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Comparison of costs and short-term clinical outcomes of per-oral endoscopic myotomy and laparoscopic Heller myotomy

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ABSTRACT

Objective: Per-Oral Endoscopic Myotomy (POEM) has seen increasing application and comparisons to laparoscopic Heller myotomy (LHM). The aim of the present study was to compare perioperative and short-term outcomes, and costs between the two procedures at a single institution.
Methods: Fifty-one consecutive patients documented in a prospective IRB approved database from January 2014 to December 2017 were included. Perioperative data, pre-operative and 3-month post-operative Eckardt Scores, and cost data were compared.
Results: Median hospital stay was comparable between POEM and LHM (1 day each). Complications were minor (Clavien-Dindo 1, 2) and rare in both groups. Median Eckardt scores improved significantly after POEM (5 to 0) and LHM (5 to 0). Normalized median costs were comparable: 14 201 USD (POEM) vs. 13 328 USD (LHM) $p = 0.45$.
Conclusions: POEM demonstrates comparable clinical outcomes and costs to LHM. Long-term issues related to GERD require ongoing assessment in POEM patients.
Summary: In patients with achalasia, extended myotomy of the lower esophageal sphincter offers excellent palliation of symptoms. In the last decades, laparoscopic Heller myotomy (LHM) has been the gold standard. Over the past decade, per-oral endoscopic myotomy (POEM) has seen wide application in specialized centers worldwide. In our patient cohort, we demonstrate, that POEM can be introduced with similar outcomes and costs compared to LHM.

Introduction

Achalasia is a rare disorder with an incidence of approximately 1 per 100 000 people per year in adults.[1] Typically, objective findings in achalasia patients show lower esophageal sphincter dysfunction along with progressive aperistalsis and dilation of the esophageal body. Symptoms typically include dysphagia, regurgitation, retrosternal pain, chest pain, cough, and weight loss.[1]

Current treatment options aim to reduce the lower esophageal sphincter (LES) pressure, thus enabling the gravity-based passage of esophageal contents into the stomach. Endoscopic Botox injection into the LES is effective, but provides only temporary relief and may impact the feasibility of future surgical therapies. As a result, Botox is typically reserved for non-surgical candidates.[2] In the last decade, three treatment modalities have been associated with lasting and effective symptom relief. Laparoscopic Heller myotomy (LHM) with or without a partial fundoplication has become the standard surgical approach. Minimally invasive surgical access results in a fast recovery, while the addition of a partial fundoplication mitigates the gastroesophageal reflux which is commonly encountered after myotomy alone.[3] Endoscopic pneumatic dilations of the LES have been the mainstay of endoscopic treatment for achalasia. In a randomized trial, outcomes following a standardized pneumatic dilation protocol were similar to those

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achieved through LHM.[4] However, pneumatic dilation was associated with a 4% perforation rate and pneumatic dilation does not appear to be equally effective in all achalasia subtypes.[5] Per-Oral Endoscopic Myotomy (POEM) for the treatment of achalasia was introduced in Japan with first results initially published 2010.[6] POEM provides an alternative endoscopic option while, like LHM, carrying out a controlled distal esophageal and LES myotomy. The international application of POEM has rapidly increased.[7]

POEM provides a potentially comparable treatment option for the treatment of achalasia. Assessing the short-term outcomes of POEM to LHM in a contemporary patient cohort while also including a cost comparison will assist future management decisions in achalasia patients.

The aim of the present study was to assess short-term clinical outcomes and procedure related costs associated with the implementation of the POEM procedure in a tertiary esophageal center. Different components of the cost analysis were assessed and compared to LHM.

Materials and methods

Patient population

Fifty-one consecutive patients treated with LHM (N = 28) or POEM (N = 23) for achalasia at a single institution between January 2014 and December 2017 were prospectively entered in an IRB-approved database. POEM was introduced in 2015 and all cases performed were included in the analysis, so that the results include the initial learning curve at our institution. The diagnosis of achalasia was based on standardized preoperative investigations including an upper endoscopy, high-resolution manometry and esophagogram. The achalasia subtype according to the Chicago classification based on manometry findings was assigned in a majority of patients.

