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Laparoscopic Heller myotomy and Dor fundoplication in the same day surgery setting with a trained team and an enhanced recovery protocol*



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ABSTRACT

Background: The length of stay after Heller myotomy is 1–5 days. The aim was to report feasibility of the procedure as same day surgery (SDS). *Methods:* Three steps of Enhanced Recovery After Surgery protocol: preoperatively, clear liquid diet for 24 hours,

Methods: Three steps of Enhanced Recovery After Surgery protocol: preoperatively, clear liquid diet for 24 hours, in preoperative area: antiemetics as dermal patch/IV form, 2: Intraoperatively, intubation in semi upright position, IV analgesics and antiemetics. 3: Postoperatively, clear liquid diet and discharge instructions. Patients were followed using a phone questionnaire. Values are median (interquartile range).

Results: Fifty-seven patients, 32 M (56%)/25F (44%), age 48 (35–59). First 45 were inpatient with LOS of 1 day. Last 12 were planned as same day surgery, 1/12 was discharged on POD#2, 11/12 (92%) were performed as same day surgery. The duration of operation: 139.5 min (114–163) inpatient: vs 123 (107–139) same day surgery, P < .01. Questionnaires were obtained in 78% inpatient at 40 months (25.6–67) vs 82% same day surgery at 8 (4–12). All were satisfied with the operation with no difference between the 2 groups.

Conclusion: Heller myotomy can be planned as same day surgery and performed successfully in majority of patients with a trained team and an Enhanced Recovery After Surgery protocol focused on prevention of nausea, and pain control in perioperative period.

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INTRODUCTION

Esophagogastric myotomy for the surgical treatment of achalasia was first described by Ernst Heller in 1914 who performed the procedure on a 49-year-old male with 30 years of dysphagia [1]. The procedure consisted of an 8 cm double, anterior and posterior extramural cardioplasty via a laparotomy approach and resulted in immediate symptomatic relief as was described by Heller: "from the day after the operation, the patient received any form of food: bread, meat, potatoes" [2]. The surgical treatment of achalasia has then evolved over the last century [2,3] to a single anterior myotomy via laparotomy [4] and has been performed via thoracotomy [5], thoracoscopically [6], and finally, via a laparoscopic approach [7], all providing great symptomatic relief. The procedure is now universally performed laparoscopically, and in

* Corresponding author at: Department of Surgery, McGovern Medical School at UTHealth, Director of Esophageal Disease Center, Memorial Hermann Southeast, 11914 Astoria Blvd. Suite 260, Houston, Texas 77089. majority of centers, in combination with a partial wrap as Dor [8,9] or Toupet fundoplication [10].

The great outcomes and minimal morbidity of the laparoscopic Heller myotomy with Dor fundoplication in esophageal centers have been widely reported [8,11], including a report with 407 patients in 2008 [12] and 505 patients in 2010 [13]. The consistent satisfactory treatment effect of laparoscopic Heller myotomy over time has been associated with gradual decrease in length of stay, from a median of 5 days in 2008 [12], to 2 days in 2009 [11], 1 day in 2010 [13] and a recent study from United Kingdom reporting 27 Heller myotomies in the same day surgery in 2016 [14].

The advances in laparoscopic techniques, the increase in surgical experience and the improvement in the perioperative care in laparoscopic surgery, including Heller myotomy, are paralleled with the increasing data on Enhanced Recovery After Surgery (ERAS). These protocols are aimed to decrease the length of stay as shown in laparoscopic bariatric [15,16] colorectal [17,18] and urologic procedures [19,20].

The aim of the study was to report the feasibility of Heller myotomy and Dor fundoplication in the same surgery setting in a single specialized esophageal center, by assembling a consistent and trained surgical team, and implementation of an ERAS protocol.

