Short-term results of fenestrated physician-modified endografts for type 1a endoleak after conventional thoracic endovascular aortic repair

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ABSTRACT

Objective: This study aims to assess the feasibility and effectiveness of physician-modified fenestrated stent grafts (PMEGs) in treating type 1a endoleak after conventional thoracic endovascular aortic repair (TEVAR) in aortic arch pathologies.

Methods: Patients who developed a type 1a endoleak after conventional TEVAR were included in the study. They underwent treatment with fenestrated PMEGs, which involved single or double fenestration for the supra-aortic trunks.

Results: Twenty patients were treated with PMEGs between October 2018 and November 2023. Among them, 25% received single fenestrated PMEGs and 75% received double fenestrated PMEGs. The technical success rate was 100% for both types. Eighty percent of the PMEGs had a landing zone in zone 0, whereas 20% had a landing zone in zone 2. There were no in-hospital deaths. After 30 days, 1 patient died as the result of an aortic-related cause (retrograde dissection). The mean follow-up time was 16.5 months (range, 0-60 months). No major adverse events such as stroke or spinal ischemia were reported. No type 1 or type 3 endoleaks were observed, and one type 2 endoleaks required peripheral endovascular reintervention.

Conclusions: The treatment of type 1a endoleaks using fenestrated PMEGs after conventional TEVAR for aortic arch pathologies is a viable option. It is associated with acceptable rates of early and midterm major morbidity and mortality. (JTCVS Techniques 2024;:1-11)

CENTRAL MESSAGE

Fenestrated PMEG is safe and efficient option in short-term follow-up for the treatment of type 1a endoleak after conventional TEVAR in aortic arch pathologies.

PERSPECTIVE

Physician-modified endograft (PMEG) represents a therapeutic option in active development for the treatment of aortic pathologies. Its use and effectiveness are beginning to be demonstrated for aneurysms and dissections of the aortic arch. We report our results of applying this technique for the treatment of type 1a endoleaks after conventional TEVAR (thoracic endovascular aortic repair).
Over the past 2 decades, endovascular treatment has emerged as the preferred approach for thoracic aortic lesions. The advancements in materials and the relative ease of use have made it the gold standard for treating a significant number of descending thoracic aortic pathologies.\(^1\)

However, despite the overall success of endovascular treatment in zone 3 of the aorta, it may not always be sufficient to prevent proximal disease progression, such as aneurysm expansion or aortic dissection. One of the major challenges in endovascular repair is the occurrence of endoleaks after thoracic endovascular aortic repair (TEVAR), which can lead to aortic diameter enlargement and increase the risk of rupture. Among various types of endoleaks, type Ia endoleaks are particularly concerning, as they indicate inadequate endovascular exclusion of the proximal segment of the pathologic aorta, potentially resulting in rapid aortic dilation and even false aneurysm formation. Managing type Ia endoleaks after TEVAR presents a surgical challenge because of the complex anatomy involved.

Traditionally, addressing such endoleaks often required morbid vascular surgeries involving transposition of 1 or more supra-aortic trunks before the placement of an additional proximal aortic stent graft. In cases of significant proximal extension, it may even necessitate concomitant cardiac surgery with extracorporeal circulation. In recent years, alongside conventional treatments, complete endovascular solutions, including branched or fenestrated endovascular grafts, have been developed. Among these solutions are physician-modified endovascular grafts (PMEGs). This technique, practiced in our center since 2015, has undergone major technical improvements that have made it simple, safe, and reproducible. Unlike custom-made, branched, or fenestrated techniques, it has the advantage of being available in emergencies and compatible with a wide range of clinical situations. Feasibility and performance studies of PMEGs for treating complex aortic arch lesions recently have been published, encompassing various types of de novo lesions such as aneurysms, dissections, and blunt thoracic injuries.\(^2\)-\(^4\)

We believe that PMEGs could offer a therapeutic option for extending the proximal coverage area while preserving the patency of supra-aortic trunks, thereby providing an endovascular solution for type Ia endoleaks after unsuccessful exclusion by conventional TEVAR. By this study, we report our experience and outcomes using PMEGs in the treatment of type Ia endoleaks after unsuccessful conventional TEVAR in zone 2 and 3.

