., M.L.P., and A.E.S. was held on November 13, 2022, in Boston, Massachusetts. The objective was to discuss the global management of patients with IE, to identify the opportunities and challenges in establishing new IE treatment paradigms, and to explore evidence gaps and examine the role of novel interventional modalities for IE. This was achieved by presentations and facilitated roundtable discussions on these topics involving thought leaders, expert clinicians, and accomplished researchers in the field. Specialists from interventional cardiology, general cardiology, cardiothoracic surgery, radiology, infectious disease, and addiction medicine from diverse geographic regions and care environments were represented.

The purpose of the current communication is to summarize and share the consensus opinions resulting from the summit. While many aspects of IE diagnosis and management were discussed, this document will focus on the role of PMA in treating IE and how it might fit into the global management of the modern endocarditis patient we encounter in our daily practice.

First, we will briefly review the clinical scenarios in which PMA might be considered for varying endocarditis subtypes: right-sided, left-sided, drug use-associated, CIED-associated, and prosthetic valve endocarditis (PVE). For each scenario, we will discuss patient selection, rationale for intervention, and evidence to date. Discussion of the multiple types of devices available and the technical aspects of the procedure are beyond the scope of this work and have been presented in detail previously.<sup>28</sup>

Next, we will consider PMA for IE in the larger context of our health care system across 3 domains: clinical collaboration, financial considerations, and academic innovation. We will emphasize the importance of building relationships across specialties and institutions in the form of interdisciplinary teams and cross-organizational partnerships, in order to better consolidate and coordinate care. We will review the compensation and reimbursement models for PMA and their implications for uptake and adaptation. We will discuss the need for high-quality research and the role of registries, quasi-experimental designs, and pragmatic approaches in a domain where randomization and long-term follow-up are challenging. We will present a proposal for a national consortium to help organize efforts to move this field forward across all these domains.

Finally, we will share what we have determined to be the most pressing outstanding questions in this space. There are many evidence gaps that must be addressed before we can fully understand which patients with IE benefit the most from PMA, what is the best technique and platform for a given patient, and when in their disease course is the optimal time to intervene.

This summit was materially supported by AngioDynamics, but the content of this report reflects solely the opinions of those present.

## Part 1: Clinical scenarios

A summary of our approach to patients for each scenario is outlined in [Table 1](#) and the [Central Illustration](#).

### Right-sided IE

The vast majority of right-sided IE (RSIE) affect the tricuspid valve (TV). RSIE represents 5% to 10% of all IE, while nearly 90% of all DUA-IE involves the right heart. The overall mortality rate of RSIE is 5% to 10%, and 70% of RSIE is caused by *Staphylococcus aureus*.<sup>29</sup> Although the majority of RSIE is treated with antimicrobials alone, 5% to 15% of patients undergo surgery with operative mortality as high as 10%.<sup>30-32</sup>

**Patient selection and rationale.** Consistent with the paradigm outlined in [Figure 1](#), the goal of PMA in RSIE may be to avoid surgery altogether as “destination therapy,” or to control their infection or embolization burden as a means to stabilize as a “bridge to surgery” to eventually address residual valve dysfunction. Therefore, we consider the use of PMA primarily for patients with TV infective endocarditis and high surgical risk who have persistent fevers, bacteremia (often defined as  $\geq 7$  days), documented recurrent emboli, and/or growth in vegetation size despite appropriate antimicrobial therapy. Early or “upfront” PMA may also be considered for cases caused by *S. aureus* or other highly virulent or resistant organisms, and for patients who are unlikely to tolerate embolization of the vegetation to the lungs from a hemodynamic or respiratory perspective, whether due to an already high burden of septic emboli or because of their underlying substrate (eg, preexisting lung disease, pulmonary hypertension, or right ventricular compromise). Although rare, it may also be considered to relieve hemodynamically significant functional tricuspid stenosis caused by obstructive vegetation.<sup>33</sup> Finally, in select circumstances where diagnostic uncertainty is high or additional pathological or microbiological testing will alter management, PMA of a right-sided lesion allows for specimen sampling without the need for sternotomy.

Patients who may be less likely to benefit from PMA include those with an acutely failing right ventricle that may not tolerate iatrogenic worsening of tricuspid regurgitation (TR) as well as those with multivalvular involvement which cannot be fully addressed by a single aspiration procedure. Although left-sided lesions may also be amenable to PMA, as discussed below, there are no published reports to our knowledge of either simultaneous or staged multivalvular PMA

**Table 1.** Approach to patient selection for percutaneous mechanical aspiration by clinical scenario.

	Consider	Caution
RSIE	<ul style="list-style-type: none"> <li>• Right intraatrial septic masses for selected patients who are at high risk for surgery (European Society of Cardiology class IIb, level of evidence C recommendation)</li> <li>• For TVIE and high surgical risk with persistent<sup>a</sup> fevers or bacteremia, recurrent emboli, and/or growth in vegetation size despite appropriate antibiotic antimicrobial therapy</li> <li>• <i>Staphylococcus aureus</i> or other highly virulent or resistant organisms</li> <li>• To reduce risk of pulmonary embolization in those with preexisting hemodynamic or respiratory compromise (such as from high septic pulmonary embolic burden, underlying right heart failure, or concurrent pneumonia, COPD, or HF exacerbation)</li> <li>• To relieve functional tricuspid stenosis</li> <li>• To collect a specimen sample if high likelihood it would affect management</li> </ul>	<ul style="list-style-type: none"> <li>• Acutely failing right ventricle that may not tolerate iatrogenic worsening of tricuspid regurgitation</li> <li>• Concomitant LSIE</li> <li>• Patent foramen ovale or atrial septal defect</li> <li>• Refractory septic shock</li> <li>• Contraindication to heparinization to ACT &gt;250 seconds</li> <li>• Poor overall prognosis</li> </ul>
LSIE	<ul style="list-style-type: none"> <li>• To promptly remove large (at least &gt;1 cm) vegetations in otherwise borderline or poor surgical candidates to reduce the early risk of embolization and/or provide more definitive source control</li> <li>• To assist with source control in those with persistent infection, to help stabilize or optimize for definitive surgery</li> </ul>	<ul style="list-style-type: none"> <li>• Significant valvular dysfunction (consider arterial return cannula to reduce the risk of intraprocedural hypotension)</li> <li>• Involvement of the subvalvular apparatus</li> <li>• Contraindication to heparinization to ACT &gt;250 seconds</li> <li>• Poor overall prognosis</li> <li>• Similar to LSIE and RSIE as above</li> </ul>
DUA-IE	<ul style="list-style-type: none"> <li>• For those with main surgical indications of source control or embolism risk reduction that are deemed prohibitive surgical risk</li> <li>• For those who may not be at high surgical risk but for whom PMA might offer definitive therapy in order to avoid sternotomy and/or prosthetic material</li> <li>• As a bridge to surgical decision to allow for optimization of underlying substance use disorder</li> </ul>	
CIED-IE	<ul style="list-style-type: none"> <li>• For those with lead vegetations &gt;2 cm concomitant with transvenous lead extraction</li> <li>• For those with lead vegetations and PFO concomitant with transvenous lead extraction</li> </ul>	<ul style="list-style-type: none"> <li>• Similar to RSIE</li> </ul>
PVE	<ul style="list-style-type: none"> <li>• Among those with bioprosthetic valves and high or prohibitive surgical risk to achieve source control or reduce embolic risk</li> </ul>	<ul style="list-style-type: none"> <li>• Similar to LSIE and RSIE</li> <li>• Mechanical valves</li> </ul>