Patients who underwent POEM were compared to patients undergoing LHM, which was considered the treatment of choice for achalasia at our institution prior to the introduction of POEM. Our primary outcomes were patient reported improvement of symptoms, assessed at a short term follow-up (up to 30 days postoperatively) and measured by Eckardt scores at a long term follow-up (up to 6 months postoperatively). Secondary outcomes were intraoperative variables (procedure time and blood loss), postoperative complications, ability to return to a normal diet, and objective assessments including pre- and post-operative esophagograms to assess the differences in esophageal dilation, esophageal emptying, and reflux.

Procedural techniques

POEM operative technique

LHM was performed by a thoracic surgeon, and all POEMS were done by a team including a thoracic surgeon and an interventional gastroenterologist. Both physicians participated in a dedicated hands-on POEM course including explant and live-models. Furthermore, a proctor was present in the operating room or endoscopy suite for the initial 10 POEM cases. POEM was performed using a similar technique, as described by Swanstrom and colleagues.[8]

Postoperatively, patients were restricted to sips of clear water until witnessed esophagogram performed on the first postoperative day assessed esophageal emptying and confirmed the absence of a full thickness esophageal injury. Typically, patients were targeted for discharge after completion of the esophagogram on post-procedure day 1. Dietary protocols direct dietary advancement with the aim of returning to normal diet in 2–3 weeks.

LHM operative technique

At our institution, LHM is routinely combined with a partial fundoplication. A Toupet posterior fundoplication was preferred. Myotomies were typically extended 5–6 cm proximally and 3 cm onto the stomach. The postoperative management corresponded to the management following POEM.

Cost analysis

The cost accounting system used at our institution has been previously described.[9] Briefly, the Alliance Decision Support system allows individual identification and tracking of all costs associated with patient treatment (Alliance Decision Support MedAssets, Inc, Atlanta, Ga). Thereby, the costs model consists of two main modules: direct and indirect costs. The Alliance cost module consists of 7 direct cost components. These are costs directly related to the departmental output. Examples are the physician salaries, room & board expenses and drugs and medical supplies for the patient. The indirect costs represent the institution overhead expenses incurred from the overhead departments, which support the operation of the revenue producing departments. Geometric regression was used to normalize costs, generated in a specific year, to the 2016 cost level.

Statistical analysis

SPSS software version 23 (IBM Analytics, Armonk, NY, USA) was used for data analyses. Continuous variables were presented as median with range or interquartile range, quantile regression was used for statistical comparisons. Categorical variables were compared using the chi-square and Fisher exact test as applicable and presented as numbers and percentages. A P-value of less than 0.05 was considered statistically significant.

Results

POEM was performed in 23 consecutive patients from June 2015 till December 2017. Similarly, 28 consecutive patients received a LHM from January 2014 till December 2017. Preoperative patient characteristics were well balanced between the two groups with no significant difference in median age, gender distribution, body mass index and comorbidities (Table 1). American Society of Anesthesiologists (ASA) Scores of 1, 2 and 3 were not equally distributed between the two groups with higher scores in the POEM group (ASA Score 1, 2 and 3 in LHM vs. POEM: 25%, 68%, 7% vs. 0%, 78% and 22%, $p = 0.02$, Table 1). The median preoperative Eckardt score was 5 vs. 5 for LHM vs. POEM ($p = 1.0$, Table 1). The most common preoperative symptoms were dysphagia and regurgitation recorded in 96% vs. 96% and 96% vs. 78% of LHM vs. POEM patients ($p = 0.89$ and $p = 0.05$, Table 1), followed by gastroesophageal reflux symptoms and retrosternal pain in 50% vs. 65% and 36% vs. 52% of LHM vs. POEM patients ($p = 0.28$ and $p = 0.24$, Table 1). Respiratory symptoms like cough and chest pain were less frequently encountered (LHM vs. POEM: 25% vs. 9% and 14% vs. 25%, $p = 0.16$ and $p = 0.11$, Table 1). No patient had a previous LHM. Previous Botox injections and pneumatic dilations were performed in 7% and 29% of the LHM- and 30% and 44% of the POEM patients (previous Botox $p = 0.06$, previous dilation $p = 0.27$, Table 1).

