



Safety and outcomes of bronchoscopic lung volume reduction with endobronchial valves under moderate sedation

Jean L. Reinoso¹, Haneen Mallah², Selina Sutchu², Michael DiRico², Pankit Patel², Karthik Vijayan², Hiren J. Mehta²

¹Division of Pulmonary, Critical Care and Sleep Medicine, Department of Medicine, University of Maryland, Baltimore, MD, USA; ²Division of Pulmonary, Critical Care and Sleep Medicine, Department of Medicine, University of Florida, Gainesville, FL, USA

Contributions: (I) Conception and design: JL Reinoso, HJ Mehta, K Vijayan; (II) Administrative support: JL Reinoso, H Mallah, S Sutchu, HJ Mehta; (III) Provision of study materials or patients: K Vijayan, M DiRico, P Patel, HJ Mehta; (IV) Collection and assembly of data: JL Reinoso, H Mallah, S Sutchu, M DiRico, P Patel, K Vijayan; (V) Data analysis and interpretation: None; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

Correspondence to: Hiren J. Mehta, MD. Division of Pulmonary, Critical Care and Sleep Medicine, Department of Medicine, University of Florida, 1600 SW Archer Road, Box 100277, Gainesville, FL 32610, USA. Email: Hiren.Mehta@medicine.ufl.edu.

Background: Chronic obstructive pulmonary disease (COPD) remains a leading cause of morbidity and mortality worldwide. Bronchoscopic lung volume reduction (BLVR) using endobronchial valves (EBV) offers a minimally invasive treatment for severe emphysema. Traditionally performed under general anesthesia (GA), this study evaluates whether BLVR performed under moderate sedation (MS) potentially has less adverse events as compared to ones done under GA.

Methods: This retrospective analysis included 65 patients who underwent BLVR with EBV placement at the University of Florida between January 2020 and June 2022. All procedures were performed under MS. Primary outcomes assessed included the incidence of pneumothorax (PTX), while secondary outcomes comprised valve removal rates, need for revision bronchoscopy, and other procedural complications.

Results: The incidence of PTX was 16.9%, lower than the previously reported rate of 26% in studies combining GA and MS. No major complications or deaths were reported. Procedures were successfully completed in all patients, with valves deployed as planned. Revision bronchoscopy was required in 21.5% of cases.

Conclusions: BLVR under MS is demonstrated to be safe and feasible, with a lower rate of complications compared to GA. These findings suggest that MS may be a preferred sedation method for BLVR, though further research is warranted to confirm these results and explore the long-term outcomes and cost implications.

Keywords: Bronchoscopic lung volume reduction (BLVR); moderate sedation (MS); chronic obstructive pulmonary disease (COPD); pneumothorax (PTX)

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Introduction

Chronic obstructive pulmonary disease (COPD) is the third leading cause of morbidity and mortality worldwide, with its prevalence expected to rise due to an aging population (1). COPD is primarily caused by smoking (2), but other etiologies include dust exposure and alpha-1

antitrypsin deficiency. A common manifestation of COPD is emphysema, which is characterized by the destruction of lung parenchyma due to chronic inflammation. This destruction leads to a loss of elastic recoil, dynamic hyperinflation, air trapping, and reduced exercise capacity (3).

Treatment for COPD focuses on smoking cessation,

preventing exacerbations, and improving quality of life. Pharmacological therapies include long-acting muscarinic antagonists (LAMA), long-acting beta-2 agonists (LABA), inhaled corticosteroids (ICS), azithromycin, and roflumilast, all of which aim to relieve dyspnea and prevent exacerbations (4-7). Non-pharmacological interventions such as pulmonary rehabilitation, supplemental oxygen therapy, and nocturnal non-invasive ventilation also play crucial roles in managing the disease (8,9).

For patients with severe emphysema who remain symptomatic despite maximal pharmacological therapy, bronchoscopic lung volume reduction (BLVR) offers a minimally invasive treatment option (10-12). BLVR with endobronchial valves (EBVs) is designed to occlude the most affected lobes, allowing air to exit during exhalation but preventing air entry during inhalation, leading to atelectasis and reduced lung volumes (13).

Traditionally, BLVR procedures are performed under general anesthesia (GA) due to its ability to facilitate airway management, suppress cough, and reduce patient movement during the procedure (14). However, GA is associated with increased risks, especially in patients with advanced age and multiple comorbidities. Moderate sedation (MS) has emerged as an alternative, potentially offering a safer approach with a comparable safety profile and procedural outcomes (15).