ACT, activated clotting time; CIED-IE, cardiac implantable electronic device–infective endocarditis; COPD, chronic obstructive pulmonary disease; DUA-IE, drug use–associated infective endocarditis; HF, heart failure; LSIE, left-sided infective endocarditis; PVE, prosthetic valve endocarditis; RSIE, right-sided infective endocarditis; TVIE, tricuspid valve infective endocarditis.

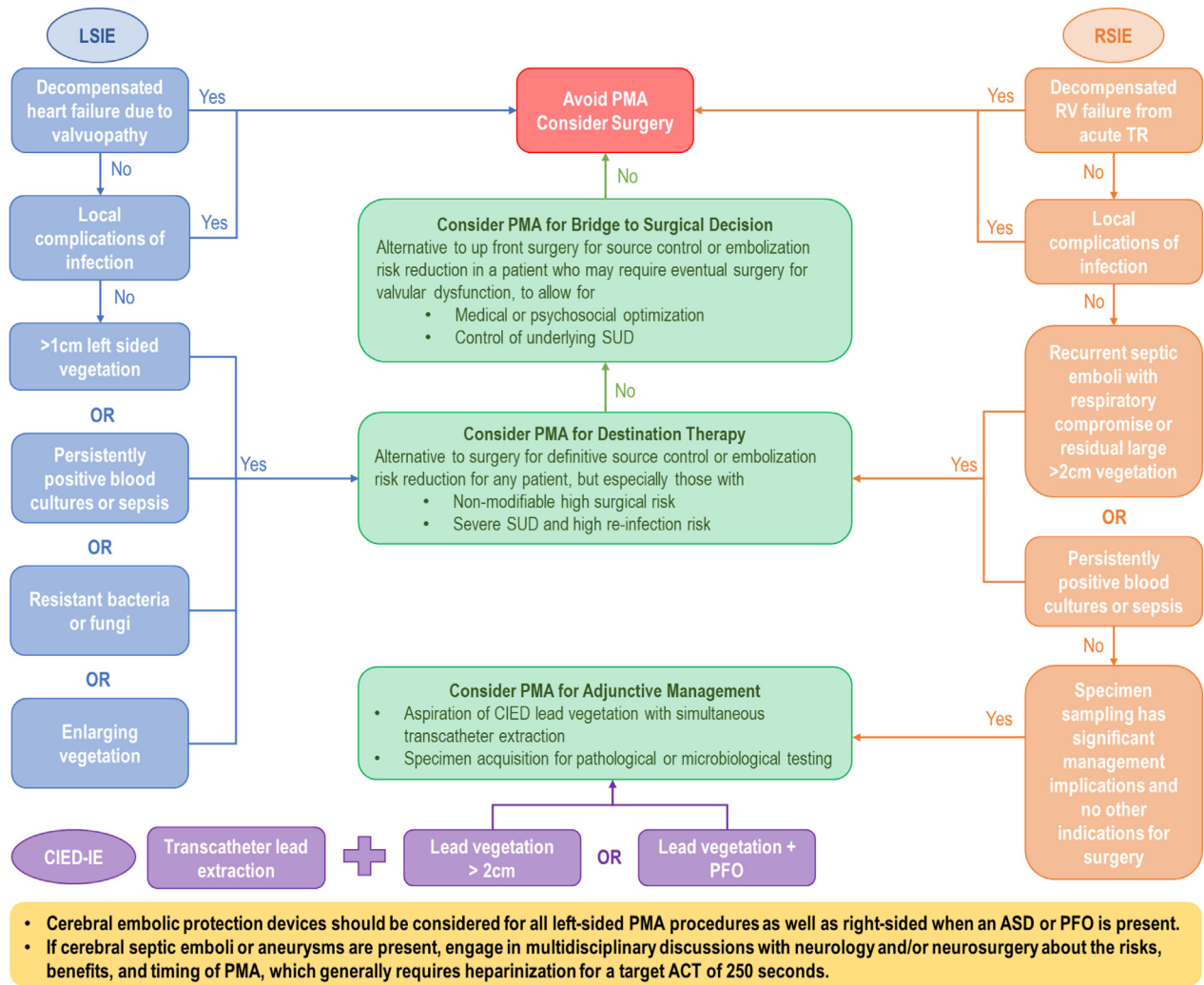
<sup>a</sup> Persistent can be defined as continued fevers, bacteremia, or lack of clinical improvement after 7 days of appropriate therapy, but no strict evidence-based cut-offs exist for PMA.

attempts. This caveat also depends on the indication and the specific clinical circumstances—for example, although removing tricuspid vegetation and leaving behind left-sided lesions may not assist in source control or mitigating systemic embolization risk, it may still be beneficial for the primary purpose of reducing further pulmonary septic emboli to the lung or obtaining a sample for pathology or culture.