**METHODS**

**Ethics**

This study was conducted in accordance with the principles of the Helsinki II Declaration, and informed consent was obtained from all patients. This study was approved by the local institutional review board, which is registered at the Office for Human Research Protections. When we approached patients for consent, we discussed potential risks and benefits of PMEG and manufactured stent grafts in detail and without bias before the procedure. The theoretical increased risk of infection associated with PMEG, the lack of standardization, and the lack of long-term outcomes were clearly explained for all patients.

**Patients**

Protocol and informed consent were approved by the institutional review board (February 9, 2018; #0001158). All patients provided informed written consent. From October 2018 through November 2023, all patients previously treated with a conventional TEVAR presenting with a type Ia endoleak were included. Only patients with a thoracic ascending aorta diameter exceeding 40 were excluded to avoid the risk of retrograde aortic dissection during surgery. Multidisciplinary teams were involved in the decision-making. Collected variables were categorized as demographic and preoperative (age, sex, comorbidities), operative (aortic anatomy, aortic pathology, graft types), and postoperative outcomes (technical achievement, reintervention, stroke, endoleak and mortality).

**Planning, Sizing, and Device Preparation**

Procedure planning and device sizing were performed using a dedicated 3-dimensional vascular imaging workstation (Endosize [Therenva] or OsiriX Imaging Software [Pixmex]) with centerline luminal reconstructions. Stent graft diameters in the proximal and distal sealing zones were oversized by 10% to 15%. Centerline luminal and external curvature reconstruction is used to measure the distance between the brachiocephalic trunk (BT) and the left common carotid artery (LCCA) and between the LCCA and the left subclavian artery (LSA) to check the dimensions and of the large and small fenestration, as well as the diameters of the BT, LCCA, and LSA. Centerline luminal reconstruction is also used to locate the origin of each vessel from the aorta in relation to its clock position and check the spatial positioning of the large window in relation to the small window (Figure E1). Volume rendering is used to determine the optimal position of the C-arm and to evaluate tortuosity of the aortic arch.

**Device Modifications**

The Valiant Captivia endograft (Medtronic) was used and modified for all procedures. Modification of the stent graft is performed on a back table in the operating theater, commencing before the start of anesthesia. For the double-fenestrated PMEG, the fenestrations were a proximal larger fenestration that incorporated the brachiocephalic trunk and left common carotid artery and a distal smaller fenestration for the LSA. Only the LSA fenestration was stented. A complete description of the device modification has
been previously reported,⁵,⁶ and the modification process is illustrated in Figure 1 and Video 1. A most recent modification consists of the addition of a preloaded guidewire for the LSA fenestration. This modification of the procedure has allowed for a better efficiency in the LSA catheterization step, which was sometimes a critical step when it was before performed retrograde through the brachial approach.

**Technical Steps**

The procedures were performed with the patient under general or local anesthesia with sedation in an operating room equipped with a hybrid theater with a fixed C-arm. Heparin (100 U/I/kg) was administered. An 18-F to 26-F, 33-cm introducer sheath (DrySeal Flex Introducer Sheath; W.L. Gore & Associates) was positioned retrograde through the common femoral access after placing the percutaneous closure system. A 6-F, 65-cm, sheath was introduced through the left brachial access into the origin of the LSA. A double-curve, 300-cm, extra-stiff 0.035-in wire (Lunderquist, Extra-Stiff DC Wire Guide; Cook Medical Inc) was positioned by the femoral access against the aortic valve. The proximal side of the preloaded guidewire was advanced thought the femoral access sheath, delivered to the LSA, and exteriorized by the brachial sheath using a 6-F helicoidal snare-loop (EN Snare; Merit Medical Systems USA) to realize an a line between femoral and brachial access. The modified thoracic stent graft was introduced over the ultrastiff guidewire through femoral access, and the preloaded guidewire was progressively pulled by the second operator from the left brachial approach to orient the fenestrations superiorly to face the supra-aortic trunk originating off the superior arch. The absence of a twist between the preloaded guidewire and the stent graft was checked at this stage and corrected in case by clockwise or anticlockwise rotation.