Type 2 achalasia, according to the Chicago classification, was most frequently encountered in both groups (43% of LHM patients and 35% of POEM patients), while type 3 achalasia, was only documented in the POEM cohort (30%) (Table 1). Median lower esophageal sphincter resting pressure and integrated relaxation pressure (IRP) were similar between the two groups (Table 1).

There was a tendency of increased median operative time for the POEM procedure (LHM vs. POEM: 139min (113–190min) vs.

Table 1
Patient demographics.

N (%)	Heller	POEM	P-value
Total	**28 (54.9)**	**23 (45.1)**	**-**
Age, median (range)	**56.5 (22–94)**	**58 (39–79)**	**0.612**
Gender			**0.723**
Female,	16 (57.1)	12 (52.2)	
Male,	12 (42.9)	11 (47.8)	
Body Mass Index kg/m2, median (range)	**27 (18.5–35.1)**	**30 (19.3–37.3)**	**0.112**
Charlson Comorbidity Index			**0.419**
0–1	15 (53.6)	9 (39.1)	
2–3	11 (39.3)	10 (43.5)	
4 or more	2 (7.1)	4 (17.4)	
American Society of Anesthesiologists Score			**0.019**
1	7 (25.0)	0 (0)	
2	19 (67.9)	18 (78.3)	
3	2 (7.1)	5 (21.7)	
High resolution manometry data			
Achalasia Chicago Classification			**0.017**
Type I	7 (25.0)	3 (13.0)	
Type II	12 (42.9)	8 (34.8)	
Type III	0 (0)	7 (30.4)	
Esophageal junction outflow obstruction	0	2	
Major disorder of peristalsis (hypercontractile esophagus)	0	1	
Not specified	9 (32.1)	2 (8.7)	
Lower esophageal sphincter resting pressure, mmHG, median (IQR)	23.6 (13.0–45.6)	40.0 (18.6–66.3)	0.197
Integrated relaxation pressure, mmHG, median (IQR)	25.0 (17.0–29.7)	20.8 (15.0–35.6)	0.423
Previous interventions			
Previous Heller Myotomy	0 (0)	0 (0)	–
Previous Botox Injection	2 (7.1)	7 (30.4)	0.061
Previous Dilation	8 (28.6)	10 (43.5)	0.268
Preoperative Symptoms			
Duration of Symptoms, median (range)	3 (1–40)	2 (0–20)	0.583
Eckardt score, median (range)	5 (2–10)	5 (2–12)	1.0
Weight loss in pounds, median (range)	15 (0–50)	7 (0–90)	0.281
Dysphagia	27 (96.4)	22 (95.7)	0.887
Retrosternal pain	10 (35.7)	12 (52.2)	0.238
Regurgitation	27 (96.4)	18 (78.3)	0.045
Gastroesophageal reflux disease	14 (50.0)	15 (65.2)	0.275
Respiratory symptoms	7 (25.0)	2 (8.7)	0.159
Chest pain	4 (14.3)	8 (34.8)	0.107

163min (71–242min), $p = 0.06$. Table 2). Mucosal injury occurred in 1 vs. 2 patients in the LHM vs. POEM group (Table 2). Both POEM patients were managed successfully with intraoperative closure of the mucosal injury and the LHM patient required a course of antibiotics for a contained pharyngeal perforation following an intraoperative placement of a Savary Bougie. Veress-needle decompression of pneumoperitoneum due to alteration in ventilation parameters was required in 8/23 POEM patients (Table 2). Median myotomy length was comparable in both groups (LHM vs. POEM: 7 cm each, $p = 1.0$, Table 2).

Median length of hospital stay was comparable between the two groups (1 days each, $p = 1.0$, Table 2). Major complications, defined as Clavien-Dindo grades 3a/b, 4a/b, and 5 did not occur. Minor complications defined as Clavien-Dindo grade 1 and Clavien-Dindo grade 2 occurred in 2 and 1 patient after LHM vs. POEM in each category ($p = 0.83$; Table 2). One patient was readmitted within 30 days in each group ($p = 0.89$, Table 2).

Patient follow-up occurred in two time intervals: an "early" follow-up included patient review within 30 days following surgery. The "late" follow-up was defined as any follow-up between 31 and 180 days. Typically, patients were scheduled for an early and a late follow-up, the latter being termed around 3–4 months

Table 2
Perioperative data.