Many operators consider a patent foramen ovale (PFO) or atrial septal defect a contraindication due to the risk of dislodging the vegetation and causing iatrogenic paradoxical embolism and stroke. However, PMA in the right atrium using a continuous suction device will generally cause RA pressures to decrease, and a protective left-to-right shunt will develop as long as the extracorporeal circuit is running. Successful PMA in a patient who presented with paradoxical embolism in the setting of RSIE and PFO, followed by subsequent attempts at transcatheter shunt closure, has been described.<sup>34</sup> Cerebral protection may also be used to mitigate stroke risk when an interatrial shunt is present. It is also unclear whether those who are in refractory septic shock benefit from this procedure, but the need for mechanical hemodynamic support is not necessarily a contraindication—for example, PMA for RSIE has been performed in a critically ill patient on veno-arterial extracorporeal membrane oxygenation.<sup>15,17,35</sup> Given the lack of data surrounding PMA systems in patients undergoing mechanical circulatory support, it is critical that efforts be made to track outcomes in the patient population. Complications related to the interaction between the PMA intervention and the support platform, such as air embolism and extracorporeal membrane oxygenation circuit-related air entrainment, are potentially serious issues and their incidence is currently unknown. The role of PMA in these higher-risk situations is still undefined and best approached through multidisciplinary collaborations on a case-by-case basis.

Tricuspid regurgitation cannot be addressed with PMA, and PMA may unmask or worsen preexisting TR following the removal of large vegetation.<sup>31</sup> Although iatrogenic valve injury is possible, in a retrospective analysis of 25 cases performed with the CAT8 Indigo Mechanical Aspiration System (Penumbra Inc), pathological analysis of the specimens found necrotic, fibrinoid debris and bacterial colonies, but no actual myocardial or valve tissue, indicating that diseased tissue may be preferentially aspirated and normal, viable tissue spared.<sup>17</sup> Regardless, compensated TR tends to be well-tolerated with appropriate medical management in the short to medium term.<sup>36</sup> If the patient can be medically stabilized, it is often preferable to delay TV replacement as long as possible and to perform the operation on an outpatient basis, ideally outside of active infection, after the nutritional status has improved and postacute care physical rehabilitation has been completed.<sup>22</sup> PMA can thus be a means to “buy time” for this stabilization and optimization. If this strategy is pursued, close outpatient cardiology follow-up with serial examinations and echocardiography is key in order to ensure the patient is referred back to surgery if and when it is appropriate.<sup>36</sup> Whether those with healed endocarditis, significant residual TR, and persistently high surgical risk are candidates for transcatheter TV replacement or transcatheter edge-to-edge repair, assuming amenable anatomy, is an area of potential future study.

**Evidence.** Retrospective, observational studies of PMA for RSIE have demonstrated high efficacy rates, whether defined as blood culture clearance, defervescence, or reduction in vegetation size, and very low short-term complication rates across multiple platforms.<sup>18,20,37,38</sup> A recent single-arm retrospective study found that surgical risk, as measured by the American College of Surgeons National Surgical



**Central Illustration.**

**Proposed algorithm for the consideration of percutaneous mechanical aspiration (PMA) in the management of infective endocarditis (IE).** This figure contains the general approach proposed by the authors for the consideration of PMA in the management of IE and does not represent a clinical practice guideline or recommendation. It presumes a background treatment with appropriate antimicrobial therapy. Local complications of infection include abscesses, pseudoaneurysms, fistulae, and heart block. Persistently positive blood cultures or persistent sepsis is defined as  $\geq 7$  days despite appropriate antimicrobial therapy. Aspiration of right-sided lesions may also be considered in the case of multidrug resistant organisms or fungi as well as enlarging vegetations, similar to left-sided infective endocarditis (LSIE). ACT, activated clotting time; ASD, atrial septal defect; CIED-IE, cardiac implantable electronic device–infective endocarditis; PFO, patent foramen ovale; RSIE, right-sided infective endocarditis; RV, right ventricular; SUD, substance use disorder; TR, tricuspid regurgitation.

Quality Improvement Program score, improved following RSIE PMA, lending empirical support to the “bridge to surgery” paradigm.<sup>39</sup> A retrospective analysis comparing RSIE PMA outcomes to published data of surgical outcomes concluded that PMA was noninferior to surgery for complete heart block and superior in terms of in-hospital mortality.<sup>20</sup> In another small study, PMA was shown to have similar outcomes to surgery with lower costs, especially among those who required intervention for recurrent endocarditis.<sup>40</sup> Data from select registries, case series, and reviews of PMA in RSIE are summarized in Table 2.<sup>15,17,18,20,39</sup>

*Left-sided IE*

The use of PMA for left-sided lesions has been limited compared to RSIE due to the need to access the systemic circulation, most often by crossing the interatrial septum, and because of the risk of iatrogenic systemic embolism and stroke. Nevertheless, there is a potential role for PMA in left-sided IE (LSIE) given what is known about the risks of surgery and the impact of embolization with this condition.

**Patient selection and rationale.** The classic indications for surgery in LSIE include heart failure, vegetation size, virulent organism, recurrent embolic phenomenon, persistent infection, spread of infection into adjacent structures with local complication, and relapsing prosthetic valve involvement.<sup>41</sup> Clinically apparent neurological insults caused by ischemic or hemorrhagic strokes from septic emboli or mycotic aneurysms are present in 20% to 40% of LSIE cases and are associated with up to 50% mortality rate.<sup>14</sup> LSIE vegetation size predicts embolization risk and randomized data support that early surgery for large vegetations is superior to delayed surgery.<sup>14,42</sup> After heart failure, persistent infection is the most common indication for surgery, and mortality in this scenario remains high even with operative debridement. It follows that prompt intervention to achieve source control of the infection and reduce the risk of embolization may be key to improving outcomes. Therefore, when a decision is made to operate, the data overall support an “as soon as possible” approach.<sup>14</sup>

Although delaying intervention for those with surgical indications can lead to irreversible harm or death, surgical management of LSIE is challenging and the path to the operating room is often not



**Table 2.** Summary of retrospective studies and reviews of percutaneous mechanical aspiration for right-sided infectious endocarditis.

