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Laparoscopic Versus Open Suturing and Omental Patch Repair of Perforated Peptic Ulcer: A Randomized Controlled Clinical Trial

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ABSTRACT

Background: The conventional open omental patch repair is the gold standard treatment for peptic ulcer perforation (PUP). Laparoscopic management has been advocated for the treatment of perforated peptic ulcers since 1990, but many concerns still exist about the technique's viability and safety.

Objective: The aim of the current study is to compare the results and outcome of open versus laparoscopic repair technique for perforated peptic ulcers.

Patients and methods: A total of 73 cases with a preoperative clinically diagnosed with peptic ulcer perforation were distributed randomly into two groups to perform either open or laparoscopic repair with an omental patch comparing their operative and postoperative results.

Results: In comparison to open surgery, laparoscopic PUP repair led to quicker oral eating and bowel movements, less postoperative discomfort, less superficial wound infections, fewer pulmonary and overall problems, secondary intervention, and a shorter hospital stay. Its sole drawback was a longer operating time.

Conclusions: Laparoscopic technique is a safe and feasible treatment modality for PUP with superior outcome when compared to open surgery.

Keywords: Laparoscopy, Peptic ulcer perforation, Omental repair.

INTRODUCTION

A major complication of peptic ulcer disease (PUD), peptic ulcer perforation (PUP), necessitates rapid surgical care [(1)].

Although the prevalence of PUD has decreased, the proportional percentage of ulcer perforations has remained largely same [(2)].

About 2-10% of PUD patients with a high mortality risk, particularly the elderly, experience perforation [(3,4)].

The most frequent and appropriate emergency technique is simple closure with or without an omental patch [(4,5)]. Laparoscopic surgery for peptic ulcer perforation has been promoted at various institutions during the past 20 years, with positive outcomes [(1,4,6)]. In 1990, the first perforated peptic ulcer sutured laparoscopic repair was carried out [(7)].

A simple, effective, and preferred technique is to simply repair the perforation with an omental patch [(8-10)]. Less discomfort, a shorter hospital stay, better cosmetic results, faster wound healing, and a decreased incidence of delayed wound complications, such as incisional hernias and scar-related issues make laparoscopic surgery of perforated duodenal ulcers superior to open repair [(6,11)].

Though laparoscopic repair has been used for a long time many questions still need answers for the best practice. The aim of the current study is to compare the results and outcome of open versus laparoscopic repair technique for PUP in emergency settings.

PATIENTS AND METHODS

From June 2018 till January 2022, 73 patients clinically diagnosed with PUP were prospectively randomized into two groups to perform either open or laparoscopic repair with an omental patch in Ain Shams University Hospitals.

Patients included in the study were 18 years old or older. Exclusion criteria included patients who had previous history of upper gastrointestinal surgery (anticipated to have intraabdominal adhesions better avoided in initial experience implementation) and associated bleeding ulcer (additional steps are needed to control bleeding). Cases with poor surgical risk were also excluded in the study (ASA IV). Patients with systolic blood pressure less than 90 mmHg were considered in a state of shock and were excluded. During operation, patients diagnosed with pathology other than a PUP were excluded from the study. The delayed presentation was considered in patients with acute abdomen lasting >24 hours before presentation. Those patients were, also, excluded; they would mostly have intraperitoneal adhesions, so better excluded in initial experience.

Randomization was undertaken by a consecutive number of closed envelopes each containing one of the two treatment techniques. No definitive ulcer surgery was done for any patient in the study (i.e., only ulcer was dealt with and no case of gastrectomy or drainage procedure). Conversion from laparoscopic to open technique occurs in case of technical difficulty, non-juxtapyloric gastric ulcers (possibility of malignancy), or size of perforations greater than 1 cm; ulcers are usually less than 1 cm unless secondary to other pathology [(12)].

Surgical Procedures: Intravenous fluids, nasogastric tube decompression, intravenous analgesics, and intravenous empirical broad-spectrum antibiotics were received by all patients prior to surgery. The open repair

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technique was performed according to the conventional technique of simple closure and omental patch repair. An upper midline exploratory laparotomy incision was used. Following peritoneal cavity probing, the site of perforation was identified. Three 2/0 polyglactin sutures were passed along the ulcer edges and tied laying the knots on one side of the ulcer. A piece of healthy omentum was withdrawn upwards to cover the perforation then the 3 sutures were tied, fixing the position of the omentum to cover the perforation site. Thorough peritoneal lavage was performed and a suction drain was left within the operative bed and brought out of the abdomen and the incision was closed in layers.