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METHODS

A retrospective study of prospectively obtained data was conducted and patients who underwent laparoscopic Heller myotomy and Dor fundoplication from 11/20/2009 to 08/17/2017 were included in the study. The study was planned as same day surgery (SDS) after 04/01/ 2015. SDS was defined as discharge in the same day as the procedure was performed (If patients spent the night in hospital with an admission of less than 24 hours, they were included in the inpatient group). Patients who had undergone a completion Heller myotomy or had a concomitant diverticulectomy were excluded from the study. All consecutive patients who were referred for first time Heller myotomy and were a surgical candidate to undergo a Heller myotomy were considered for same day surgery. Patients' characteristics and perioperative data were subtracted from electronic health records. Patients were followed prospectively by the operating surgeon, using a structured questionnaire administered by telephone. The details of the questionnaire were previously reported [21]. The questionnaire was focused on relief from preoperative symptoms, including dysphagia, regurgitation and weight loss, ability to eat as desired, weight gain in lbs., new postoperative symptoms such as heartburn and bloating, and overall satisfaction with the operation. While the questionnaire mostly assessed the outcomes, the main aspect related to same day surgery versus inpatient, was the overall patient satisfaction with the operation, as patients may or may have not been more satisfied to be discharged the same day after the procedure. The study was approved by the institutional board review at UTHealth and Memorial Hermann Southeast Hospital.

All patients underwent an upper endoscopy, a high-resolution manometry and a video esophagram prior to Heller myotomy. Grades of achalasia were assessed by the traditional radiographic classifications based on esophageal diameter: grade I, <4 cm; grade II, 4 to 6 cm; grade III, >6 cm; grade IV, >6 cm and/or a sigmoid-shaped esophagus [12,22].

All procedures were performed by the same surgical and anesthesia team. Steps of laparoscopic Heller myotomy and Dor fundoplication were previously described [23]. The only change we made in our technique was the use of HARMONIC® scalpel, (Ethicon, Somerville, New Jersey) instead of endoscissors and electrocautery, to extend the myotomy superiorly. This change was implemented to decrease bleeding from the muscle edges, spend less time on hemostasis and have a drier field to prevent mucosal injury.

The length of myotomy extended from the diaphragmatic crus to 3 cm distal to the gastroesophageal junction on the greater curvature. The completion of the myotomy was verified by an intraoperative endoscopy, where air insufflation was given while the scope was placed in the distal esophagus. If the myotomy was complete, the gastric distension would be achieved by insufflating air in the distal esophagus. If the stomach did not distend, the myotomy was extended, more commonly, distally, and all the residual fibers were divided. At the completion of myotomy, gastric distension was easily achieved by insufflating air in the distal esophagus, and there was easy passage of the scope through the gastroesophageal junction. The extent of the myotomy was verified endoscopically in the antegrade and retroflexed view to assess the length of the myotomy above and below the gastroesophageal junction and to reassure an adequate myotomy.

The Enhanced Recovery After Surgery (ERAS) protocol to facilitate same day surgery procedures included 3 steps. The details of each step are depicted in Table 1. The use of scopolamine patch, and dosage of Tylenol and Zofran and the exact time of delivery of medications in 3 phases were put together through the ERAS protocol.

Step1: Preoperatively, patients were instructed to have clear liquid diet for 24 hours the day before surgery and nothing by mouth after midnight the night before surgery. In the preoperative holding area: antiemetics as dermal patch and in IV form, 1 dose of IV antibiotics and 1 dose of anticoagulation were given. **Step 2: Intraoperatively**, intubation

Table 1

The 3 Steps ERAS Protocol for the Same Day Surgery, Heller Myotomy and Dor fundoplication

| 1. Preoperative: | |
|--------------------|---|
| - | Clear liquid diet for 24 hours prior to surgery |
| | Preoperative holding area: |
| | a. Scopolamine patch |
| | b. Zofran 4 mg IV |
| | c. Cefoxitin 1 gram IV |
| | d. Heparin 5000 units S/Q |
| 2. Intraoperative: | |
| | a. Tylenol 1000 mg IV at the time incision |
| | b. Marcaine 5% local injection prior to skin incision |
| | and prior to skin closure |
| | c. Zofran 4 mg IV prior to extubation |
| | d. Foley removal prior to extubation |
| 3. Postoperative: | |
| | a. Check dressings |
| | b. Clear liquid diet |
| | c. Assess ability to void |
| | d. Review discharge instructions with the patient |

