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Abdelhafez Seleem
Department of general surgery al_azhar university., abdelhafzsalim83@gmail.com

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Risk Factors of Mucosal Injury During Laparoscopic Heller Cardiomyotomy

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Abdelhafez Seleem,[1] MD.

** Corresponding Author:*
Abdelhafez Seleem.
abdelhafzsalim83@gmail.com

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[1]*General surgery Department, Faculty of Medicine, Al-Azhar University, Cairo, Egypt.*

ABSTRACT

Background: Laparoscopic Heller cardiomyotomy has been widely adopted as a successful option for managing achalasia. However, intraoperative mucosal perforation is a common and dreadful complication of this technique.
Aim of the study: We conducted this study to detect these possible risk factors for mucosal injury and to elucidate its impact on operative and post-operative outcomes.
Patients and Methods: The data of consecutive 52 patients diagnosed with achalasia and subjected to laparoscopic Heller cardiomyotomy were retrospectively reviewed. They were allocated into two groups according to the occurrence of intraoperative mucosal injury: Group A (No-perforation group) and Group B (Perforation group).
Results: Mucosal injury was detected in 9 patients (17.31%), and these patients were included in Group B, while the remaining cases were included in Group A. Most preoperative data were statistically comparable between the two groups, apart from age and history of previous balloon dilatation. The former was significantly older, whereas the latter was significantly higher in Group B. Mucosal perforation was associated with a significant increase in operative time and blood loss, and it was mainly performed by low-volume surgeons. Group B also showed a significant prolongation in the duration of hospitalization and more delay in oral start.
Conclusion: Old age, previous balloon dilatation, and low surgical expertise are the main risk factors for mucosal injury during Heller cardiomyotomy. These factors should be considered when performing this operation, especially the history of previous dilatation. Patients with the previous risk factors should be performed with highly experienced surgeons.

Keywords: *Achalasia; Heller cardiomyotomy; Mucosal perforation.*

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INTRODUCTION

Achalasia represents an oesophagal motility disease in which there is oesophagal aperistalsis and failed relaxation of the lower oesophagal sphincter (LES)[1]. It results from progressive degeneration of the myenteric oesophagal plexus[2,3]. It is a rare clinical entity, with an incidence and prevalence of one and ten per 100000 individuals, respectively [4]. The patient usually presents with difficulty swallowing, regurgitation, weight loss, and chest pain [5].

As dysphagia is the main symptom of this disease, current treatment modalities focus on alleviation of this symptom[6] **.** Multiple methods exist for managing such a disease, including botulinum toxin injection, endoscopic balloon dilatation, surgical Heller cardiomyotomy with fundoplication, and peroral endoscopic myotomy **.**[7,8]

Currently, laparoscopic Heller cardiomyotomy with anterior fundoplication is the most often used treatment for achalasia, as it can improve long-term outcomes in approximately 90% of patients[9,10]. It entails mechanical disruption of oesophagal and gastric muscle fibres leading to enhanced oesophagal emptying and relief of dysphagia**.**[11]

To obtain such an outcome, all muscle fibres should be divided with complete exposure of the underlying mucosa. [6] As a result, an intraoperative mucosal injury could occur during this procedure. In fact, multiple studies have reported that this dreadful complication is the most common complication during the myotomy procedure. [12,14].

According to our extensive literature research, there are few publications dealing with the risk factors for mucosal injury during the Heller operation. Therefore, we conducted the present study to detect

these possible risk factors and to elucidate their impact on operative and post-operative outcomes.

PATIENTS AND METHODS

After receiving approval from our medical school's local scientific committee, this retrospective investigation was carried out at the General Surgery Department of Al-Azhar University Hospitals. The study was designed for adult patients diagnosed with achalasia who underwent laparoscopic Heller cardiomyotomy at our department during the period between January 2015 and December 2021 (seven-years period). We excluded patients whose age below 18 years, who underwent the open Heller procedure, or who had recurrent achalasia after a primary Heller procedure were excluded from the current study.