The same surgical team that treated patients in the open group also treated patients in the laparoscopic group. The patient was placed in a Lloyd-Davis posture with a reverse Trendelenburg tilt after receiving general anesthesia and muscular relaxation, and a nasogastric tube was inserted. Between the patient's legs was the primary surgeon. On the patient's right side was the first assistance surgeon (the cameraman), and on the left was the second assistant surgeon. Using the open "Hasson Technique," a camera port (10 mm) was inserted initially. The right-hand operating port (10 mm) was placed medial to the left midclavicular line, just above the umbilicus, and the left-hand operating port (5 mm) was placed in the right midclavicular line, above the umbilicus, after the development of the pneumoperitoneum. For liver retraction, (5 mm) port was added to the epigastrium. The peritoneal cavity was examined, and then the pyloro-duodenal region was thoroughly examined for perforation. Compression of the stomach's antrum and the first portion of the duodenum, which caused fluid and bubbling to flow from the perforated site, made it easier to identify the perforation. Peritoneal soiling and fluid were sampled for bacteriological analysis.

The perforation size was roughly estimated in relation to the distance between the two jaws of an operating grasper (**Figure 1)**.

The perforation was closed with three interrupted suture of 2-0 polyglactin (**Figure 2**).

On both sides of the hole, the two ends of the sutures were left uncut. The grasper at the epigastric port was used to lift a healthy portion of omentum upward and position it over the hole.

The sutures were tied not too tight (to avoid patch ischemia) nor too loose (to avoid patch slippage) arching over the omental flap (**Figure 3**), ensuring sealing of the perforation by the tied sutures and at the same time using the omental (serosal) patch to cover the ulcer and enhance tissue regeneration. Thorough peritoneal lavage was then performed, confirming the absence of any hidden collections in spaces in the peritoneal cavity. A suction tube drain was placed in the sub-hepatic space and a second drain was left in the pelvis in case of generalized peritonitis. In both groups, the patch was reinspected one more time before closure to assure neither change of color (indicating ischemia or engorgement) nor displacement of the patch. Postoperatively, Proton pump inhibitors, parenteral analgesics, intravenous fluids, and broad-spectrum antibiotics were administered according to our institutional drug protocol.

A nasogastric tube feeding with oral Gastrografin was done 48 hours following surgical intervention for all patients to insure closure of the perforation. Feeding was resumed as soon as bowel movement was detected (by abdominal auscultation or having the patient passing flatus).

Patients were discharged when they resume normal feeding, were fully ambulated and needed only oral analgesia. All patients were given the go-ahead to resume their regular activities, and they were asked to record the time of resuming the full daily activities and return to work. Patients were followed up at the outpatient clinic at one month, three months, and six months following surgery. An upper gastrointestinal endoscopy was performed 2 months following surgery to estimate the ulcer healing, and treat the patients accordingly.

Figure (1): A 42-year-old with 2 mm perforation in the pre-pyloric region presented to our ER after 3 hours from onset of pain.

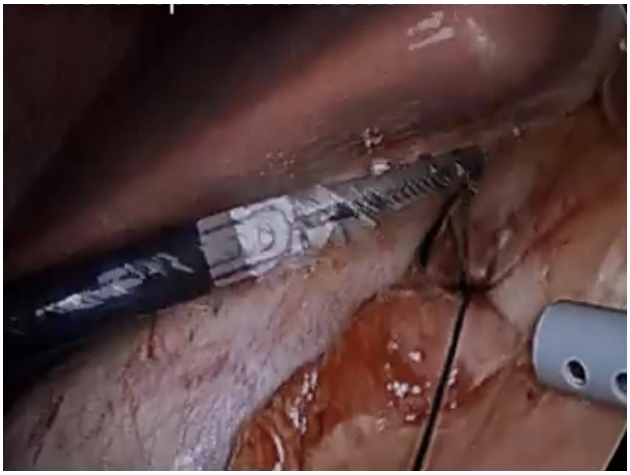

Figure (2): Perforation closed with intracorporeal knot both ends are anchored on both sides of the perforation.