This study aims to evaluate BLVR with EBVs under MS as an effective alternative with less adverse events as compared to similar procedure done under GA. We hypothesize that BLVR under MS is not only feasible and

effective but may also reduce some of the risks associated with GA, particularly post-procedural complications such as pneumothorax (PTX). This retrospective analysis reviews our experience with BLVR under MS, focusing on the incidence of PTX, valve removal, revision bronchoscopy, and other procedural complications. We present this article in accordance with the STROBE reporting checklist (available at <https://jtd.amegroups.com/article/view/10.21037/jtd-24-1707/rc>).

Methods

Study design and participants

This retrospective study was conducted at the University of Florida Health and included all patients who underwent BLVR between January 2020 and June 2022. A total of 86 patients were referred for the procedure, and 69 patients underwent bronchoscopy. Of the patients undergoing bronchoscopy, 65 ultimately underwent EBV placement and 4 patients did not have the valves placed due to positive collateral ventilation (CV) on Chartis® Pulmonary Assessment System (PulmonX Corporation, Redwood City, CA, USA) intraprocedurally. The study received approval from the institutional review board (IRB) of University of Florida (IRB#202202332). Since it was a retrospective chart review study with minimal risk of harm to participants, informed consent was waived. The study conformed to the Declaration of Helsinki (as revised in 2013).

Figure 1 shows detailed flowchart of number of patients screened, excluded and ones included in final analysis. Patient demographics, comorbidities, baseline pulmonary function tests (PFT), target lobe parameters including target lobe volume in mL and volume of ipsilateral non-target lobe volume in mL were recorded. We also calculated the ratio of target lobe volume to ipsilateral non-target lobe volume defined as lobe ratio. Complications including PTX, worsening dyspnea, valve revision, lack of improvement and repeated infections were documented and reported for the study. Only one type of valve was used: The Zephyr® Endobronchial Valve (PulmonX Corporation). The size and type of valves placed were up to proceduralists' discretion.

All patients were assessed for eligibility in the interventional pulmonology clinic before the procedure. The selection criteria mirrored those of the LIBERATE trial (16), including patients with advanced emphysema, significant hyperinflation (residual volume >175% of

Highlight box

Key findings

- Bronchoscopic lung volume reduction (BLVR) done under moderate sedation (MS) may have lower rate of complications especially pneumothorax as compared to what is quoted in literature when procedure is done under general anesthesia.

What is known and what is new?

- BLVR can be safely performed under MS with similar efficacy as demonstrated in LIBERATE trial.
- We report that BLVR done under MS may have significantly lower rates of pneumothorax than quoted in literature.

What is the implication, and what should change now?

- Larger studies are needed to confirm the findings of our study.
- If our findings are confirmed in larger study, it may potentially change practice of how BLVR is performed.

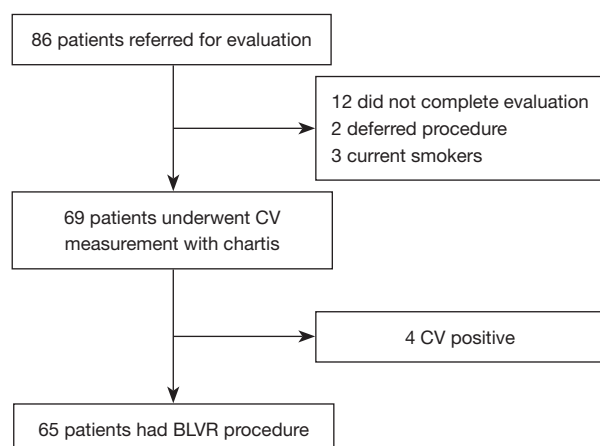


Figure 1 Flow chart showing patient screened and total excluded and enrolled. CV, collateral ventilation; BLVR, bronchoscopic lung volume reduction.