	Scantland et al, <sup>39</sup> 2023	George et al, <sup>18</sup> 2017	Akhtar et al, <sup>17</sup> 2021	Zhang et al, <sup>20</sup> 2023	Mourad et al, <sup>15</sup> 2023
N	24	33	25	29	142
Platform	AngioVac	AngioVac	Penumbra	AngioVac	Variable
Age, y	34.8 ± 10.7	37 ± 12	35.2 ± 12	41.3 ± 10.1	39.1 ± 14.4
IDU, %	91.7	72.7	100	82.7	79.6
Vegetation size, cm	2.4 ± 0.8	2.1 ± 0.7	2.4 ± 0.8	2.46 ± 0.76	2.4 ± 1.1
Severe TR, %	–	18.1	–	82.7	28.2
Procedure time, min	101.5 ± 36.9	–	–	–	–
Bypass time, min	–	–	–	16.8 ± 8.8	–
Outcomes	Improvement in mean NSQIP score: 34.6 to 27.9 (P = .007)	Postprocedure vegetation size: 0.82 ± 0.7 cm Persistent vegetation: 82.6% Subsequent bacteremia: 15.2%	Clearance of postprocedure cultures: 88%	Clearance of postprocedure cultures: 96.5% Fever resolution: 95.6%	Clearance of cultures after procedure: 78.9%
Percentage of debulking, %	86.1 ± 12.2	61 (no SD reported)	77 ± 22	71 (no SD reported)	–
Debulking success	>70% debulked: 87.5% > 90% debulked: 20.8%	–	–	–	–
Mortality, %	30-day mortality: 0.0	In-hospital mortality: 9.1	In-hospital mortality: 12.5 (all secondary septic shock)	In-hospital mortality: 6.9	In-hospital mortality: 8.5 30-day mortality: 9.9
Procedural complication, %	Pneumothorax: 3.0 Neck hematoma: 3.0	Intraprocedural death: 0.0 Effusion and tamponade: 3.0 Access site bleeding: 3.0 Transfusion: 33.0 Worsening TR: 43.5	Intraprocedural death: 0.0 Vascular complications: 0.0 Transfusion: 28.0	Procedure-related mortality: 0.0 Access site complications: 0.0 Pericardial effusion: 0.0 Worsening TR: 0.0 Heart block: 0.0	Worsening TR: 9.9 Access site complications: 0.0 Cardiac wall injury/pericardial effusion: 1.4
Subsequent TVR, %	20.8	9.1	–	0.0	7.0

Values are mean ± SD unless otherwise noted.

IDU, injection drug use; NSQIP, National Surgical Quality Improvement Program; TR, tricuspid regurgitation, TVR, tricuspid valve replacement.

straightforward. Patients are routinely at elevated surgical risk due to their acute illness superimposed on chronic comorbidities and frailty. Minimally invasive surgical approaches in such conditions may not be available in all centers. The state of the coronary arteries is often unknown. Malnutrition is common and tissue quality may be poor. Prior sternotomies and adhesions also increase the technical difficulty and surgical risk. The presence of cerebral septic emboli increases the risk of poor neurological outcomes on cardiopulmonary bypass. Large vegetations increase the risk of intraoperative stroke and periprocedural death. Cases are frequently rescheduled due to rapidly changing clinical circumstances. Finally, social issues and SUD can lead to challenging and prolonged postoperative care and poor outcomes despite a technically excellent operation.

Hence there are many legitimate reasons why surgery may be delayed or not offered despite otherwise compelling indications. Indeed, more than 20% of patients with LSIE and guideline indications for surgery have their surgery delayed or do not receive surgery at all due to perceived poor prognosis, stroke, sepsis, hemodynamic instability, or preoperative death.<sup>43,44</sup> Those with indications who are denied surgery because of prohibitive operative risk have a poor prognosis with low survival despite subsequent medical therapy and supportive care.<sup>43,44</sup>

Therefore, PMA may be considered for patients with LSIE as a bridge to surgery by optimizing their surgical risk profile. Prompt removal of large vegetations in otherwise borderline or poor surgical candidates may lower the upfront stroke and arterial embolization risk. Early PMA can allow time for more definitive surgical management, may help avoid a cerebrovascular event, and may also make any subsequent surgery safer by reducing the intraoperative stroke risk. For those with sepsis due to persistent infection, by assisting with source control, PMA may help reduce or eliminate vasopressor requirements, again stabilizing the patient for definitive surgery and reducing perioperative risk.

We also may consider PMA as a destination therapy for patients with LSIE and surgical indications for whom timely surgery cannot be achieved. For nonoperative candidates who have amenable anatomy and

are not in decompensated heart failure from acute valvular dysfunction, PMA may be able to provide definitive source control or reduce the risk of embolization better than medical therapy alone, obviating the need for surgical intervention.

**Evidence.** A case series by Qintar et al<sup>45</sup> described 10 consecutive patients at 2 institutions who underwent left-sided PMA for vegetation or thrombus. The mean age was 58.3 ± 17.3 years; the predominant indication was prevention of recurrent embolic events. One patient was actively using injection drugs. An arteriovenous circuit configuration was employed for 6 patients, with the remaining arterioarterial; all patients had bilateral cerebral embolic protection. The average bypass time was about 9 minutes, and the procedural success rate (defined as aspirating 70%-100% of the material) was 80%, which is similar to those reported for right-sided cases (see Table 2). There were no reported complications across a follow-up range of 1 to 16 months.<sup>45</sup> This series, in combination with other successful case reports, demonstrates the feasibility and safety of PMA for LSIE and serves as justification for moving forward with larger registries and trials.<sup>15,37,44,46–49</sup>

#### DUA-IE

Drug use–associated IE often represents a subset of RSIE, as 90% of patients with DUA-IE have right-sided involvement, though left-sided involvement is not infrequent.<sup>29</sup> Hence, most of what applies to the general RSIE and LSIE populations also applies to patients with DUA-IE, but with special consideration given to their unique demographics and underlying SUD.

**Patient selection and rationale.** Compared to non-DUA-IE, patients with DUA-IE have longer lengths of stay, incur higher health care costs, and have similar short-term survival, even though they tend to be younger with fewer baseline comorbidities.<sup>10,50–55</sup> Surgically managed

patients with DUA-IE have a nearly 50% greater hazard of death and more than double the hazard of reoperation compared to patients who receive surgery for non-DUA-IE.<sup>55</sup>

In DUA-IE, the primary disease process is the underlying SUD, which is the true “source” of the infection. It follows that “source control” cannot be obtained without aggressive management of the SUD.<sup>12</sup> Attempting to surgically treat DUA-IE without an achievable plan to manage the SUD often results in trading one disease (native valve endocarditis) for another (PVE). Recurrent substance use is the most common cause of death after surgery for DUA-IE, and short-term mortality of repeat surgery for DUA-IE is at least twice that of the initial surgery.<sup>24,56</sup>

