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A Randomized Study Comparing Laparoscopic *Versus* Open Repair of Perforated Peptic Ulcer Using Suture or Sutureless Technique

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Objective
This study compares laparoscopic *versus* open repair and suture *versus* sutureless repair of perforated duodenal and juxtapyloric ulcers.

Background Data
The place of laparoscopic repair of perforated peptic ulcer followed by peritoneal toilet of the peritoneal cavity has been established. Whether repair of the perforated peptic ulcer by the laparoscopic approach is better than conventional open repair and whether sutured repair is better than sutureless repair are both undetermined.

Methods
One hundred three patients were randomly allocated to laparoscopic suture repair, laparoscopic sutureless repair, open suture repair, and open sutureless repair.

Results
Laparoscopic repair of perforated peptic ulcer (groups 1 and 2) took significantly longer than open repair (groups 3 and 4; 94.3 ± 40.3 *vs.* 53.7 ± 42.6 minutes; Student's t test, $p < 0.001$), but the amount of analgesic required after laparoscopic repair was significantly less than in open surgery (median 1 dose *vs.* 3 doses) (Mann-Whitney *U* test, $p = 0.03$). There was no significant difference in the four groups of patients in terms of duration of nasogastric aspiration, duration of intravenous drip, total hospital stay, time to resume normal diet, visual analogue scale score for pain in the first 24 hours after surgery, morbidity, reoperation, and mortality rates.

Conclusions
Laparoscopic repair of perforated peptic ulcer is a viable option. Sutureless repair is as safe as suture repair and it takes less time to perform.

Perforated peptic ulcer can be treated by a wide range of options that varies from conservative nonoperative treatment to immediate definitive ulcer surgery.

Some patients with perforated ulcer can be managed successfully by nonoperative means.[1] The chief objections to this treatment are uncertainty or error in diagnosis, the unknown site and pathology of the perforation,[2] and the unlikely response in elderly patients in whom this treatment is more attractive.[1] However, routine definitive ulcer surgery in the form of highly selective vagotomy has been suggested in patients with perforated duodenal ulcer because this operation is unlikely to cause long-term side effects and because the prediction of the clinical course after simple repair of the ulcer is unreliable.[3-5] However, even the strongest advocate for immediate definitive ulcer surgery for perforated peptic ulcer agrees that simple repair is indicated for patients who are poor surgical risks because of major concurrent medical illness or shock, for patients who have heavy bacterial contamination of the peritoneal cavity because of delay in surgery, and when a surgeon experienced in ulcer surgery is not available.[2,6,7] Fewer surgeons currently have acquired enough expertise in performing highly selective vagotomy with advances in medical therapy. Simple closure remains an attractive option for perforation in most centers.[2,6]

Reports of laparoscopic treatment have shown that peritoneal toilet can be performed effectively and perforations can be closed safely.[8-14] Whether repair of the perforation by the laparoscopic approach is better than by conventional open repair is undetermined. Laparoscopic repair of perforated peptic ulcer can be done by the suture[8,9,12,13] or the sutureless technique.[10,11,12,14] This prospective randomized study undertook to compare 1) laparoscopic *versus* open repair and 2) suture *versus* sutureless repair of perforated peptic ulcer.

METHODS

From August 1992 to December 1994, all patients admitted to the surgical ward of our hospital with a clinical diagnosis of perforated peptic ulcer were considered part of the study. The absence of free gas under the diaphragm on plain radiography did not exclude patients from this study. The following criteria were used for prerandomization exclusion: 1) complicated ulcers that required definitive ulcer surgery; 2) associated bleeding ulcers; 3) unsuitability for laparoscopic procedures like previous operations; 4) serious associated cardiopulmonary diseases that precluded a long operation; 5) no consent from patient for randomization; and 6) clinical sealed-off perforated ulcers.

Computer-generated blocked random numbers were used to assign the type of surgery, which was written on a card sealed in a completely opaque envelope. Envelopes were drawn randomly by the senior duty nurse in the operating department when an operating room was booked after the clinical decision to operate had been made.

Surgery was done under general anesthesia with muscle relaxation. All patients received 750 mg cefuroxime and 500 mg metronidazole at the time of induction of anesthesia. Premedication was prescribed at the discretion of the duty anesthetist. Surgery was carried out as soon as possible after the clinical decision to operate. Surgery at night was not a contraindication to randomization and inclusion in the study.

All surgery was done by members of the surgical team on duty the day the patient was admitted. Those who performed laparoscopic suture or sutureless repair of perforated peptic ulcer had previous experience in this operation, laparoscopic cholecystectomy, and laparoscopic appendicectomy, and all had attended a training course including surgery in animals and simulators. Surgeons with limited experience of the operation were assisted by a more experienced colleague. Open surgery was done by surgeons with previous experience of the operation or with supervision by a more senior colleague if such experience was limited. Thus, for both laparoscopic and open surgery, normal training practices continued during the study.

Operating Techniques

Group 1: Laparoscopic Suture (Fig. 1)

The technique already has been reported.[13] Suturing was done with a needle holder. The needle was passed through the duodenum near the perforation and through a mobilized patch of omentum. An extracorporeal Roeder knot[15] was tied in the suture and passed down to fix the patch over the perforation. Additional sutures were passed, as required, to surround the perforation. This was followed by peritoneal lavage with normal saline.