Table 1 Baseline demographics, PFT, and target lobe parameters

Variables	Value
Demographics	
Male, n (%)	33 (50.77)
Age (years), mean (SD)	69.29 (0.72)
BMI (kg/m ²), mean (SD)	24.9 (0.5)
Chronic steroids, n (%)	17 (26.15)
Baseline PFT, mean (SD)	
FVC%	63.7 (2.0)
FEV1%	31.5 (1.4)
TLC%	119.3 (2.7)
RV%	210.8 (6.1)
RV/TLC	109.9 (6.5)
Target lobe parameters, n (%)	
RUL	12 (18.46)
RUL + RML	10 (15.38)
RLL	9 (13.85)
LUL	22 (33.86)
LLL	12 (18.46)

PFT, pulmonary function test; SD, standard deviation; BMI, body mass index; FVC, forced vital capacity; FEV1, forced expiratory volume at 1st second; TLC, total lung capacity; RV, residual volume; RUL, right upper lobe; RML, right middle lobe; RLL, right lower lobe; LUL, left upper lobe; LLL, left lower lobe.

Table 2 Some StratX parameters with median values

StratX parameters	Value
Destruction score, mean (SD)	
910	62.4 (1.43)
950	37.23 (1.91)
Target lobe volume (mL), mean (SD)	1,788.3 (60.1)
Other lobe volume (mL), mean (SD)	1,503 (54.5)
Target/ipsilateral lobe ratio (SD)	1.26 (0.06)
Emphysema characteristic, n (%)	
Heterogenous (>15% difference in destruction scores as mentioned in StratX report)	46 (70.7)

SD, standard deviation.

predicted), and high symptom burden (modified Medical Research Council dyspnea score ≥ 2) despite optimal medical therapy and pulmonary rehabilitation. *Table 1* shows some baseline demographic, target lobe and PFT characteristics. Fissural integrity and hyperinflation were evaluated using high-resolution computed tomography (HRCT) and the StratX[®] Lung Analysis Platform (PulmonX Corporation). CV was assessed with the Chartis[®] Pulmonary Assessment System (PulmonX Corporation). StratX parameters are shown in *Table 2*.

Patients were excluded if they had significant gas exchange abnormalities including diffusion capacity of lungs for carbon monoxide (DLCO <20% predicted), significant airway disease (asthma, unstable chronic bronchitis, clinically significant bronchiectasis), significant paraseptal emphysema, congestive heart failure, more than two exacerbations in the last year, or suspicious nodules indicative of active infection or malignancy.

All EBV placements were performed under MS, administered by an endoscopy nurse under the supervision of the interventional pulmonologist. After the procedure, a portable chest X-ray was taken in the recovery area. Patients were admitted for 72 hours post-procedure and monitored daily by the pulmonary consultation team. To prevent exacerbations, all patients received prophylactic prednisone 40 mg daily for five days, starting 2 days prior to procedure and continuing for 3 additional days after the procedure.

Patients were discharged with instructions to seek immediate medical attention if symptoms of PTX occurred and were given wristbands indicating their risk status.

Table 3 Sedation medications with dose and procedure duration

Procedure parameters	Value
Midazolam dose (mg), mean (SD)	4.72 (0.2)
Fentanyl dose (mcg), mean (SD)	118.75 (27.7)
Procedure duration (min), mean (SD)	36.9 (1.65)
Valves placed, median [IQR]	3 [3, 4]

SD, standard deviation; IQR, interquartile range.

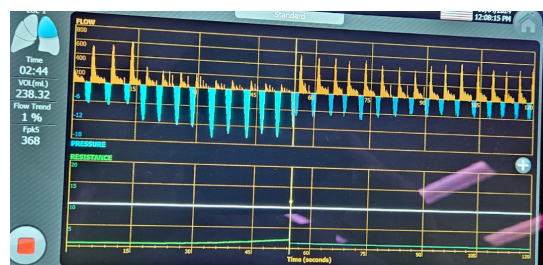


Figure 2 It shows Chartis tracing of a CV negative patient where flow in yellow is seen to decrease and pressure in blue increases and yellow resistance ball rises. As soon as balloon is deflated (half way point), flow increases and pressure decreases with corresponding decrease in resistance confirming negative CV. CV, collateral ventilation.

Follow-up was conducted within two weeks post-discharge to monitor for any complications or side effects.

Procedure and sedation considerations

All BLVR procedures were performed in a bronchoscopy suite equipped with fluoroscopy. Patients were positioned in a supine position, and MS was administered by an endoscopy nurse under the direct supervision of the interventional pulmonologist. The sedative regimen included midazolam and fentanyl, titrated to achieve adequate conscious sedation while maintaining spontaneous respiration and patient cooperation. Supplemental oxygen was provided to maintain oxygen saturation above 90%. Median dose of midazolam used was 4 mg and fentanyl of 118 mcg as demonstrated in *Table 3*.