N (%)	Heller	POEM	P-value
The total number of patients per procedure	N=28	N=23	
Operative time, median minutes (range)	**139 (113–190)**	**163 (71–242)**	**0.055**
Blood loss, median ml (range)	**10 (0–75)**	**0 (0)**	**<0.001**
Total myotomy length, median cm (range)	**7 (5–8.5)**	**7 (5–12)**	**1.0**
Esophageal myotomy, median cm (range)	**5 (3–6)**	**5 (3–10)**	**1.0**
Mucosal injury	**1 (3.6)**	**2 (8.7)**	**0.439**
Veress needle decompression	**0 (0)**	**8 (34.8)**	**0.001**
Length of hospital stay, median days (range)	**1 (1–4)**	**1 (1–2)**	**1.0**
30-day mortality	**0 (0)**	**0 (0)**	**-**
30-day Readmissions	**1 (3.6)**	**1 (4.4)**	**0.887**
Complications			**0.827**
Clavien-Dindo Grade I	2 (7.1)	1 (4.4)	
Clavien-Dindo Grade II	2 (7.1)	1 (4.4)	
Clavien-Dindo Grade IIIa-V	0 (0)	0 (0)	

Table 3
Outcome comparison.

N (%)	Heller	POEM	P-value
Early Follow-up (1–31 days)	**22 (78.6)**	**21 (91.3)**	**0.213**
Days after surgery, median (range)	9 (3–31)	10 (2–29)	0.762
Dysphagia	1 (4.6)	4 (19.1)	0.138
Retrosternal pain	1 (4.6)	2 (9.5)	0.522
Regurgitation	0 (0)	2 (9.5)	0.138
Diet			0.085
Diversified diet	5 (22.7)	5 (23.8)	
Soft or puree food only	16 (72.7)	10 (47.6)	
Liquids only	1 (4.6)	6 (28.6)	
Late Follow-up (30–180 days)	**22 (78.6)**	**9 (39.1)**	**0.004**
Days after surgery, median (range)	102 (37–297)	83 (30–155)	–
Weight loss	0 (0)	1 (11.1)	0.175
Dysphagia	3 (13.6)	1 (11.1)	0.849
Retrosternal pain	1 (4.6)	2 (22.2)	0.131
Regurgitation	3 (13.6)	1 (11.1)	0.849
Eckardt score, median range	0 (0–2)	0 (0–2)	1.0
Diet			0.863
Diversified diet	20 (90.9)	8 (88.9)	
Soft or puree food only	2 (9.1)	1 (11.1)	
Liquids only	0 (0)	0 (0)	
Esophagogram follow-up	**18 (64.3)**	**11 (47.8)**	**0.238**
Improved dilation	13 (72.2)	7 (70.0)	0.901
Improved EGJ narrowing	17 (94.4)	7 (70.0)	0.077
Improved esophageal emptying	17 (94.4)	11 (100)	0.426
Improved peristalsis	2/17 (11.8)	4/8 (50.0)	0.037

postoperatively including an esophagogram assessment. Deviations from the scheduled follow-up schedule were usually related to patients hesitant to return from long distances for routine follow-up. Early follow-ups were available for 79% of LHM and 91% of POEM patients ($p = 0.21$). Late follow-ups were available in 79% of LHM and 39% of POEM patients ($p > 0.01$). Postoperative esophagograms were available in 64% of LHM and 48% of POEM patients ($p = 0.24$). Median postoperative Eckardt scores after 3 months were 0 both LHM and POEM, respectively (Table 3). While the majority of patients were eating a soft diet during the early follow-up after LHM and POEM respectively (73% vs. 48%, $p = 0.09$), the majority of patients reported no diet restriction during the late follow-up (diverse diet: LHM vs. POEM: 91% vs. 89%, $p = 0.86$, Table 3). Esophageal emptying, esophagogastric junction narrowing and esophageal dilation as assessed by esophagogram improved similarly in a majority of LHM and POEM patients (Table 3). On post-operative esophagrams, provoked reflux was reported in 1 patient per group and spontaneous reflux was reported in one patient after POEM.