Preoperative preparation included history taking, clinical examination in addition to the preoperative laboratory, radiological and endoscopic investigations. A barium meal examination was ordered for all cases as a preliminary investigation for dysphagia and to assess the shape of the oesophagus. The diagnosis of achalasia was confirmed via oesophagal manometry, which showed the classic findings of achalasia, including oesophagal aperistalsis, failure of oesophagal relaxation, and increased lower oesophagal sphincter pressure (LES). An upper gastrointestinal endoscopy was also ordered to exclude pseudoachalasia, especially in old patients. All patients received the same preoperative care, and informed consent was obtained from all of them after explaining the benefits, risks, and outcomes of the surgical intervention.

The procedure was performed via laparoscopy using the five-port technique. The camera port was inserted above the umbilicus, while the two working ports were inserted at the same level at the right and left midclavicular lines. An epigastric port was inserted for liver retraction, while the other one was inserted at the left anterior axillary line. The operation was started by dissection of the part flaccida and the phrenicoesophageal membrane till exposing the abdominal oesophagus, cardia and upper part of the stomach. Heller myotomy was done using either a harmonic scalpel or ligasure device. The length of the myotomy was 7 cm above the cardia and 3 cm below it. Saline was injected into the nasogastric tube present in the oesophagus to notice any leakage from the oesophagal or gastric mucosae. If leakage was detected, it was repaired using interrupted vicryl 4/0 sutures, and the leakage test was repeated. This was followed by Dor fundoplication over the myotomy part as a protective method against reflux. A surgical drain was inserted below the left lobe in most cases. All patients received the standard post-operative care, and most cases were allowed to start oral fluid intake on the first post-operative day unless a mucosal injury was encountered.

Based on the incidence of intraoperative mucosal injury, the included patients were divided into two groups; Group A included patients without perforation, and Group B included patients with perforation. The mucosal injury was established when a full-thickness perforation was detected either at the oesophagal side, gastric side, or esophagogastric junction. [6]

Data collection included preoperative data (age, sex, body mass index BMI, smoking, comorbidities, symptoms, disease duration, previous balloon dilatation, oesophagal shape and LES pressure values), operative data (surgeon experience, operative time, and blood loss), and post-operative data (day of oral fluid intake, hospital stay, and mortality). Surgeon experience was classified according to their academic degree (A for the professor, B for assistant professor, and C for lecturer).

Statistical analysis

SPSS version 26 for Windows® was used to code, process, and analyse the data. The qualitative data was given as a number (frequency) and a percentage. The Chi-Square test was used to compare groups. The non-parametric data were expressed as median and range, whereas the parametric data were expressed as mean and SD. The student's t-test was used to compare two groups with normally distributed quantitative variables, and the Mann-Whitney U-test was employed if the data were abnormally distributed. To identify dependent and independent risk factors, researchers utilised regression analyses (univariate and multivariate). For all the applied tests, a p-value less than 0.05 was considered significant.

RESULTS

In our retrospective series, the intraoperative mucosal injury was detected in nine patients, with an incidence of 17.31%. The included participants were divided into Group A (43 cases without perforation) and Group B (nine cases with perforation).

When comparing the two study groups, group B had significantly older ages compared to Group A (50.11 vs 40.91 years respectively – $p < 0.001$). Nevertheless, gender distribution and BMI were statistically comparable between the two groups. Furthermore, there was no significant difference in the prevalence of smoking or other medical comorbidities between our two groups.

The duration of the disease ranged between two and seven years in both groups. Dysphagia was the most common presentation, followed by regurgitation and chest pain. All of the previous symptoms showed no significant difference between the two groups ($p > 0.05$). However, previous balloon dilatation was reported by 6.98% and 88.89% of patients in Groups A and B, respectively, with a significant increase in association with mucosal injury ($p < 0.001$).

Preoperative investigations, including barium swallow findings and LES pressure, were not significantly different between the two groups. The previous data are shown in Table 1.

The duration of operation showed a significant prolongation in Group B (87.78 vs 73.79 minutes in Group A - $p < 0.001$). Moreover, Group B showed a significant increase in the amount of intraoperative blood loss (67.67 vs 29.19 ml in Group A – $p < 0.001$). Regarding surgeon experience, it was evident that lower experience was associated with an increased risk of mucosal injury ($p = 0.016$). Table (2) shows the previous data.

Both the day of oral fluid intake and duration of hospitalization were significantly increased in patients with mucosal injury ($p < 0.001$), as shown in Table 3. No mortality was encountered in the current study.

Old age, previous balloon dilatation and low surgeon experience were significant risk factors for mucosal injury on univariate analysis. Only previous balloon dilatation maintained its significance on the multivariate one (Table 4).