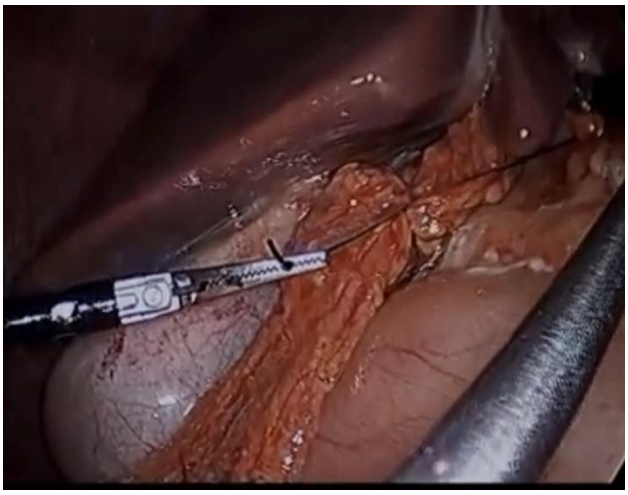

Figure (3): A healthy piece of omental patch pulled upwards overlying the perforation and fixed with the same stitch arching above the perforation

Ethical consent:

This study was ethically approved by the Institutional Review Board of the Faculty of Medicine, Ain Shams University. Written informed consent was obtained from all participants. This study was executed according to the code of ethics of the World Medical Association (Declaration of Helsinki) for studies on humans.

Statistical Analysis:

Data were entered into Excel 2013 and transferred to Statistical Package for Social Sciences (SPSS) version 22.0 for analysis. Qualitative data were defined as numbers and percentages. Chi-Square test and Fisher's exact test were used for comparison between categorical variables as appropriate. Quantitative data were tested for normality by Kolmogorov-Smirnov test. Normal distribution of variables was described as mean and standard deviation (SD) or median with interquartile range. Independent sample t-test/Mann-Whitney test was used for comparison between groups. P value ≤ 0.05 was considered to be statistically significant.

RESULTS

A total of 73 patients with a preoperative clinical diagnosis of PUP were prospectively recruited, and 11 patients were excluded (4 patients with associated bleeding ulcer, 3 patients with large peptic ulcer more than 1 cm, 2 patients with perforated appendix, 1 with ileal perforation and 1 with perforated gastric cancer). Only 62 patients were randomized into 2 groups and subjected to the final analysis.

The *Laparoscopy Group* included 32 patients and the *Open Surgery Group* included 30 patients. **Table 1** summarizes the demographic data and disease criteria in the 2 studied groups. No statistical significance was observed regarding age, gender, and ASA classification. PUP locations and diameters of perforations were well matched in the two groups.

Table (1): Patients demographic preoperative data and disease characteristics.

Variable	Laparoscopic Group n= 32	Open Group n= 30	P value
Age (years) Mean (SD)	43.7 (18.4)	48.1 (17.8)	0.55
Sex (n) (%)			
Male	26 (81.25)	23 (76.6)	0.37
Female	6 (18.75)	7 (23.3)	
ASA classification (n) (%)			
I	17 (53.1)	15 (50)	0.76
II	11 (34.37)	10 (33.3)	
III	4 (12.5)	5 (16.63)	
Ulcer history (n) (%)	6 (18.75)	7 (25.3)	0.36
Smoking (n) (%)	24 (75)	21 (70)	0.73
Alcohol (n) (%)	8 (25)	8 (26.6)	0.69
NSAIDs (n) (%)	7(21.8)	6(20)	0.84
Site of perforation (n) (%)			
Duodenum	22(68.7)	24(75.2)	0.14
Pylorus	2(6.24)	2(6.6)	
Prepyloric	8(25)	4(13.3)	
Diameter of perforation (mm) Mean (SD)	6.3(2.2)	5.2(3)	0.5

Three patients (1 in the laparoscopy group, 2 in the open surgery group) had omentum adherent to the site of perforation; the omentum was carefully mobilized to unleash the perforations, and the repair was done as described formerly. Conversion to open technique was done in 5 cases: 3 patients in whom perforation could not be identified, and two had difficult dissection around the ulcer region. The laparoscopic procedure was completed in 27 (84.3%) patients.

Various outcomes comparing the two groups are listed in **Tables 2.** There was a lower visual analog pain score in the laparoscopic group on postoperative first and third postoperative days. No significant difference was observed between the two groups concerning the time of removal of the Ryle tube or the time to resume a normal diet.

Table (2): Operative and postoperative findings and results of the 2 studied groups.