**FIGURE 1.** Modification process of the double-fenestrated PMEG. A, Endograft after deployment on the back table and retrieval of the proximal markers. B, Creation of the fenestration using a blade for the large fenestration and a cautery device for the small fenestration. C, Preloading from the back into the sheath and the deployed endograft, through the small fenestration. DE, Resheathing using snuggers and cotton vessel loops. F, Resheathed PMEG.
Angiography was performed perpendicular to the LSA with an angle defined on the preoperative reconstruction through the left humeral sheath. The mean blood pressure was lowered to approximately 80 mm Hg to optimize accuracy, and the deployment was carried out progressively with fluoroscopic guidance by the main operator while the second operator progressively pulled the preloaded guidewire during the deployment in order to avoid the rare blocking of the guide and to allow the good positioning of the subclavian fenestration in front of its ostium. After complete deployment, the release system was removed and a 9-F; 80-cm sheath was advanced by the femoral access over a preloaded 0.035-inch guidewire through the LSA fenestration into the stent graft lumen. An 8- to 12-mm diameter, 32- to 59-mm-long balloon-expandable covered stent (Getinge Advanta V12, Bentley-BeGraft, Bard-Lifestream, Bentley-BeGraft, Bard-Lifestream) was deployed with 5 mm of protrusion into the aortic stent graft lumen. The subclavian stent was flared with a standard 10-mm balloon concomitantly with aortic stent graft inflation (Coda LP balloon catheter; Cook Medical Inc). Completion angiography was performed to check the position of PMEG, the supra-aortic trunk patency, and the disappearance of the endoleak. During the procedure, the BT blood flow was monitored with a right radial artery pressure arterial catheter. Cerebral perfusion was systematically assessed using near-infrared spectroscopy (INVOS; Medtronic). Principal steps of the procedure are presented in Figure 2 and Video 2.

Follow-up
Study follow-up time was defined as the date of the last postoperative clinical evaluation. All surviving patients underwent at least postoperative surveillance imaging (contrast-enhanced computed tomography [CT] scan) at 1, 3, 6 months and then annually. An example of 3-dimensional reconstruction of CT scan control at 1 month is reported in Figure 3.

Statistical Analysis
Categorical data are presented as frequencies; continuous variables are expressed as mean and range or standard deviation. All statistical analyses were performed using IBM SPSS Statistics 24 software (version 24.0.0.0).

Technical Terms and Evaluation Criteria
Technical success was defined by success of stent graft deployment, primary patency of supra-aortic trunks, and absence of type 1a endoleak on immediate arteriographic control. Reintervention was defined by need for completion surgery, either endovascular or open, in the short or long term. Stroke was clinically defined by the occurrence of sensory or motor neurologic deficit or involvement of cranial nerves, confirmed by imaging examination as being a consequence of the procedure. Endoleak was radiologically assessed during follow-up examinations or intraoperative arteriography. It was defined as the persistence of blood flow outside the graft within the aneurysmal sac after endoluminal repair. A significant increase in the diameter of the aneurysmal sac without visualization of the endoleak constituted an indirect sign of endoleak.

RESULTS
From October 2018 through November 2023, 20 patients had type 1a endoleak after conventional TEVAR and were treated with a PMEG. All patients gave written consent. All of them presented with significant increase of diameter of aortic arch at the control CT scan. Most patients (18; 90%) were treated emergently for persistent thoracic pain, pseudoaneurysm or aortic rupture. Mean duration between TEVAR and the endoleak treatment was 62 months (min-max, 11-110 months).

Baseline characteristics of the patients are shown in Table E1. Mean age was 80 years, 90% were male, 85% presented with hypertension, and 60% were classified American Society of Anesthesiologists class III or IV. The initial surgical indication is represented in Figure E2. Technical details of the first surgery are included in Table 1.

Before the intervention, 95% of patients had already been treated with conventional TEVAR, with 65% landing in zone 3 and 30% in zone 2. One patient had a total debranching in zone 0 with replacement of the ascending aorta. Four (20%) patients had LSA transposition into LCC, with 1 having an extra right carotid-subclavian bypass for an aberrant right subclavian artery. One patient (5%) was already treated with fenestratedendovascular aortic repair with a single fenestration on LSA. Two had a hemi-arch replacement for acute type A dissection. One patient wasn’t revascularized on the LSA. Operative details of PMEG for the treatment of the type 1a endoleak are included in Table 2.