Pre-procedure preparation

Before the procedure, patients received a detailed explanation of the procedure and potential risks, including PTX, valve migration, and respiratory infections. Informed

consent was obtained. A baseline assessment, including vital signs, arterial blood gas analysis, and spirometry, was performed.

Bronchoscopic procedure

Once adequate sedation was achieved a flexible bronchoscope was inserted through the patient's mouth or nose and advanced to the target lobe identified preoperatively using HRCT and the Chartis® Pulmonary Assessment System. The bronchoscope was navigated to the segmental bronchi of the target lobe, where CV was assessed in real-time. If CV was deemed absent or low, EBVs were deployed. Patients were considered to be CV negative if the flow reduced to zero on 5 consecutive spontaneous breaths with corresponding increase in pressure and breath flow trend was less than 10% after adequate flushing of Chartis catheter and demonstrating that there was no catheter blockage as shown in *Figure 2*. To avoid false CV positive, Chartis assessment was performed for at least 6 minutes in the target lobe if there was concern for CV. Average duration of CV assessment was 2 minutes and 30 seconds from the time of balloon inflation. The choice of valve type and size was determined by the bronchoscopist based on the patient's anatomy and the specific characteristics of the target lobe. Valves were carefully placed to ensure complete occlusion of the segmental bronchi, promoting atelectasis of the diseased lobe. The sequence of valve placement was done in an order so that they do not obstruct the deployment of subsequent valves. Prior to deployment of valves, care was taken to visualize distal bifurcating carina to ensure the valve is deployed proximal to the carina. When in doubt, valves were oversized to treat lower lobes more distally. An average of 3 valves were used per patient.

Post-procedure management

Immediately following valve placement, a portable chest X-ray was performed to check for PTX and verify the correct position of the valves. Patients were monitored in the recovery area for at least two hours before being transferred to a regular ward for continued observation. Standard post-procedure care included oxygen therapy, bronchodilators, and pain management as needed. Patient were transferred with an arm band suggesting high risk for PTX and a pigtail chest tube kit was kept at bedside at all times during hospitalization.

Patients were admitted for 72 hours post-procedure to

monitor for potential complications. Daily rounds were conducted by the pulmonary consultation team to assess recovery and manage any arising issues. Prophylactic prednisone (40 mg daily for five days) was prescribed to mitigate the risk of exacerbations as mentioned above.

Sedation considerations

MS was chosen to balance the need for patient comfort and procedural success while minimizing the risks associated with GA.

Close monitoring of vital signs, including heart rate, blood pressure, respiratory rate, and oxygen saturation, was maintained throughout the procedure. The presence of an experienced sedation team was crucial to promptly address any sedation-related complications. Midazolam and Fentanyl were used in all procedures to achieve appropriate level of conscious sedation. Mean doses as shown in *Table 3* were 4 mg for midazolam and 118 mcg for fentanyl. All patients received appropriate local analgesia with topical lidocaine. Average duration of procedure was 36.9 minutes with administration of first dose of sedation considered to be start time and removal of scope from patient documented as sedation end time.

Discharge and follow-up

Before discharge, patients received detailed instructions on recognizing symptoms of PTX, such as sudden chest pain and shortness of breath, and were advised to seek immediate medical attention if these symptoms occurred. Patients were also provided with wristbands indicating their recent BLVR procedure and potential risk for PTX.

Follow-up visits were scheduled within two weeks post-discharge to assess for complications and evaluate the clinical efficacy of the EBV placement. During these visits, repeat spirometry and imaging were performed to monitor lung function and valve position. If atelectasis did not occur by 1 month after treatment in a lobe that has been confirmed as CV negative, valve position was evaluated on CT and for the incorrectly positioned valves, replacement/revision was considered.

This comprehensive approach ensured the safety and efficacy of BLVR under MS, highlighting the importance of meticulous procedural planning and post-procedural care.

Outcome measures

The primary outcome measure of this study was the incidence of complications directly attributed to BLVR procedure including post procedure PTX, need for valve revision, lack or improvement or worsening dyspnea and recurrent infections. Complications were identified based on clinical symptoms and confirmed through chest radiography or computed tomography (CT) scans. The timing, management, and resolution of all complications were documented.