Variable	Laparoscopic Group n=32	Open Group n=30	P value
Mean operative duration (range) minutes	95 (80-110)	75 (60-90)	0.025
Median (range) number of IM analgesic injections	1 (1-10)	7 (1-23)	<0.001
Mean (SD) pain score			
• Day 1	3.5 (1.4)	6.4 (1.5)	<0.001
• Day 3	1.6 (1.1)	3.3 (1.1)	<0.001
Median (range) of NG tube duration (days)	4 (2-33)	6 (2-10)	0.28
Median (range) of IV fluids duration (days)	6 (2-35)	8 (2-26)	0.09
Median (range) to resume normal diet (days)	6 (3-30)	8 (3-25)	0.06
Median (range) of hospital stay (days)	8 (4-30)	10 (4-37)	0.003
Median (range) of return to daily activity (days)	11 (6.9)	28 (17.2)	0.001

Table 3 summarizes the complications and mortalities of the 2 studied groups. Although there were 4 wound infections in the open group, only 1 of them required reoperation for wound dehiscence, however, no statistical significance was observed. One of the patients from the *Laparoscopic Group* developed a wound infection and was managed conservatively.

Leakage was observed in one patient in the *Laparoscopic Group* and re-explored for open drainage with re-suturing and patching the ulcer. One patient in the *Open Surgery Group* had a localized leakage in the sub-hepatic region that was managed conservatively through ultrasound-guided percutaneous drainage.

Discharge from the hospital was significantly earlier in the *Laparoscopic Group* than the patients in the *Open Surgery Group*. In addition, patient of in the *Laparoscopy Group* returned to daily activity earlier than those in the *Open Surgery Group* (11 versus 28 days, P- value of 0.001).

Two cases in the *Laparoscopy Group* developed latter wound problems. Umbilical sepsis developed in 1 patient, and the other complained of persistent pain in the umbilicus. Both of them responded well to conservative management with oral medication and wound care. Four patients in the *Open Surgery Group* had delayed wound complications: one patient complained of a hypertrophic scar and the other three reported persistent pain in the abdominal wounds.

None of the patients in the *Laparoscopic Group*, but only 1 patient in the *Open Surgery Group* died in the postoperative period. He was 75 years old, diabetic, and classified as ASA III. He suffered from aspiration pneumonia and passed away of adult respiratory distress syndrome (ARDS).

Table (3): Complications and mortality of the 2 studied groups.

Variable	Laparoscopic Group n= 32	Open Group n= 30	P value
Wound infection	1	4	0.076
Chest infection	0	4	0.005
Leakage	1	1	-
Intraabdominal collection	1	0	0.39
Prolonged ileus	0	1	0.61
Reoperation	2	1	0.14
Wound and port site complications	2	4	0.1
Mortality	0	1	0.25

DISCUSSION

PUP has a 1.5-3% incidence range, a 5% lifetime frequency, and a 1.31–20% death rate [(13)]. It is a dangerous problem that needs to be treated right away with surgery to seal the hole. For the past three decades, open repair has been the norm. The laparoscopic method is now more frequently used to address sudden abdominal problems. In several clinics, laparoscopic repair is frequently performed to treat PUP [(14-15)]. In the literatures, PUP were treated laparoscopically using simple closure, regular Graham's omentopexy, modified Graham's omentopexy, and fibrin glue closure procedures[(14,16-20)].

In our study, the patient's demographic data of the study (Laparoscopic) and the control (Open) groups were similar, with male predominance in both groups i.e., 81.2% males in the laparoscopic group (LG) and 76.6% in the open group (OG). Our results go with many studies as patients operated upon for PUP were mostly males [(18, 21, 22-24)]. In our study, preoperative risk indicators such ASA scores did not vary, patients' comorbidities, and surgical observations such as location and diameter of perforation, between both study groups. In our present study, we advocated the standard three sutures technique in closure of the perforation. A longer mean operating time was observed in the LG (95 vs. 75 mins). The technique and findings were consistent with many studies [(5, 19, 24-26)].

Siu *et al.* [27] in their prospective controlled clinical trial, reported a significantly shorter mean operation time in the *Laparoscopic Group*. One of the few studies that contradicted in the literature was this one. **Siu *et al.*** [27] advocated using only one stitch (instead of the standard three sutures) for the closure of small perforations less than 1 cm in diameter and using the same stitch to fix the omentum to the perforation is an appealing option in such small perforation. This is actually feasible as there is no need to reorient the direction of closure of those small defects. The actual role of the serosal patch is assumed to be a stimulating factor for cellular proliferation rather than the actual closure of those small defects.