was performed in the semi upright position, IV analgesics at the time of incision and at the time of extubation were given. Prior to extubation: Antiemetics were given and the Foley catheter was removed. Step 3: **Postoperatively**, in the recovery room: the care was provided by a team of trained thoracic nurses. Careful attention was paid to assess for nausea and provide adequate pain control if needed. The dressings were checked for any signs of bleeding. Clear liquid diet was started and the ability to void was verified. Discharge instructions as previously reported [24] were reviewed with patients by the operating surgeon and were reinforced by thoracic nurses. A copy of the discharge instructions was given to the patients. None of the patients required a nasogastric tube. Postoperative esophagram was not obtained on any patients, for 3 main reasons: 1. All patients underwent an upper endoscopy in the operating room to confirm the completion of myotomy and to assess for leak. A second upper endoscopy was performed, after completion of Dor fundoplication to assess easy entrance into the stomach and rule out torsion at the level of the gastroesophageal junction. Therefore, an esophagram did not add any additional diagnostic value for detection of leak. 2. Drinking barium immediately after surgery, may result in gagging, may be difficult to ingest for the patient and may result in retained Barium in the stomach. We believe the first drink after surgery should be a pleasant experience for the patients with a fruit juice of their choice. 3. An unnecessary esophagram will result in unnecessary costs.

Patients were seen in the clinic at 5–9 days, 3 months and 1 year after surgery. The diet was advanced to soft diet 2 weeks after the surgery and gradually to regular diet as tolerated by patients.

Statistical analysis

Variables were compared using a chi-square or Fisher's exact test for categorical variables and an analysis of variance (ANOVA) or Kruskal-Wallis test for continuous variables.

The null hypothesis was rejected at a nominal alpha of P < .05. All computations were performed using SAS software version 9.4 (SAS Institute Inc., Cary, NC). Values are presented as median and interquartile range (IQR).

RESULTS

There were 67 patients. Completion Heller myotomy (n = 7) and patients who had an epiphrenic diverticulectomy in addition to Heller myotomy (n = 3) were excluded. A total of 57 patients were included in the study. There were 32 males (56%) and 25 females (44%), age 48 (35–59) years. The first 45 were performed as inpatient procedure with median length of stay of 1 day, the last 12 were planned as same day surgery. One patient who regurgitated at the time of intubation

was discharged on POD#2 (added to the inpatient list): 11/12 (92%) were performed as same day surgery. There was no difference between age, BMI, ASA and radiographic classifications between the 2 groups. Details are shown in Table 2. None had mega esophagus in a sigmoid shape (stage IV as per classic radiographic classification). The most common chief complaint was dysphagia. There was no difference between the chief complaint, overall symptoms and the use of Proton Pump Inhibitors prior to surgery between the 2 groups, as shown in Table 3. There was no difference between the number of patients who had Balloon dilation or Botox injections and the number of interventions per patient between the 2 groups, as shown in Table 4.

The duration of operation was 131 min (113–158), inpatient: 139.5 (114–163) vs SDS: 123 (107–139), P < .01. There was no transfusion, conversion, or leak. There were no readmissions.

The follow up questionnaire was obtained by the operating surgeon in 45/57(79%) at 32 months (12–61), inpatient 36/46 (78%), at 40 (25.6–67) vs SDS: 9/11 (82%) at 8 (4–12). The results are shown in Table 5.

DISCUSSION

Our study shows that laparoscopic Heller myotomy is a procedure with great outcomes that can be performed in the same day surgery setting in esophageal centers. Our findings confirm the simplicity of the procedure as previously reported in 2 large series of 407 patients in 2008 with a conversion rate of 0-1.5% and a leak rate of 0.5% [12] and 505 patients in 2010 [13] with a leak rate of 0.4%. The great outcomes of Heller myotomy have been associated with gradual decrease in length of stay over time from a median length of stay of 5 days in 2008 [12], to 2 days in 2009 [11] and 1 day in 2010 [13]. Subsequently, a study from United Kingdom in 2016 reported feasibility of Heller myotomy in the same day surgery in an esophageal center with high number of benign esophageal surgeries [14]. The study included 60 patients with achalasia who underwent laparoscopic Heller myotomy and Dor fundoplication over a 4-year period. Patients were divided in 2 groups with similar patient's characteristic and clinical presentations. The first 33 patients (55%) were discharged on POD#1 and 27 consecutive patients (45%) were discharged on the same day. There was no difference in symptomatic relief between 2 groups, 1 patient with planned same day surgery had a leak and required reoperative surgery. The authors implemented a clinical pathway, used for same day surgery after a partial fundoplication, based on prevention and control of pain and nausea [25]. Similarly, in a study with 24 patients over a 7-year period, 5 patients were discharged after 23 hours and subsequently, 2 patients were discharged on the same day. None required readmission [26].