The cost analysis showed similar overall costs and hospital costs for the LHM vs. POEM procedure (total costs: 13.328 USD vs. 14.201 USD, $p = 0.45$, hospital costs: Table 4). POEM was associated with higher clinic (physician) costs compared to LHM (7.423 USD vs. 4.926 USD, $p > 0.01$, Table 4).

Discussion

The present study was designed to evaluate short-term outcomes of POEM and LHM in consecutive patients with achalasia treated at a tertiary referral center. Special emphasis was put on a detailed cost analysis. In line with previous reports, we found excellent and comparable symptom relief associated with both POEM and LHM with a median Eckardt score of 0 at a median follow-up of 102 days vs. 83 days for LHM and POEM, respectively. Other single center comparative studies reported similar results with mean Eckardt scores of 1 vs. 1 and 1.7 vs. 1.2 for LHM and POEM, respectively.[10,11] A recent meta-analysis of comparative studies assessing outcomes after POEM and LHM found lower postoperative Eckardt scores after POEM.[2] However, only two studies contributed data on postoperative Eckardt scores. Similarly, a meta-analysis, pooling data from 53 studies on LHM and 21 studies on POEM, evaluating 5834 and 1958 patients per group respectively, reported improved levels of dysphagia associated with POEM.[12]

Objective outcome assessment with postoperative esophagograms was obtained in a majority of patients in the present study. Esophageal dilation and esophageal emptying improved in the majority of POEM and LHM patients. In addition, there was a trend towards improved peristalsis after POEM and improved esophagogastric junction (EGJ) narrowing after LHM. The trend towards improved EGJ narrowing after LHM could be explained by the fact that, in LHM, the complete muscular layer is divided, while POEM includes only a division of the inner, circular muscle layer. The trend of improved postoperative peristalsis after POEM compared to LHM has not been investigated so far. Since the esophagogram results constitute a subjective interpretation, we think that this phenomenon should be further investigated by postoperative HRM. This would enable an objective quantification of the postoperative improvement of peristalsis. It must be highlighted that our results may be biased by the fact that postoperative esophagograms were available in only 11/23 patients in the POEM group and 18/28 patients in the LHM group. Follow-up esophagograms have been infrequently reported in the literature. Hungness and colleagues assessed timed-barium esophagograms in POEM patients only and reported a significant improvement in contrast column heights.[13,14]

Postoperative reflux was assessed in the present study subjectively as part of the patient history and objectively by postoperative esophagograms. Upper endoscopies and pH-studies were not routinely performed postoperatively. Heartburn assessed 30 days and 6 months after the index surgery was reported in 2 patients in the POEM group compared to 1 patient after LHM. Similarly, reflux on postoperative esophagogram, 3–4 months after surgery, was reported in 2 patients after POEM and present in 1 patient after LHM. Our results do not show a significantly increased reflux after POEM as compared to LHM. However, the interpretation of our results is limited by the patient number, and the 3-month follow-up rate of only 49% in the POEM group. We believe this incomplete objective follow-up reflects that patients travel long distances to reach a specialized center and are disinclined to return when they do well.

A recent meta-analysis showed that despite a similar rate of subjective GERD symptoms, patients undergoing POEM had a

Table 4
Cost data.

Median USD (IQR)	Heller	POEM	P-value
Total costs	**13 328 (11 897–15 148)**	**14 201 (12 263–17 232)**	**0.447**
Total hospital cost	**7717 (7037–9945)**	**7760 (4674–13 419)**	**0.993**
Total clinic cost	**4926 (4496–6120)**	**7423 (5762–8066)**	**<0.001**
Surgery Dep.	2896 (2720–2981)	1775 (0–1828)	<0.001
Anesthesia Dep.	1822 (1537–2796)	3361 (2132–3969)	0.001
Gastroenterology Dep.	0 (0)	2515 (1775–3009)	–