Intraoperative Results
Technical success was 100%. In total, 75% were treated with a double-fenestrated PMEG. One of the single PMEGs was targeting a total debranching in zone 0. In total, 80% of the PMEGs were landing in zone 0 and 20% in zone 2, and 85% of the PMEGs were stented with 6 on the LCC, 10 on the LCA, and 1 stent in the debranching bypass. The only patient who was initially treated with a single fenestrated endovascular aortic repair on the LSA was treated with a single fenestrated PMEG targeting the LCC and had a carotid-LSA bypass. An example of proximal evolution after TEVAR in zone 3 with type 1a endoleak treatment by PMEG is presented in Figure 4.

Regarding 30-day results, after surgery, mean hospital stay was 4 days (min-max, 2-15 days). No patient died during hospital stay. Mean follow-up time was 16.5 months (min-max, 0-60 months). One patient died during the first 30 days after surgery because of retrograde type A aortic dissection 15 days after the procedure. No stroke or spinal ischemia were reported. 1 early peripheral reintervention was necessary for thrombectomy of an ili-femoral bypass.
After 30 days, no patients died from aortic-related causes during the follow-up. No type 1 nor type 3 endoleak was observed. Three type 2 endoleaks were detected on control CT scan at 1 month. Two of them weren’t present on the CT scan at 3 months. One type 2 endoleak originating from the LSA required a supplementary endovascular surgery to extend coverage of the left subclavian artery. No major adverse event (stroke, spinal ischemia) have been reported lately. One year after the PMEG, 1 patient needed a total excision of endovascular material in reason of aortobronchial fistula and a pericardial patch reconstruction with surgical success. Details of the follow-up are included in Table 3.


DISCUSSION

The results from the present study suggest that the use of single- and double-fenestrated PMEGs is a feasible strategy for the treatment of Ia endoleak after TEVAR for aortic arch pathologies with excellent technical success and low morbidity and mortality. Open surgery remains the reference standard for a few aortic arch repair indications (aneurysm, for example). Even for elective procedures, the mortality and stroke rates have remained significant, especially for elderly patients and those with major pre-existing comorbidities. Beckmann and colleagues report an early reintervention for bleeding in 18% of the patients, definitive renal epuration in 4%, paraplegia in 4%, and...
11% of stroke with severe sequel. Mortality was approximately 16%.

Because many patients will be deemed unsuitable for open repair, alternatives have emerged, and less-invasive procedures have been developed. Debranching TEVAR has been shown to be effective in the long term for distal aortic arch aneurysm exclusion, especially in high-risk patients. Voigt and colleagues found a high risk of peripheral nervous lesions, with 25% phrenic lesions, 5% recurrent lesions, and 2% axillary plexus lesions, associated with a substantial risk of loss of vision and mortality during the period between the 2 surgical stages when patients do not show up for the second operation; Konstantinou and colleagues reported that debranching TEVAR resulted in more perioperative complications and required a longer operative time compared with fenestrated TEVAR.

The endovascular approach for aortic repair can result in long-term complications, including the occurrence of endoleaks, with type 1 endoleaks being the most serious. Indeed, type 1 endoleaks leads to a significant risk of rapid evolution and rupture. They occur as the result of a lack of proximal (type 1a) or distal sealing (type 1b). Studies have identified long neck insufficiency and excessive angulation as the main predictive factors for the development of type 1a endoleaks, which can contribute to the bird-beak effect. Although type 1b endoleaks can be managed by adding a distal covered extension, the treatment of type 1a endoleaks is more challenging. Managing type 1a endoleaks must take into account the supra-aortic trunks, and the strategic choice must be carefully adapted to the patient’s overall condition, considering options such as open, hybrid, or totally endovascular surgery.

If the initial procedure has a sealing in zone 3, and zone 2 seems favorable, there are many options. Covering of the LSA without revascularization of the left upper limb has been proposed and mostly used in emergency cases. Results compared with revascularization of the left upper limb are not convincing, as reported by Matsumura and colleagues: greater rate of stroke (odds ratio [OR], 2.58), spine ischemia (OR, 2.69), and upper-limb claudication (OR, 47.7). For this reason, both the American and European guidelines have recommended consideration of LSA revascularization in elective zone 0, 1, or 2 TEVAR to reduce the risk of neurologic complications.