We previously reported the importance of a trained surgical team in decreasing operative time and costs of laparoscopic hiatal hernia repair [24]. The key is to have a trained and dedicated team and the daily and constant reinforcement of the protocol, as it becomes the integral part of the practice of the surgical team. We believe the reduction in the

| Table | 2 |
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Demographics and radiographic staging. SDS: same day surgery

| | All (n = 57) | Inpatient $(n = 46)$ | $\begin{array}{l}\text{SDS}\\(n=11)\end{array}$ | Р |
|-----------------------------------|------------------|----------------------|---|-----|
| Age | 48 (35–59) | 43 (34–58) | 57 (45-66) | .24 |
| BMI | 26.9 (23.3-30.6) | 26.56 (22.9-30.6) | 27.8 (23.3-30.9) | .86 |
| ASA | 2 (2-3) | 2 (2-2) | 3 (2-3) | .07 |
| Gender | 25F (44%) | 21F (43%) | 5F (46%) | 1.0 |
| | 32 M (56%) | 26 M (57%) | 6 M (54%) | |
| Radiographic stagi | ng | | | |
| I: <4 cm | 20 (35%) | 15 (33%) | 5(45%) | .46 |
| II: ≥ 4 and ≤ 6 | 24 (42%) | 19 (41%) | 5(45%) | .46 |
| III: >6 cm | 13 (23%) | 12 (26%) | 1(10%) | .46 |
| IV: >6 cm and or Sigmoid Shape | None | None | | |

Table 3

Preoperative symptoms and the use of PPI. SDS: same day surgery

| | All (n = 57) | Inpatient (n = 46) | SDS (n = 11) | Р |
|--------------------------------|--------------------------|--------------------------|-------------------------|-----|
| Most common chief complaint | Dysphagia 45/57 (79%) | Dysphagia 38/46 (83%) | Dysphagia 7/11 (64%) | .09 |
| Dysphagia | 57/57 (100%) | 46/46 (100%) | 11/11 (100%) | 1.0 |
| Regurgitation | 54/57 (95%) | 44/46 (96%) | 10/11 (91%) | .48 |
| Heartburn | 12/57 (21%) | 9/46 (20%) | 3/11 (27%) | .68 |
| Nocturnal cough | 40/57 (70%) | 32/46 (70%) | 8/11 (73%) | 1.0 |
| Weight loss % patients | 40/57 (70%) | 33/46 (72%) | 7/11 (64%) | .72 |
| Weight loss (lb) | 15 (0-40) | 13.8 (0-30) | 20 (0-50) | .50 |
| Pneumonia | 4/57 (7%) | 3/46 (7%) | 1/11 (9%) | 1.0 |
| Chest pressure | 26/57 (46%) | 21/46 (46%) | 5/11 (45%) | 1.0 |
| PPI use | 35/57 (61%) | 30/46 (65%) | 5/11 (46%) | .31 |

operative time for SDS group in our study is multifactorial and is mainly related to improvement in the knowledge and experience of the entire surgical team. All procedures were performed by the same team as we believe consistency is an essential component to achieve great outcomes. The surgeon's operative experience is a factor, as practice and repetition makes better, but for this particular procedure, at the time SDS was started, the surgeon's learning curve had mostly passed. As all procedures were performed by the same surgeon, the most important factor seem to be the experience of the entire surgical team and not solely improvement in surgeons' experience with the procedure. In addition, the use of harmonic scalpel for superior extension of the myotomy, results in less bleeding. The drier field results in a less time for hemostasis, increases the visibility, reduces the chance of mucosal injury and ultimately, results in less operative time. We believe the most important step in achieving SDS was the readiness of a trained team, as the surgical team became more familiar and comfortable with this operation.