Therefore, establishing a therapeutic alliance and optimizing medications for opioid use disorder is critical to optimizing outcomes in DUA-IE, but this often requires time. Decompensated heart failure or paravalvular complications that can only be treated with surgery should be performed without delay if the patient is a candidate, similar to patients with non-DUA-IE.<sup>24</sup> For patients with DUA-IE whose main surgical indication is source control or embolism risk reduction, we consider PMA if they are deemed prohibitive surgical risk. It should also be considered for those who may not be at high surgical risk but for whom PMA might offer definitive therapy to avoid a sternotomy or prosthetic material given the known risks of SUD relapse, reinfection, and reoperation. By avoiding the prolonged recovery that comes with a major surgical procedure, the underlying SUD can remain the therapeutic focus. Finally, PMA may serve as a bridge to surgery or surgical decision-making, in order to allow for optimization of their SUD and more accurate prognostication. It is essential that the expert opinions and assessment of addiction medicine specialists be included in the shared decision-making around PMA in DUA-IE, and we believe they should be incorporated into the multidisciplinary endocarditis team whenever possible.<sup>12,24,57</sup>

**Evidence.** Much of the evidence reviewed for RSIE and LSIE applies to those with DUA-IE. A recent scoping literature review of 51 case reports, case series, and small cohort studies found that of the 142 patients who underwent PMA for IE, 80% had a history of injection drug use, indicating that this population predominates in the literature.<sup>15</sup> In a retrospective cohort of patients with right-sided DUA-IE who underwent PMA after being deemed high surgical risk, the overall survival was high, and short-term readmission rates were low, though outcomes were worse among those presenting with septic shock.<sup>17</sup> A retrospective observational cohort study compared 43 persons who inject drugs with RSIE who received TV surgery with 42 who received PMA. Within the caveat of residual confounding inherent to the study design, they found no significant difference in adjusted 12-month mortality between the 2 groups.<sup>19</sup> A similar analysis of 100 patients also found no difference in 1-year survival between surgery and PMA; in addition, those who underwent PMA had undergone the procedure earlier in their hospital course and had a lower overall length of stay.<sup>58</sup> The breakdown of patients with DUA-IE in key studies and case series to date is given in [Table 2](#).

#### CIED-associated endocarditis

Complete device extraction is recommended for systemic CIED infection, and early device removal is associated with improved outcomes.<sup>59</sup> The management of CIED infection has evolved over the past decades, moving away from surgical removal of infected leads toward transvenous lead extraction, with open surgical extraction becoming a backup option of last resort in modern practice.<sup>60</sup> However, questions remain as to which strategy should be preferred in the setting of systemic CIED infections with large (>2 cm) vegetations, especially among those with high surgical risk.<sup>61</sup> Concomitant PMA of large right-sided

vegetations as an adjunct to transvenous lead extraction procedures has been demonstrated to be a safe and feasible alternative to surgery in this scenario.<sup>62–64</sup>

**Patient selection and rationale.** A current European Heart Rhythm Association international consensus document recommends complete device removal with percutaneous transvenous lead extraction whenever possible, and states that it is reasonable to perform PMA of lead vegetations >2 cm for patients with systemic infection concomitant with transvenous lead extraction based on observational data.<sup>65</sup> PMA of vegetations adherent to infected CIED leads immediately prior to percutaneous extraction may facilitate source control of infection and reduce the embolic risk associated with transvenous lead removal without concomitant aspiration. This in turn may lead to improved clinical outcomes by mitigating the embolic burden on the lung prior to and during the extraction as well as the accompanying systemic inflammatory response that comes with the presence of infected debris. We therefore consider PMA for patients with large lead vegetations or PFO prior to transvenous lead extraction, during the same procedure.

**Evidence.** Although PMA plus transvenous lead extraction is associated with better outcomes compared to surgery, this is based on observational data subject to confounding by indication.<sup>63</sup> A systematic review of 88 patients (average age, 65.9 years) who underwent aspiration followed by lead extraction of 205 infected leads with a mean vegetation size of 2.8 cm and average lead implant duration of 5.3 months, reported a complete lead vegetation aspiration success rate of 93.2% with no aspiration related complications and no periprocedural deaths.<sup>66</sup> In another scoping review of 152 patients with CIED-IE who underwent PMA of their infected leads prior to planned extraction, it was found that 1.3% had worsening TR, 1.3% had access site injury, and 0.7% rate of coronary sinus tear, retroperitoneal bleed, hemothorax, and pericardial effusion. Overall in-hospital mortality was 4.6%, and 30-day mortality was 6.6%.<sup>15</sup>

A multinational retrospective study of 101 patients with 247 leads (average age, 68.2 years; mean lead implant duration, 81.7 months; 67.3% *Staphylococcus* species) who underwent aspiration for either vegetations >2 cm or smaller vegetations with concomitant PFO demonstrated a high success rate for both complete vegetation removal and subsequent lead extraction with few major complications.<sup>59,60</sup>

#### PVE

Aspiration of infected material from prosthetic valves is much less commonly encountered in the literature. Nevertheless, it has been described on the right side in young patients with congenital heart disease and infected pulmonary bioprosthetic valves as a means to control infection and defer surgical intervention.<sup>25</sup> A prosthetic TV was involved in 5 of 142 patients included in a scoping review of PMA for IE, but their individual outcomes were not reported.<sup>15</sup> Debulking of left-sided prosthetic valve vegetations has been described at least twice, both with favorable outcomes—one had a residual paravalvular leak that was managed expectantly and another that was immediately followed by planned transcatheter mitral valve-in-valve replacement.<sup>48,49</sup>

#### When to exercise caution

Antibiotics and surgery, when indicated, remain the foundational management of IE and should be pursued aggressively when appropriate, with PMA reserved for the situations described above after careful consideration. As outlined in the [Central Illustration](#) and [Table 1](#), there are also several clinical scenarios where it is necessary to proceed with caution or avoid PMA entirely. Decompensated heart failure due to

valvular insufficiency from endocarditis cannot be fixed with PMA, and there is the risk that PMA may result in iatrogenic worsening of valvular dysfunction; hence, PMA may be of limited utility and poses potential harm. Similarly, PMA cannot address local complications of infection, such as abscesses or pseudoaneurysms.