	Group A (n = 43)	**Group B (n = 9)**	**P value**
Age (years)	40.91 ± 6.26	50.11 ± 5.51	< 0.001*
Gender			
-Male	21 (48.84%)	5 (55.56%)	0.714
-Female	22 (51.16%)	4 (44.44%)	
BMI (kg/m2)	22.20 ± 1.98	22.99 ± 2.36	0.302
Comorbidities			
-Diabetes	4 (9.3%)	1 (11.11%)	0.867
-Hypertension	6 (13.95%)	2 (22.22%)	0.532
Smoking	6 (13.95%)	1 (11.11%)	0.820
Disease duration (years)	4 (2 – 7)	5 (2 – 7)	0.892
Symptoms			
-Dysphagia	43 (100%)	9 (100%)	1
-Regurgitation	36 (83.72%)	8 (88.89%)	0.969
-Chest pain	22 (51.16%)	4 (44.44%)	0.714
Previous balloon dilatation	3 (6.98%)	8 (88.89%)	< 0.001*
Oesophagal shape			
-Straight	40 (93.02%)	8 (88.89%)	0.672
-Sigmoid	3 (6.98%)	1 (11.11%)	
LES pressure (mmHg)	47.93 ± 7.39	47.44 ± 7.37	0.858

Table 1: Preoperative data.

	Group A (n = 43)	**Group B (n = 9)**	**P value**
Operative time (min)	73.79 ± 7.25	87.78 ± 5.24	< 0.001*
Blood loss (ml)	29.19 ± 5.79	67.67 ± 8.14	< 0.001*
Surgeon experience			
-A	27 (62.8%)	2 (22.22%)	0.016*
-B	10 (23.26%)	2 (22.22%)	
-C	6 (13.95%)	5 (55.56%)	

Table 2: Operative data.

	Group A (n = 43)	**Group B (n = 9)**	**P value**
Oral start (day)	1 (1 – 2)	6 (5 – 7)	< 0.001*
Hospital stay	2 (1 – 3)	6 (6 – 8)	< 0.001*
Mortality	0 (0%)	0 (0%)	1

Table 3: Post-operative data.

	Univariate analysis	OR	95% CI for OR	P-value
Old age	0.004*	1.226	0.927-1.621	0.153
Gender	0.714			
BMI	0.298			
Diabetes	0.867			
Hypertension	0.536			
Smoking	0.821			
Disease duration	0.833			
Dysphagia	0.999			
Regurgitation	0.698			
Chest pain	0.714			
Previous balloon dilatation	< 0.001*	1.856	1.420- 2.005	0.046*
Oesophagal type	0.675			
LES pressure	0.855			
Surgeon experience (grade C)	0.011*	1.006	0.746-1.117	0.258

Table 4: Regression analysis to detect predictors of mucosal injury during the Heller procedure.

DISCUSSION

Although the Heller cardiomyotomy procedure has been extensively discussed in the literature with its complications and outcomes[1,15,16] **,**the risk factors of intraoperative mucosal injury, which is the most dreadful complication of this procedure, is poorly discussed. That is why we conducted this study, and this represents an advantageous point in favour of our study.

Of the included 52 patients, 9 patients had an intraoperative mucosal injury, with an incidence rate of 17.31%. In the previous systematic review conducted by Campos et al., the incidence of mucosal perforation after the same procedure ranged between 0 and 33%[10]. Our incidence rate lies within the previously mentioned range.

In the current study, we noted an increased risk of perforation in the elderly patients, and old patient age was a significant risk factor for this complication on the univariate analysis. Tsuboi and his associates also noted a significant increase in patients age in the mucosal injury group (48.3 vs 44.2 years in the other group – p = 0.047). Old age was also a significant risk factor for perforation on regression analysis (p < 0.05). Authors attributed this finding to the fragile tissues encountered with old age, which make the mucosa more liable to perforation[6]. Contrarily, other authors reported no significant difference regarding the same parameter as it had median values of 46 and 44 years in the perforation and no-perforation groups, respectively (p = 0.52)[12]

Our findings revealed no statistical difference between the two groups as regard gender distribution. Another study reported a non-significant impact of patient gender on intraoperative mucosal injury (p = 0.862)[6] **,**which is in accordance with our findings.