A way of endovascular revascularization of the LSA without initial endograft modification is thoracic branched endografts (branched endovascular aortic repair).

### TABLE 1. Technical details of the first surgery of 20 patients

<table>
<thead>
<tr>
<th>Variables, n (%)</th>
<th>N = 20</th>
</tr>
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<tbody>
<tr>
<td>Single-fenestration TEVAR</td>
<td>1 (5)</td>
</tr>
<tr>
<td>TEVAR</td>
<td>19 (95)</td>
</tr>
<tr>
<td>Proximal landing zone 0</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Proximal landing zone 2</td>
<td>6 (30)</td>
</tr>
<tr>
<td>Proximal landing zone 3</td>
<td>13 (65)</td>
</tr>
</tbody>
</table>

**TEVAR**, Thoracic endovascular aortic repair.

### TABLE 2. Operative details of 20 patients ongoing fenestrated PMEG for 1a endoleak

<table>
<thead>
<tr>
<th>Variables</th>
<th>N = 20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative</td>
<td></td>
</tr>
<tr>
<td>1a endoleak, n (%)</td>
<td>20 (100)</td>
</tr>
<tr>
<td>Persistent thoracic pain, n (%)</td>
<td>17 (85)</td>
</tr>
<tr>
<td>Rupture, n (%)</td>
<td>3 (15)</td>
</tr>
<tr>
<td>Pseudoaneurysm, n (%)</td>
<td>2 (10)</td>
</tr>
<tr>
<td>Duration since treatment, mo, mean (min-max)</td>
<td>62 (11-110)</td>
</tr>
<tr>
<td>PMEG fenestration, n (%)</td>
<td></td>
</tr>
<tr>
<td>Single fenestration</td>
<td>5 (25)</td>
</tr>
<tr>
<td>Double fenestration</td>
<td>15 (75)</td>
</tr>
<tr>
<td>Proximal landing zone, n (%)</td>
<td></td>
</tr>
<tr>
<td>Zone 0</td>
<td>16 (80)</td>
</tr>
<tr>
<td>Zone 2</td>
<td>4 (20)</td>
</tr>
<tr>
<td>Stented artery, n (%)</td>
<td></td>
</tr>
<tr>
<td>LCC</td>
<td>6 (30)</td>
</tr>
<tr>
<td>LSA</td>
<td>10 (50)</td>
</tr>
<tr>
<td>Debranching bypass</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Technical success, n (%)</td>
<td>20 (100)</td>
</tr>
</tbody>
</table>

**PMEG**, Physician-modified endograft; **LCC**, left common carotid; **LSA**, left subclavian artery.
Gore Thoracic Branched Endograft device incorporates a single internal retrograde branch for arch vessel perfusion. The 3-year midterm results of the early feasibility trial were recently published, showing favorable patency and durability with low rates of graft related complications. This cohort consisted of 40 patients (31 zone 2 and 9 in zone 0 or 1). Freedom from death at 1 and 3 years was 90% and 84%, respectively. A second arm of the study involves deployment of the side branch in zone 0 or 1. This involves deployment in either the innominate or left common carotid artery with extra-anatomic bypass of the left common carotid or left subclavian artery.14

Cook Medical has designed an inner branch arch endovascular graft that seals in the ascending aorta and has up to 3 proximal internal sealing stents with active fixation barbs on the most proximal sealing stent. A retrospective multicenter analysis of the first 38 patients treated with this device was published in 2014. The 30-day mortality was 30% in the first 10 patients and 7.1% in the subsequent 28 patients, which suggest a significant learning curve with patient selection and procedural experience.

Haulon and colleagues15 recently reported a systematic review on customized (branched and fenestrated) and non-customized (parallel graft or surgeon-modified fenestrated...
TEVAR) device techniques for endovascular repair of the aortic arch. Their review of the literature from 2000 to 2022 included 30 studies and 2135 patients. Pathologies included aortic dissection (48%) and aneurysm (46.9%). Custom-designed fenestrated and branched custom devices had a technical success rate of 98.3% and 98.7%, respectively; 30-day mortality was 3.8% and 5.4%, and stroke rates were 12.3% and 11%. The main limitation of this technique is the need of catheterization of the supra-aortic trunk, which can create a long operating time and a steep learning curve.