Secondary outcome measures included feasibility of performing CV assessment with Chartis® Pulmonary Assessment System, ability to successfully deploy valves, rates of valve removal and revisions, and percentage of patients with radiographic atelectasis 4 weeks post procedure.

Statistical analysis

Stata 18 (StataCorp, College Station, TX, USA) was used for all statistical analysis, descriptive and central tendency statistics were used for all demographic and PFT values. The primary outcome was post-procedure PTX up to 72 hours post-procedure, secondary outcomes were valve removal and chest tube days. For dichotomous outcomes, we used logistic regression and for continuous variables linear regression was used to adjust for other variables such as PFT values, age, sex, body mass index (BMI), chronic oral steroid use, target lobe volume and volume ratio (target lobe volume/ipsilateral non-target lung volume).

Results

Out of the 65 patients who underwent BLVR, 50.77% were male. Most patients (83.08%) were taking triple inhaler therapy with ICS, LABA, and LAMA, and a total of 17 patients (26.15%) were on chronic oral steroids. The mean age was 69.29 years with a standard deviation of 0.72 years, and the mean BMI was 24.9 kg/m² with a standard deviation of 0.5 kg/m². The most common target lobes chosen for BLVR deployment were the right upper lobe alone in 18.46% of cases, the right upper lobe and right middle lobe in 15.38% of cases, and the left upper lobe in 33.85% of cases. The mean procedure duration was 36.9 minutes with a standard deviation of 1.65 minutes.

Table 4 Post procedural complications which was the primary outcome of the study

Complication	Rate, n (%)
Pneumothorax	11 (16.92)
Revision bronchoscopy	14 (21.5)
Worsening dyspnea	3 (4.6)
Lack of improvement	10 (15.38)
Repeated infections	1 (1.53)

Table 5 Details of post procedural complications and their respective subgroup analysis

Predictors	Odds ratio	P value
Pneumothorax		
Age	0.96	0.79
Sex	6.66	0.11
BMI	0.67	0.05
Chronic steroid use	1.73	0.61
Target lobe volume	1.01	0.28
Target/other lobe ratio	6.22	0.14
Valve removal		
Age	1.01	0.95
Sex	3.27	0.18
BMI	0.78	0.13
Chronic steroid use	2.01	0.53
Target lobe volume	1.01	0.21
Target/other lobe ratio	0.02	0.05

BMI, body mass index.

Table 6 Details of post procedural complications and their respective subgroup analysis

Chest tube days	B coefficient	P value
Age	-0.08	0.55
Sex	3.32	0.19
BMI	-0.31	0.14
Chronic steroid use	6.43	0.08
Target lobe volume	-0.01	0.79
Target/other lobe ratio	-1.56	0.71

BMI, body mass index.

The PTX rate was 16.92% (n=11). Male sex showed a trend toward a higher risk of developing this complication, with an adjusted odds ratio (aOR) of 6.66 [P=0.11, 95% confidence interval (CI): 0.66–67.24]. A higher target lobe volume to ipsilateral non targeted lobe volume ratio also showed an increased risk of PTX; however, this was not statistically significant (aOR 6.22, P=0.14, 95% CI: 0.53–72.16).

All patients who developed a post-procedure PTX had a small-bore chest tube inserted by the pulmonary team. The mean chest tube duration was 11.45 days with a standard deviation of 1.7 days. There was a non-statistically significant trend towards longer duration (β 6.43, P=0.08, 95% CI: -1.22 to 14.09) in patients taking chronic oral steroids. There was no significant association between PFT values and the risk of PTX, valve removal, or chest tube duration.

Regarding other secondary outcomes, the procedure, including performing CV evaluation and deploying valves if CV-negative, was successfully performed in all patients. None of the cases were canceled or terminated due to comorbidities, intraprocedural complications, or the inability to accurately perform CV testing or deploy valves. None of our patients had mortality directly attributed to the procedure, and none of our patients required ICU admission, persistent ventilator dependence, or experienced an acute exacerbation of COPD post-procedure.