Even in cases where PMA may be appropriate, several procedural and patient factors should be considered. If pursuing a left-sided approach or a right-sided approach in the presence of a PFO, cerebral embolic protection should be considered. Anemia and thrombocytopenia should be identified and evaluated; although there are no established thresholds, transfusion should be considered to support the patients undergoing PMA, accounting for potential blood loss related to any underlying bleeding diathesis, access complications, or the aspiration itself, especially if the platform does not allow for blood recirculation. Finally, in the presence of cerebral embolic sequelae, it is critical to engage in multidisciplinary discussions with neurology or neurosurgery prior to any PMA attempt regarding the risks, benefits, and timing of the procedure, as it generally requires heparinization for a target activated clotting time of 250 seconds during device utilization.

## Part 2: PMA and the health care system

In order to address evidence gaps, increase safety, standardize care, ensure appropriate reimbursement, and provide equitable access, we next consider PMA for IE in the context of our modern health care system.

### Clinical collaboration

Multidisciplinary endocarditis teams are recommended by major society guidelines and have been demonstrated to improve patient outcomes.<sup>41,67,68</sup> Teams specifically dedicated to DUA-IE are now being formed to meet the demand of expertise required to care for these patients.<sup>57,69</sup> These teams should be at the forefront of shared decision-making around PMA for IE.

In addition to raising awareness and improving collaboration within their own institution, these teams can also lead the effort to create centers of excellence that can go on to serve as a referral hub for a given region. Teams at such centers may also offer consultative advice to regional community hospitals, helping to triage potential transfers and ensure those who may benefit from PMA are appropriately considered. Once established, teams and centers can collaborate more formally across institutions and with major societies on a national and international level, sharing their experiences and cooperating in research efforts.

### Financial considerations

In 2014, the AngioVac system (AngioDynamics) was granted U.S. Food and Drug Administration approval “for use as a venous drainage cannula and for removal of fresh, soft thrombi or emboli during extracorporeal bypass for up to 6 hours.”<sup>70</sup> In 2023, the US Food and Drug Administration granted Breakthrough Device designation for “the non-surgical removal of vegetation from the right heart.” This pathway allows for expedited assessment and accelerated review of the AngioVac system for this expanded indication.<sup>71</sup>

There is currently no Current Procedural Terminology (CPT) code specifically for PMA for IE. The descriptor for CPT Code 0644T is “Transcatheter removal or debulking of intracardiac mass via suction device, percutaneous approach, with intraoperative reinfusion of aspirated blood, including imaging guidance, when performed.” This is a category III code for “emerging technologies, services, and procedures,” and the Centers for Medicaid & Medicare Services does not

establish standard reimbursement levels for category III codes. More specifically, the approval and use of 0644T “does not guarantee coverage by third party health payors or set a national or local payment level for physician services.”<sup>72</sup>

In order to be reimbursed, there must be documentation of medical necessity as well as attestation of actual physician work including time and intensity as a percentage to the “normal” expected amount for a given procedure that includes clinical staff time, supplies, equipment, and liability, within the medical record. Physicians can also attempt to “crosswalk” a reference procedure with an established, agreed-upon payment to CPT 0644T in the hopes that the payor accepts the interchangeability and provides compensation at the same rate.<sup>72</sup> Taking it one step further, they can attempt to negotiate a value-based rate with the payor, looking beyond just the procedure itself and including the value of improved net health outcomes as well as the complexity, clinical impact, and resource utilization compared to other treatments for the same condition, in the context of the total time and skill needed for all components of periprocedural care.<sup>71</sup>

Including Healthcare Common Procedure Coding System code C1757 indicates that a thrombectomy/embolectomy catheter was used in the case. Although Healthcare Common Procedure Coding System codes usually do not result in greater payment, they can help track the use of supplies, which in turn may be used to decide future reimbursement rates. Relevant codes, including the International Classification of Disease-10 Procedure Coding System and Medicaid Severity Diagnosis Related Groups, are listed in Table 3.<sup>72</sup>

Advocacy from medical organizations, especially those representing interventional cardiologists, is needed in order to secure reimbursement for PMA for IE and minimize the documentation burden placed on interventionalists in order to obtain appropriate compensation commensurate to the level of effort and technical skill required for all of the procedure types described in this statement. Furthermore, accurate and consistent documentation and coding are crucial to ensuring the accuracy of any future claims-based research.

### Innovation and research

We propose the need for a consortium for PMA in IE. The consortium should engage in active data collection, play a role in procedural and site development, and interface with the industry to provide recommendations and guide future device iterations. The objectives would be to accumulate procedural data, follow long-term outcomes, share information for best practices (both at a procedural and programmatic level), produce peer-reviewed research, secure funding, advocate for appropriate reimbursement, advise industry, and ultimately improve patient outcomes.

To form this consortium, we offer the organizational structure outlined in Figure 2. An initial steering committee will develop the mission and charter and recruit members to serve in 3 permanent committees: an Executive Committee, a Data and Research Committee, and a Membership Committee.

The responsibilities of the Executive Committee include acting as a liaison between industry, societies, regulators, policymakers, and the consortium, approving actions of the other committees, securing funding and grants for consortium operations, scheduling and organizing meetings, and establishing a budget and approving expenditures.

The responsibilities of the Data and Research Committee include creating and updating the variable list for data entry forms, maintaining and housing the database (or contracting with a vendor to do so), receiving research requests and approving data use agreements, and creating periodic reports for both site participation and patient outcomes.

Finally, the Membership Committee would establish the parameters for consortium participation, approve new members, and recruit



**Table 3.** Relevant coding for percutaneous mechanical aspiration in infective endocarditis.<sup>72</sup>

CPT	Code description	
0644T	Transcatheter removal or debulking of intracardiac mass (eg, vegetations, thrombus) via suction (eg, vacuum, aspiration) device, percutaneous approach, with intraoperative reinfusion of aspirated blood, including imaging guidance, when performed	
37799	Unlisted procedure, vascular surgery	
HCPCS	Code description	AngioVac product/item numbers
C1757	Catheter, thrombectomy/embolectomy	Cannula with Dilator (20°)/965251930 Cannula with Dilator (180°)/H96 5251940 Cannula Only F1885/H965252000 Cannula with Dilator (20°), Circuit and Bubble Traps (2)/H965251950 Cannula with Dilator (180°), Circuit and Bubble Traps (2)/H965251960 System with Circuit F1885/H965252010
ICD-10-PCS	Code description	MS-DRG numbers
02CJ3ZZ	Extirpation of matter from Tricuspid valve, percutaneous approach	270, 271, 272 Other major cardiovascular procedures
02C63ZZ	Extirpation of matter from Right atrium, percutaneous approach	228, 229 Other cardiothoracic procedures
02CK3ZZ	Extirpation of matter from Right ventricle, percutaneous approach	228, 229 Other cardiothoracic procedures

CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-PCS, International Classification of Disease-10 Procedure Coding System; MS-DRG, Medicare Severity Diagnosis Related Groups.