substantially higher incidence of esophagitis on postoperative upper endoscopy and a higher rate of pathologic pH-studies in the postoperative setting.[12] Similarly, Inoue and colleagues reported outcomes of 500 consecutive POEM procedures and showed subjective GERD symptoms in 19% of patients, while endoscopic evidence of esophagitis was present in 59% of patients postoperatively.[15] Recently, seven tertiary academic centers published their cumulative GERD outcome data on 282 POEM patients.[16] Postoperative pH studies were available for each patient and 233 (83%) patients had an endoscopic follow-up study. Objective GERD as defined by a DeMeester score $\geq$14.72 was present in 58% of patients at a median follow-up of 12 months, 23% of patients had evidence of reflux esophagitis on endoscopy and GERD was asymptomatic in 60% of cases.[16] Since our practice did not include postoperative pH studies or upper endoscopies as follow-up investigations, our data lacks a comprehensive postoperative reflux assessment. Considering the recent publications quoted above, routine assessment of postoperative reflux with pH-studies or upper endoscopies should be selectively considered in symptomatic patients in order to assess the need for further medical or surgical treatment, and to avoid sequelae of uncontrolled reflux.

Perioperative data, including operation time, length of myotomy and postoperative complications, were similar between the two groups. These results are in-line with a systematic review of studies comparing POEM and LHM.[2] However, this study did include our POEM learning curve and POEM procedural times are decreasing with greater experience, which may affect future costs.

Minor complications (Clavien-Dindo grade 1–2) occurred in 14% of LHM and 9% of POEM patients and major complications (Clavien-Dindo grade 3–5) did not occur. Our outcomes in the POEM group were similar to the outcomes of an international multicenter study, where 137/1826 POEM patients had postoperative complications, with 6.4% mild, 1.7% moderate, and 0.5% severe adverse events as graded according to the American Society for Gastrointestinal Endoscopy (ASGE) lexicon's severity grading system.[17]

In contrast to a meta-analysis documenting longer hospitalizations after POEM, we found a similar length of stay in both groups.[12] In their meta-analysis, Schlottmann and colleagues showed an increased length of stay associated with the POEM procedure with POEM patients staying an average of 1.03 days longer in hospital than their LHM counterparts.[12] These results should be interpreted with caution. Considering the novelty of the POEM procedure, the majority of the analyzed studies might have included the early POEM learning curve.[19] Our finding of equal hospital stay was in line with the results of another specialized center.[13] In contrast, Docimo and colleagues showed a marked decrease in length of stay after POEM (31h vs. 56h, $p < 0.01$), reporting outcomes on 44 POEM and 122 LHM patients operated from 2006 - 2015.[18] Since length-of-stay is not only dependent on patient outcome, but also reflects clinical routine (which might change over the years), we decided to include only contemporary LHM patients for comparison in our analysis. At the present time-point, POEM is performed at our institution as an inpatient procedure with a one-night hospital stay.

Health care costs represent a major concern throughout medical subspecialties. As such, any new procedure or medical treatment has to be evaluated for its cost-outcome-efficiency. Few studies have compared the costs associated with POEM to the standard: LHM. Miller and colleagues calculated incremental cost-effectiveness ratios, where LHM costs were set to 1.[20] In their single-center analysis including 104 POEM and 42 LHM patients over a 4 year-period at Case Medical Center, Cleveland, POEM costs were found to be 1.058 the costs of LHM with a similar annual cost per cure between the two procedures.[20] In the present study, we found no difference in total and hospital-associated between POEM and LHM. Clinic-associated costs were substantially higher in the POEM cohort, which reflects the fact that all POEM procedures were done by a team of two (consultant) physicians (thoracic surgeon and an interventional gastroenterologist). This approach facilitated introducing POEM at our institution with virtually no major morbidity and comparable results to LHM. For the future, after the learning curve, POEM will be performed by a surgeon or interventional gastroenterologist only, which might lead to decreased costs for this intervention at our institution. This data may be particularly important with respect to negotiating with insurers to improve the routine coverage of POEM by private insurance in the United States.

A limitation to the present study is the relatively small patient number, which also indicates, that the current results include our learning curve. Nevertheless, these outcomes suggest that a POEM program can be introduced with comparative outcomes and costs when compared to a contemporary cohort of LHM patients.

Conclusion

POEM is a relatively novel procedure with long-term outcome data being currently published. The procedure is associated with equivalent palliation of symptoms and similar costs and hospital stay when compared to the established surgical technique (LHM). However, recent publications showing a higher incidence of GERD after POEM which was confirmed in the current study, reflect the need for additional long-term follow-up studies of POEM in the future.

Conflicts of interest

The authors have no conflict of interest to declare.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.amjsurg.2019.07.026.

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