Others authors promoted in situ laser fenestration. The significant disadvantages of the latter include the stroke risk, technical difficulties associated with angulation of the target artery relative to the stent graft, and endoleaks around the LSA.16,17 Even in reference centers, the use of in situ fenestration techniques has been associated with a 12% rate of perioperative strokes, and 56% of cases have required additional supra-aortic bypass procedures. The technique is not particularly convenient for emergent cases.18

Another type of full endovascular technique is the chimney technique. In the treatment of thoracic aortic disease, better short- and midterm outcomes for endoleaks and branch vessel patency have been demonstrated with PMEGs than with the chimney technique.19 The latter seems to result in imperfect exclusion because of the high rate of gutter leaks.20 Major disadvantages included the large number of major secondary procedures required, including subclavian carotid bypass and aortic reintervention for type Ia endoleaks from gutters or proximal stent compression, for example, Wang and colleagues21 report 10.7% perioperative type Ia endoleak (more represented when double chimney was used).

Regarding the possible limits of PMEG, the question of fabric durability still needs to be evaluated. Metal fatigue and material deterioration are known complications of stent-grafting. These alterations might have an effect on the general ring stability of the graft. In the published recent series, no stent fractures were detected by routine radiologic follow-up examinations.22 Some other limitations of this study can be cited as the limited number of patients included and the monocentric, retrospective, and descriptive characteristics of the review. A study with prospective inclusion appears to be necessary, including more patients and longer follow-up to detect late endoleaks.

CONCLUSIONS

The use of single- and double-fenestrated PMEGs appears to be a safe and efficient technique for the treatment of Ia endoleak after failure of TEVAR treatment in zone 2 or 3. The PMEG device can be adapted to any configuration, as it can be combined or not with debranching and is particularly valuable in emergent cases. The total endovascular approach it offers present a low rate of perioperative neurologic complications, making it a favorable choice. Furthermore, it is crucial to maintain follow-up and conduct long-term evaluations to establish long-term efficacy and the absence of late endoleak over time.

Conflict of Interest Statement

The authors reported no conflicts of interest.

The Journal policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

The authors are grateful to all of those with whom they have had the pleasure to work during this and other related projects.

References


**Key Words:** physician modified stent graft, fTEVAR, endovascular repair, endoleak
FIGURE E1. Example in EndoSize (Therenva), determining the trigonometric position of the supra-aortic trunks (A) and measuring the external length of the aorta (B) to perform fenestrations on the endograft.
FIGURE E2. Initial surgical indication of thoracic endovascular aortic repair.

TABLE E1. Baseline characteristics of 20 patients with 1a endoleak after TEVAR

<table>
<thead>
<tr>
<th>Variables</th>
<th>N = 20</th>
</tr>
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<tbody>
<tr>
<td>Age, y, mean (min-max)</td>
<td>80 (55-83)</td>
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<tr>
<td>Male, n (%)</td>
<td>18 (90)</td>
</tr>
<tr>
<td>HTA, n (%)</td>
<td>17 (85)</td>
</tr>
<tr>
<td>Dyslipidemia, n (%)</td>
<td>9 (45)</td>
</tr>
<tr>
<td>Smoking &gt;30 PA, n (%)</td>
<td>17 (85)</td>
</tr>
<tr>
<td>Renal insufficiency, n (%)</td>
<td>5 (25)</td>
</tr>
<tr>
<td>Coronary artery disease, n (%)</td>
<td>4 (20)</td>
</tr>
<tr>
<td>COPD, n (%)</td>
<td>7 (35)</td>
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<tr>
<td>Diabetes mellitus, n (%)</td>
<td>6 (30)</td>
</tr>
<tr>
<td>Arrhythmia, n (%)</td>
<td>5 (25)</td>
</tr>
<tr>
<td>ASA III or IV, n (%)</td>
<td>12 (60)</td>
</tr>
</tbody>
</table>

HTA, Hypertension; COPD, chronic obstructive broncho-pneumopathy, ASA, American Society of Anesthesiologists.