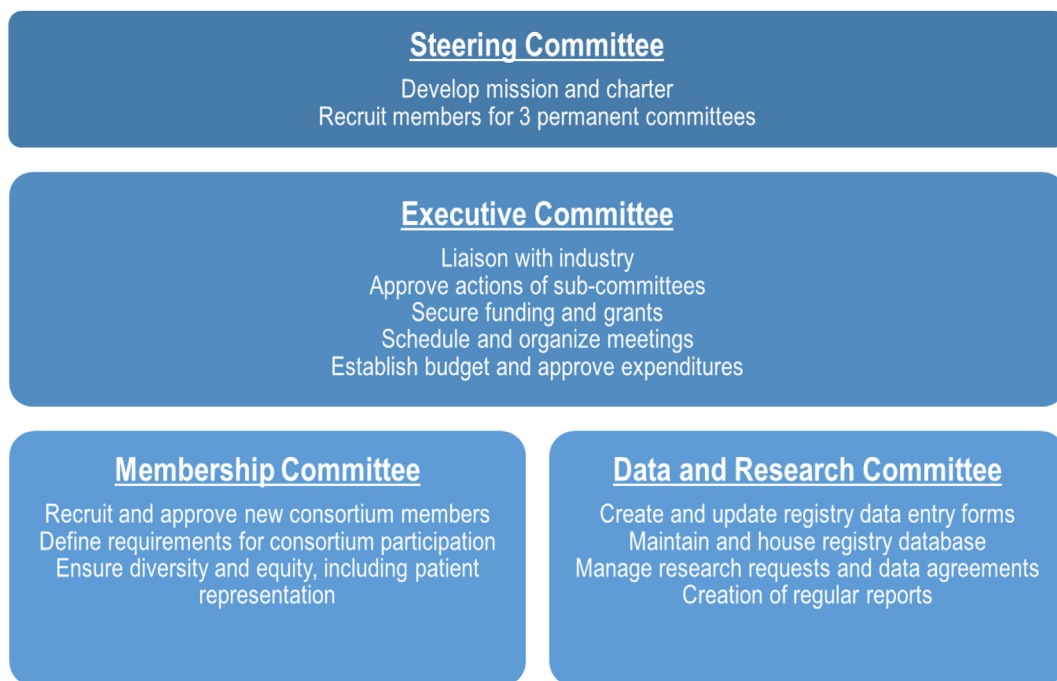
new members for the consortium. To participate in the consortium as a member, they must submit case information, long-term outcomes, and participate in annual meetings. Committee participation and participation in study development and publication would be optional.

### Part 3: Unanswered questions

The purpose of the consortium would be to allow for a structured, rigorous, and sustainable approach to address the many evidence gaps and unanswered questions.

### Standardization of care

Every multidisciplinary endocarditis team is unique. How do we standardize the level of PMA care among institutions with different cultures and resources? What is the necessary amount of support to run a PMA program for IE safely and effectively? For example, is it possible to equitably provide PMA to patients with DUA-IE if there are no addiction-trained clinicians on the endocarditis team or available for consultation? Should interventionalists become core members of the endocarditis team at PMA centers if they are not already? Or should they be involved on an ad hoc basis, and if so, when is the ideal time for consultation?

**Figure 2.**

**Proposed organization of a consortium for percutaneous mechanical aspiration in infective endocarditis.** This figure outlines the proposed organizational structure of a consortium dedicated to improving the evidence base and outcomes of percutaneous mechanical aspiration in infective endocarditis.

Given the resources required, PMA for IE will be limited to facilities that have the necessary infrastructure and technical expertise. In order for this procedure to be accessible to all those who may benefit, we propose a “hub and spoke” referral model where a centralized tertiary center receives requests from the surrounding region which raises questions of process and practicality. With this in mind, how can we standardize transfer workflows around PMA? In what ways, if any, should they differ from established practices for other advanced catheter-based procedures, for both transferring and receiving hospitals? What is the role of “round trip” transfers, where a potential candidate for PMA is transferred, evaluated in person, the PMA is performed if appropriate, and once the patient is stabilized postprocedure, they return to the referring facility? This may be of particular importance for patients with DUA-IE, as being discharged from a facility close to where the patient resides may be key in securing the necessary SUD care and support after their inpatient stay is complete.

#### Awareness and education

Raising awareness of PMA as a therapeutic option for IE and providing education on periprocedural care will be necessary for ensuring this practice is implemented safely and equitably. This must be achieved at multiple levels: locally within institutions, nationally and internationally among professional societies, and collaboratively across disciplines and care roles. What are the best practices for disseminating information within and between health systems? What are the forums for institutions to share their experiences and proceduralists to share their skills?

#### Patient selection, procedural performance, outcomes, and research

Discerning the indications and contraindications remains the largest and most important challenge in this space. While we have postulated

candidate patient populations and proposed mechanisms of benefit for each, robust prospective registry and eventually randomized data are required to test these hypotheses. Given the clinical complexity and heterogeneity of the proposed patient populations, considerable time, effort and funding will be needed to answer these questions through iterative investigations. Since this inaugural meeting, many summit participants have collaborated with other investigators nationwide to share patient outcomes in a pooled multisite registry, including over 20 centers. Initial findings from this registry are expected to be published in late 2024.

In the meantime, rigorous retrospective analyses using preexisting electronic health records and claims data employing quasi-experimental methods such as propensity matching or difference-in-differences approaches to compare similar patients who received PMA to those who did not may help provide insight into these issues. This requires a validated mechanism for accurately identifying and classifying patients with IE who undergo PMA for their IE using billing or procedural codes, which is yet to be established.

A collection of additional questions in these domains are outlined in Table 4.

#### Conclusions

Percutaneous mechanical aspiration has emerged as an option for carefully selected patients with IE as a complementary treatment modality, whether a bridge to eventual surgery pending optimization of unmodifiable risk factors or their underlying SUD, a salvage destination therapy for those deemed inoperable, an adjunct to infected transvenous lead extraction, or a means of nonsurgical sample acquisition for analysis.