Fourteen patients (21.5%) had a revision bronchoscopy after the index procedure, all revisions were done after follow-up visits due to a lack of improvement in symptoms and or lack of atelectasis on follow up imaging. Of the 14 patients needing valve revision, 8 patients (12%) of them had procedure due to lack of lobar atelectasis on follow up imaging, additional 3 (5%) patients needed revision due to mild hemoptysis and pneumonia whom on revision bronchoscopy were found to have significant granulation tissue and additional 4 (6%) needed revision and removal of valves due to lack of clinical benefit. All patients who developed PTX after implantation had at least some (n=5) or all valves (n=6) removed due to persistent air leak. Aside from the presence of PTX (aOR 12.7, P=0.006), no other variables were associated with an increased risk for valve removal. No other significant complications were noted with the procedure post-valve placement. *Table 4* illustrates complications post-procedure and *Tables 5,6* shows subgroup analysis for some of the major complications.

Discussion

The preference for GA in BLVR and CV measurement for EBV is primarily based on its advantages in airway management, cough suppression, reduced distortion during CV measurements, and shorter procedural times (15,17,18). However, this preference is not founded on direct comparisons between GA and MS in large randomized trials, where both sedation methods have been employed.

Our data corroborate findings from other studies that have utilized the Chartis® Pulmonary Assessment System to differentiate patient phenotypes during CV assessment. Notably, Herzog *et al.* developed an algorithm for CV assessment in spontaneously breathing patients (19). Expert panels recommend MS for its ability to allow sufficient tidal breathing for accurate Chartis® Pulmonary Assessment System measurements (13,20), which is typically achieved using a combination of a benzodiazepine and an opiate, along with a topical anesthetic to minimize cough. In our cohort, we used midazolam combined with fentanyl and topical lidocaine, with mean doses of 4.72 mg for midazolam, 85.65 and 118.75 mg for fentanyl.

PTX is the most significant complication post-BLVR, occurring in up to 30% of cases and potentially being fatal (21,22). Other common complications include acute exacerbation-like events, valve expectoration, or misplacement necessitating additional procedures (23). This study is pioneering in assessing the safety of BLVR under MS. The observed rates of PTX, COPD exacerbations, and hemodynamic instability were lower than reported in the literature, and all procedures and valve deployments were successfully completed. Our rates of valve removal and revision align with existing literature. We believe that reduction in PTX rate to half by performing BLVR under MS could be practice changing and not previously reported in literature. Further head-to-head trials with GA are required to validate findings of our study.

Long-term sustainability of BLVR's therapeutic effect remains challenging, with a significant proportion of patients requiring revision bronchoscopy. Our study's valve revision bronchoscopy rate was 21.5%, which is lower than the 41% reported by Roodenburg *et al.* (24). This difference may reflect the proficiency of the proceduralist in performing BLVR under MS. The primary reasons for revision bronchoscopy in our cohort included lack of symptom improvement, valve expectoration, and granulation tissue formation around the valve.

Our study has several limitations, including its single-

center, retrospective nature, and focus on safety and feasibility rather than efficacy data regarding quality of life improvements and lung function tests post-procedure. Additionally, the procedures were conducted at an academic center by highly experienced interventional pulmonologists, which may limit the generalizability of the findings to smaller centers with less MS experience. Our study however provides valuable insight into safety and feasibility of BLVR performed under MS and may reduce complications associated with the procedure which may be attributed to GA. And although we do not have cost analysis performed as a part of study, it is implied that by not using anesthesia services, BLVR done under MS can reduce healthcare cost associated with the procedure.

Conclusions

BLVR performed under MS appears to be safe and associated with lower complication rates compared to the expected rates with GA. Specifically, our PTX rates were lower than the anticipated 30% seen in other studies. Although head-to-head comparisons between GA and MS for BLVR are limited, other studies in advanced bronchoscopic procedures have demonstrated comparable safety and outcomes between the two sedation methods. Our findings suggest that with experienced proceduralists, MS may be the preferred sedation method for BLVR, pending confirmation from larger studies.

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None.

Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at <https://jtd.amegroups.com/article/view/10.21037/jtd-24-1707/rc>

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Conflicts of Interest: All authors have completed the ICMJE

uniform disclosure form (available at <https://jtd.amegroups.com/article/view/10.21037/jtd-24-1707/coif>). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study received approval from the institutional review board (IRB) of University of Florida (IRB#202202332). Since it was a retrospective chart review study with minimal risk of harm to participants, informed consent was waived. The study conformed to the Declaration of Helsinki (as revised in 2013).

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