We believe that the extended conventional suturing approach and laparoscopic peritoneal lavage, which necessitates switching up patient postures in order to aspirate all abdominal quadrants, may be to blame for the greater operating time in the *Laparoscopic Group*. In addition, setting up the laparoscopic equipment and the technical difficulty may play a role when reporting initial experience in our center i.e., at the beginning of the learning curve.

Fewer analgesics and less postoperative pain may be one of the main advantages of laparoscopic surgery significantly evident in our study (during both 1st and 3rd postoperative day). This goes with the observations of many authors [21,23-34,28]. **Siow *et al.*** [21] revealed VAS ratings in the *Laparoscopic Group* were considerably lower in their investigation. Additionally, the *Laparoscopic Group* in the LAMA research exhibited lower VAS ratings on days 1, 3, and 7. However, there was no distinction in the VAS values examined on days 28 and 29. The postoperative second-day VAS score in the *Laparoscopic Group* was lower in a research by **Kumar *et al.*** within the first 12 hours of a different clinical trial visual analogue scores were comparable across the 2 groups. However, from the 24th hour onward, the *Laparoscopic Group*'s scores were considerably lower [28].

It is worth to state that **Lau *et al.*** [29], found no difference in pain score between Open and *Laparoscopic Group* within the first 24 hours. i.e., our study and the literature both showed that the *Laparoscopic Group* had considerably lower VAS scores. In the *Laparoscopic Group*, our patients started oral feeding a lot sooner. Our findings [4,17,24] are consistent with earlier oral feeding being observed in the *Laparoscopic Group* in other studies. The most likely reasons for an early restoration of gastrointestinal mobility following laparoscopic surgery include less gastrointestinal intervention, less postoperative discomfort, and early mobilization [17].

It was believed that passing gas was a sign of postoperative bowel motions, which had already started in the *Laparoscopic Group*. To our knowledge, no research has compared the length of time needed for bowel motions to resume following upper gastrointestinal procedures. Numerous studies indicated that the length of hospital stays in the *Laparoscopic Group* was shorter [4,5,19,21,24,26], whereas others found no appreciable changes [23, 30-31]. In the *Laparoscopic Group*, hospital stays lasted for noticeably less time. This may be accounted for by earlier oral eating, a return to regular bowel motions, and less postoperative discomfort.

In the study, there was decreased evidence of superficial wound infection in the *Laparoscopic Group* [19,24,31]. Similar to this, we found that the *Laparoscopic Group* had considerably reduced superficial wound infection (1 vs. 4 patients).

As in our meta-analysis, **Gabriel *et al.*** [32] meta-analysis found that the *Laparoscopic Group* had less pulmonary problems (0 vs. 4 patients, P=0.005). This observation could be explained by postoperative discomfort in the *Open Surgery Group*, which makes patients have breathing problems and limits chest motion, leading to postoperative atelectasis.

There is no statistically significant difference between the two groups for intra-abdominal abscess, prolonged ileus, postoperative leakage, or fascial separation. The *Laparoscopic Group* saw much less difficulties overall though. Numerous other studies that contradicted our findings found no difference between the two groups in terms of postoperative leakage, delayed ileus, and intra-abdominal abscesses [19,25,26,31,33].

Reoperation rates in the earlier trials were comparable between the *Laparoscopic Group* and *Open Surgery Group* [17,19,25,32]. In the current study, both groups had similar rates of reoperation and the number of patients who had interventional drainage.

In the current study, we observed no significant difference in deaths in both groups (0 vs. 1 patient). This is similar finding by **Zhou *et al.*** [17], who reported no mortality difference in both groups in randomized controlled trials. Additionally, **Tan *et al.*** [31] noted that both groups' death rates were comparable. **Varcus *et al.*** [34] reported that mortality was greater in *Open Surgery Group*. However, *Open Surgery Group* also included individuals in his research who had high ASA scores and prior septic shock. The elevated death rates in the open group may have been brought on by this. In our investigation, both groups' death rates were the same. This could be as a result of the exclusion of individuals in septic shock and the similarity in ASA ratings between the two groups.

CONCLUSIONS

The laparoscopic technique is a safe and feasible treatment of PUP and superior to open surgery. In comparison to open surgery, laparoscopic PUP repair leads to sooner oral and bowel movements, less postoperative discomfort, less superficial wound infections, fewer pulmonary and overall problems, secondary intervention, and a shorter hospital stay. Its sole drawback was a longer operating time.

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