There has been a growing body of evidence on implementation of ERAS protocols aimed to decrease length of stay as is shown in laparoscopic bariatric [15,16], colorectal [17,18], and urologic procedures [19,20]. Our study emphasizes the importance of implementing an ERAS protocol to devise a reproducible pathway to assure feasibility of Heller myotomy in the same day setting. We believe protocols should be easy to remember and simple to apply. Our ERAS protocol has 3 main components which are all equally important and are applied preoperatively, intraoperatively and postoperatively. The protocol is based on prevention and control of post-operative pain and nausea and implementation of a multidisciplinary approach to perioperative care provided by a dedicated and trained surgical team including, nurses, anesthesiologist and surgeon. As medications and steps may seem basic in our protocol, before 04/2015, the usage of these medications and application of these steps were at times missed and were not applied in a systematic manner with solids steps and clear dosage that were put in place through the ERAS protocol. The use of scopolamine

Table 4

Number of patients who had interventions and number of interventions per patient prior to Heller myotomy and Dor fundoplication. SDS: same day surgery

| | | n = 46) (| (n = 11) | |
|--|------------------|----------------|--------------------|--------------------------|
| Botox injections 10 | /57 (18%) 7, | /46 (15%) | 3/11 (27%) | 1.0 .39 .33 |
| 5 | , , , | , , | ., | 1.0 1.0 |
| Botox injections0 (Balloon and botox injections1 (| 0–0) 0 0–2) 1 | (0-0) (0-2) | 0 (0–1) 1 (0–2) | .11 .47 .46 .47 |

Table 5

Symptomatic questionnaire via phone

| | All 45/57 (79%) | Inpatient 36/46 (78%) | SDS 9/11 (82%) | Р |
|--|-----------------------|-----------------------------|----------------------|-------|
| Duration to the time of questionnaire (months) | 32 (12-61) | 40 (25.5-67) | 8 (4-12) | .0003 |
| Free of preoperative symptoms | 39/45 (87%) | 31/36 (86%) | 8/9 (89%) | .83 |
| Able to eat as desired | 44/45 (98%) | 35/36 (97%) | 9/9 (100%) | .61 |
| Return to daily activity <2 weeks | 37/45 (82%) | 28/36 (78%) | 9/9 (100%) | .12 |
| Satisfied with the operation | 45/45 (100%) | 36/36 (100%) | 9/9 9 (100) | 1.0 |
| PPI use | 3/45 (6.7%) | 2/36 (5.6%) | 1/9 (11.0)% | .53 |

patch, and dosage of Tylenol and Zofran and the exact time of delivery of medications in 3 phases were put together through the ERAS protocol. We believe a protocol should not consist of solely new medications or steps, but should be a simple guideline with reproducible pathways that can be easily applied and followed. The ERAS protocol may have not been the most important factor in achieving SDS, as no protocol can be applied without a dedicated and trained team, but we believe the systematic approach to control pain and nausea in our protocol to prevent the need for hospitalization following surgery facilitated the feasibly of the procedure as same day surgery.

The perioperative patient care is an important factor in achieving good outcomes in SDS. The Foley catheter is removed prior to extubation to decrease patient discomfort. One element that we have improved since this study is not to place Foley catheter for our Heller myotomies. Nasogastric tube is used in many centers with the assumption to prevent gastric distension that may put the Dor fundoplication and the stitches under tension. We decompress the stomach at the end of the procedure endoscopically, therefore gastric distention will be prevented. The placement of the nasogastric tube is associated with discomfort that decreases patient mobility, increases the risk of gagging that could result in nausea and retching, while providing minimal, if any benefit. We believe that prevention of nausea is an essential factor in patient comfort at the time of recovery that facilitates the ability to tolerate PO and allows earlier discharge. Therefore, the prevention of nausea was started in the preoperative holding area and continued in all steps of patient care, including the operating room and the recovery room. Similarly, the prevention of pain is crucial and was started at the time of intubation and systematically in all steps of patient care until the patient was discharged.

It is crucial to provide clear instructions to patients as what to expect after the procedure including shoulder and neck pain as the result of CO2 insufflation. The pain can be severe at time, most commonly improves about 24 hours and is facilitated by early ambulation. Clear discharge instructions devised in our center (as previously reported) [24] were reviewed with patients by the operating surgeon and were reinforced by thoracic nurses prior to discharge and a copy was given to the patients. One element of discharge instructions included full liquid diet for 2 weeks, which is another area for improvement in our future cases. The diet can be advanced to "as desired", 1 week or even 48 hours after surgery, possibly after patient passes gas or has a bowel movement, as Heller himself fed his first patient with potato and meat, the day after surgery [2].