Rigorous research is needed for us to understand the benefit of PMA compared to medical therapy and surgery across various indications

**Table 4.** Additional unanswered questions in percutaneous mechanical aspiration for IE.

Preprocedure
<ul style="list-style-type: none"> <li>• Which patients benefit from PMA in IE and by what metrics?</li> <li>• When is the optimal time to intervene in a given clinical scenario?</li> <li>• What are the key characteristics that influence the effect of PMA on outcomes (eg, vegetation size, length of antibiotic treatment, pathogen resistant profile, the degree of preexisting tricuspid regurgitation, the presence of septic or cardiogenic shock, severity of underlying SUD)?</li> <li>• What are the minimum and maximum size-cut offs for vegetations, if any, and what modality should be used to measure them?</li> </ul>
Periprocedure
<ul style="list-style-type: none"> <li>• What defines technical success for each of the indications (RSIE, LSIE, and CIED-IE) and how should this be ascertained?</li> <li>• What level of additional valvular dysfunction, if any, is to be expected or acceptable?</li> <li>• Is full debridement required to improve outcomes?</li> <li>• Are vegetations in the subvalvular apparatus safe for aspiration?</li> <li>• When and how should a PFO or ASD be ruled out prior to proceeding with PMA?</li> <li>• Which platform is ideal for a given patient and what are the main factors that should influence device choice?</li> <li>• Should PMA attempts be made at multivalvular disease?</li> <li>• If so, is it better to proceed with simultaneous or staged procedures?</li> <li>• What special considerations should be taken for patients on mechanical circulatory support undergoing PMA?</li> </ul>
Postprocedure
<ul style="list-style-type: none"> <li>• What follow-up imaging should routinely be done and when?</li> <li>• What are the standards for documentation and billing?</li> </ul>
Outcomes and research
<ul style="list-style-type: none"> <li>• What are the standard complication, safety, and efficacy data that should be collected for a registry?</li> <li>• What are the short-, medium-, and long-term safety and efficacy outcomes of PMA compared to both medical and surgical therapy for each of the proposed indications?</li> <li>• What are the ideal design and patient inclusion criteria for prospective registries?</li> <li>• What combination of ICD-10 and CPT codes accurately identify IE, DUA-IE, and PMA patients in claims data?</li> <li>• What should the patient population, outcomes, and design be for the first randomized control trial of PMA in IE?</li> </ul>

ASD, atrial septal defect; CIED-IE, cardiac implantable electronic device–infective endocarditis; CPT, Current Procedural Terminology; DUA-IE, drug use–associated infective endocarditis; ICD-10, international classification of disease-10; IE, infective endocarditis; LSIE, left-sided infective endocarditis; PFO, patent foramen ovale; PMA, percutaneous mechanical aspiration; RSIE, right-sided infective endocarditis; SUD, substance use disorder.

and clinical scenarios. In addition to establishing an evidence base, implementation efforts are needed to define and disseminate best practices and ensure fair remuneration for providers and equitable access for patients. Our proposed consortium can help provide the organization, funding, and planning needed to address evidence gaps, standardize documentation and billing, perform advocacy work, and help make certain that all patient populations who are shown to benefit from this procedure are able to access it. PMA for IE has great promise, but significant work remains if we are to fully realize its potential in the care of modern endocarditis patients.

### Declaration of competing interest

Yasir Akhtar declares honoraria from being on the speaker bureau for AngioDynamics and Penumbra. Benjamin Bearnot declares stock holdings in HazardLock, Inc. Stephanie El Hajj Younes declares being paid speaker honoraria for AngioDynamics. William Brent Keeling declares consulting for AngioDynamics. John Moriarty declares consulting for AngioDynamics, Penumbra Medical, Innova Vascular, Pavmed, Pfizer, and Boston Scientific. Lucas X. Marinacci declares funding from NIH/NHLBI T32HL160522 and NIDA R25DA013582. Molly L. Paras declares speaking for events sponsored by AngioDynamics without financial remuneration and grant support from the American College of Cardiology. Seenu Reddy declares consulting for AngioDynamics. Kenneth Rosenfield declares consulting for and/or being on the scientific advisory board for Althea Medical, AngioDynamics, Boston Scientific, Contego, InspireMD, Magneto, Mayo Clinic, Neptune Medical, Philips, Summa Therapeutics, SurModics, Thrombolex, Terumo, and Truic; holding equity in Accolade, Access Vascular, Aerami, Althea Medical, Contego, Cruzar Systems, Embolitech, Endospan, InspireMD, JanaCare, Magneto, Orchestra BioMed, PQ Bypass, ProSomnus, Shockwave Medical, Summa Therapeutics, Thrombolex, Truic, and Valcare Medical; and being a board member of the National PERT Consortium. Raymond Schaerf declares advising and receiving payment for travel and for lectures from AngioDynamics, Medtronic, and Cook Medical, membership of the Medical Advisory Board, and payment for board work from Abbott, and advising and receiving payment for consulting from Xcardia. Sanjum S. Sethi declares honoraria and consulting fees from Boston Scientific, Inari, Terumo, Janssen, Chiesi, Argon, and Penumbra. Eric Secemsky declares funding from NIH/NHLBI K23HL150290, the US Food and Drug Administration, and SCAI Grants to the institution from Abbott/CSI, BD Biosciences, Boston Scientific, Cook, Medtronic, Philips, and speaking and consulting for Abbott/CSI, BD Biosciences, BMS, Boston Scientific, Cagent, Conavi, Cook, Cordis, Endovascular Engineering, Gore, InfraRedx, Medtronic, Philips, RapidAI, Rampart, Shockwave, Siemens, Terumo, Thrombolex, VentureMed, and Zoll. M. Rizwan Sohail declares honoraria and consulting fees from Medtronic, Philips, and AngioDynamics. Christoph Starck declares payment to his institution related to his activity as speaker fees, honoraria, consultancy, advisory board fees, investigator, and committee member of AngioDynamics, Abiomed, Atricure, Medtronic, Spectranetics, Biotronik, LivaNova (Sorin), and Cook Medical and departmental or institutional research funding from Cook Medical and Hylomorph. Pedro Villablanca declares consulting fees from Edwards Lifesciences, Medtronic, AngioDynamics, and Abiomed. Evin Yucel declares speaking for events sponsored by AngioDynamics without financial remuneration. The remaining authors report no disclosures or conflicts of interest.

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