In our study, the prevalence of smoking and other medical comorbidities was statistically comparable between our two groups. In line with the previous findings, other authors reported no significant impact of smoking or other comorbidities on the incidence of such a complication. Nevertheless, circulatory comorbidity was a significant risk factor for perforation on univariate analysis (p = 0.043) **.**[6]

Analysis of the patient's symptoms before the operation revealed no significant differences between our two study groups. In accordance with our findings, other researchers reported that preoperative symptoms did not have a significant impact on this complication (p = 0.14)[12] **.**

We did not notice any significant statistical difference between the two groups as regard disease duration. Even the two groups had similar ranges of disease duration. Tsuboi and his coworkers also negated any significant relation between disease duration and the development of this complication (p = 0.345)[6], which coincides with our findings.

LES pressure values showed no significant difference between the two groups in the current investigation. Similarly, Salvador et al. likewise found no significant difference in basal LES pressure between the perforation and non-perforation groups (p = 0.66) [12].

Balloon dilatation was the strongest predictor of intraoperative mucosal injury, and that variable showed its significance on both univariate and multivariate analyses. Balloon dilatation leads to submucosal microhemorrhage, which will heal by fibrosis. This, in turn, will lead to loss of the correct dissection plane during the subsequent surgical procedure, which results in an increased mucosal injury risk.

Morino et al. confirmed our findings regarding the increased risk of mucosal injury in patients with previous balloon dilatation. This complication was encountered in two out of the seven cases who had previous dilatation (28.57%), compared to no cases (0%) in the group without previous dilatation[17]. On

the other hand, Salvador et al. contradicted our findings, as previous endoscopic interventions were reported by 12% and 20.7% of patients in the perforation and no-perforation groups, respectively, which was comparable on statistical analysis (p = 0.45) .[12]

We did not notice any significant difference between the two groups regarding preoperative oesophagal shape. Previous authors noted a significant increase in the prevalence of sigmoid-shaped oesophagus in the mucosal perforation group (23.88% vs 14.3% in the other group – p = 0.045). However, that difference turned insignificant on multivariate analysis (p > 0.05)[6] .

In the current study, operations performed by low volume surgeons were more prevalent in the mucosal perforation group. This variable was a significant risk factor on univariate analysis. Other authors confirmed our findings, as low-volume surgeons were a significant predictor for that complication (experience < 5 cases), and this was evident on both univariate and multivariate analyses[6] .In the same context, Zaninotto and his coworkers analyzed the data of consecutive 400 cases undergoing the same procedure, and they noticed that all intraoperative complications were detected in the early 50 cases, indicating the significant association between low experience and intraoperative complications[18]. Another study denied the previous findings, as no significant relation was noted between the surgeon experience and the incidence of such a complication .[12]

In the perforation group, there was a considerable increase in intraoperative blood loss. Likewise, the mucosal perforation group was associated with a considerable increase in intraoperative blood loss, according to Tsuboi and his colleagues (p < 0.001) .[6]

In our study, the operative time showed a significant increase in association with mucosal perforation. It is reasonable that the time needed for suturing the mucosal defect, along with repeated leakage tests, would cause some prolongation of the operative time in association with perforation. A previous study confirmed the previous perspective .[6] Although operative time was prolonged in association with perforation in the study conducted by Salvador et al. (163 vs 135 minutes in the no-perforation group), that difference was statistically insignificant (p = 0.06) .[12]

We usually delay oral intake for patients with esophageal perforation, leaving some time for the mucosa to heal, and that could explain the significant prolongation of hospital stay in association with perforation. As the patients are not allowed to discharge before oral intake, it is expected to encounter an increase in the duration of hospitalization in the perforation group. Likewise, Salvador and his coworkers reported that mucosal injury was associated with a significant prolongation of the hospital stay (median = 10 vs 5 days in the other group – p = 0.001) .[12]

Despite the fact that our study handles a rare perspective, it has some limitations. The small sample size collected from a single centre and lack of long-term follow up are its main drawbacks. These limitations should be well handled in the upcoming studies.

CONCLUSION

Old age, previous balloon dilatation, and low surgical expertise are the main risk factors for mucosal injury during Heller cardiomyotomy. These factors should be considered when performing this operation, especially the history of previous dilatation. Patients with the previous risk factors should be cautiously performed by highly experienced surgeons.

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