While the role of a team for implementation of 3 steps of the same day surgery protocol is crucial, patient section is equally important. The median age of patients in the study from United Kingdom [14] was 41 years old and the median age in our study population was 48. The young age of population could be contributing factor to make same day surgery feasible, as the procedure may not be possible in older patients with comorbidities. Even with planned same day surgery, patients should be observed or admitted if clinically indicated, as we did in 1 of our patients who regurgitated and aspirated at the time of intubation. The patient had a dilated esophagus with copious retained food

and bile, despite instructions to be on clear liquid for 24 hours prior to surgery. Emergent bronchoscopy showed minimal bile in the airway. The patient was extubated at the end of procedure and was kept for observation. She had leukocytosis which resolved on POD#2 and she was discharged.

Interestingly, none of our patients had a mega esophagus in a sigmoid shape (stage IV as per classic radiographic classification). The presence of stage IV achalasia would have made the operation more complicated and possibly not feasible in the same day surgery setting as was seen in one of our patients with a very dilated esophagus. The absence of stage IV achalasia in our population can be explained by advancements in radiographic techniques, and multimodality treatment of achalasia that may have prevented the progression of the disease into the decompensated sigmoid shaped esophagus.

As the presentation of achalasia is changing over time, so has the use of Heller myotomy. A study on trends in the utilization of Heller myotomy for achalasia in the United States from 1992 to 2011 showed the number of Heller myotomies performed in the U.S. has increased from 1576 in 1992 to 5046 in 2011, with in hospital mortality of 0.9% to 0.3% and LOS of 7 days to 2 days [27]. In contrast, now with the usage of other modalities such as Balloon dilations, Botox injections, and now POEM (Per Oral Endoscopy Myotomy), and a heterogeneous data on outcome of Heller myotomy in some centers including a rate of mucosal tear of 3.9–12% [12,28], a conversion rate of 0–1.5% [12,28], a leak rate of 0.5% and the traditional median length of stay of 2-5 days [11,12], the usage of Heller myotomy may be deceasing over time. It is important to emphasize the advantages of Heller myotomy and Dor fundoplication that is unique to this operation Including: 1. Correction of the distal esophageal angulation following esophageal mediastinal mobilization, which facilitates esophageal emptying, 2. Dor fundoplication, in addition to providing an anti-reflux barrier, as shown in a randomized trial with significantly less pathologic reflux compared to Heller myotomy alone, 9.1% vs 48%) [29], anchors the stomach to the edges of the myotomy and to the diaphragmatic crus, keeping the distal esophagus in its new and more direct anatomical position.

With advances in techniques of laparoscopic surgery, implementation of ERAS protocols, excellent symptomatic outcomes, a gradual decrease in the length of stay and increasing data supporting the feasibility of Heller myotomy in the same day surgery setting, the use of Heller myotomy for treatment of achalasia should be revisited. The essential requirement include the implementation of a simple protocol, and presence of a trained and dedicated team, most importantly, to reinforce the protocol daily and repetitively, until it becomes an integral and effortless practice of the surgical team.

The continuous success of Heller myotomy over years confirms the comments made by Herman J. Moersch at Mayo clinic in 1933, stating: "There is probably no disease that responds more satisfactory to a proper treatment than cardiospasm" [30]. It is time to show that the procedure is a simple minimally invasive intervention with great out comes, that can be performed in the same day surgery setting and should remain as the key therapeutic tool in our armamentarium of approaches for the treatment of achalasia.

Conclusion

Laparoscopic Heller myotomy is a simple intervention for the treatment of achalasia and can be planned as same day surgery and successfully performed in majority of patients. The requirements include assembling a trained and experienced surgical team, and implementation of a recovery protocol focused on prevention of nausea and adequate pain control in the perioperative period. Clear instructions to the surgical team and patients are essential.

Limitations

We acknowledge the limitations of the study, which include low number of patients. In addition, patients may have underrepresented their symptoms or potential dissatisfactions to the operating surgeon, who obtained the questionnaires. The long term outcomes between two groups may have differed if the questionnaires were obtained at a later time.

Disclosures

Author contribution:

Farzaneh Banki for study design, writing the manuscript and collecting data;

Chandni Kaushik for study design and data collection,

Madison Milhoan for study design and data collection;

Anshu Khanna for study design and statistical analysis;

Andre Miller for study design and implication of the ERAS protocol, Munish Chawla for study design and critical review;

Charles Miller for study design, statistical analysis and critical review.

Conflict of interest

No conflict of interest for any of authors.

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