Group 2: Laparoscopic Sutureless Repair (Fig. 2)

The technique of laparoscopic repair with gelatin sponge and fibrin glue has been reported.[14] A piece of gelatin sponge (Spongostan; Ferrosan, Soeborg, Denmark) 20 × 15 × 10 mm thick sheet was rolled into a

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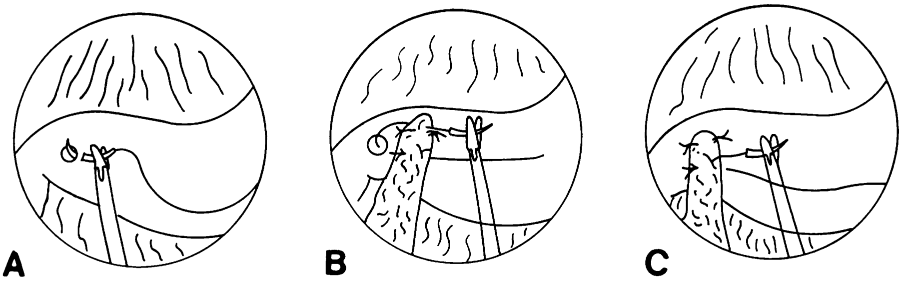

Figure 1. Laparoscopic suture repair. (A) Stitch passing through perforation. (B) Stitch then passes through a mobilized piece of adjacent omentum. (C) Omentum fixed in position by tying knot. Further stitches are applied around the perforation.

cone. This plug was grasped with a forceps and back-loaded into a 10-mm reducing sheath for insertion into the abdominal cavity. The plug was placed into the perforation so that the base of the cone protruded onto the serosal surface. A prewarmed 2-mL volume of two-component fibrin sealant (Tisseel; Immuno, Vienna, Austria) was injected slowly via a double lumen catheter around the plug to secure it. Peritoneal lavage was performed before completion of the operation.

Group 3: Open Suture Repair

The technique is well described in standard textbooks.[2,6,7] Through an upper midline incision, a wad of omentum was drawn under an arch of full-thickness absorbable sutures placed on either side of the perforation, and then the sutures were tied. Peritoneal toilet followed.

Group 4: Open Sutureless Repair

Through an upper midline incision, the repair was done with gelatin sponge and fibrin glue as in group 2. This was followed by peritoneal toilet.

Operating time was the time from induction of anesthesia to the administration of a reversal agent. Anesthesia was induced in the operating room with the patient on the operating table, in keeping with our normal practice. Each surgeon was free to convert a laparoscopic procedure to an open one or to proceed to a definitive ulcer surgery, if necessary.

Postoperative Management

Postoperative management consisted of H_2 receptor antagonists, nasogastric aspiration, and intravenous fluid. Standard analgesic was prescribed to all patients (1 mg/kg pethidine intramuscularly every 4 hours on demand). Antibiotics were continued every 8 hours the first day and then stopped.[16] All patients received a water-soluble contrast meal within 48 hours of the repair of the perforation. Every patient was visited at the same time each day by one of two assessors to record progress. The number of doses of pethidine given during the previous 24 hours was recorded. A visual analogue scale ([VAS]; 10-cm horizontal line without graduations) was completed by the patient to indicate the general level of pain during the first 24 hours of the operation. Reintroduction of diet was defined as the ability to tolerate an oral intake of at least 100 mL/hour (fluid diet) or normal hospital meals (solid diet). The length of hospital stay was the number of days after surgery (day 0) spent in the general surgical ward. Any patients transferred to a convalescent hospital for social reasons rather than going directly home was considered discharged.

Patients in the four groups were given similar verbal instructions to return to normal activity and to work as soon as they felt fit enough to do so. All patients were assessed by the treating team approximately 4 weeks postoperatively in the outpatient clinic. A standard questionnaire was completed by the doctor during the consultation to assess return to normal activity, return to work, and complications. Return to normal activity is defined as return to normal daily activity without assistance. Occupation was classified into four categories: sedentary, light manual (which included household work), heavy manual, and retirement. For patients who

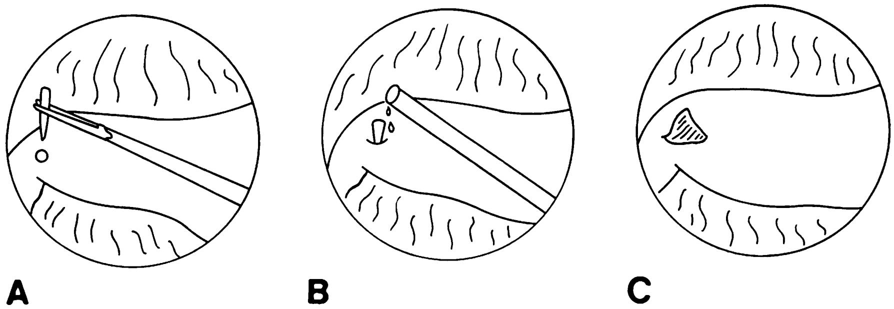

Figure 2. Laparoscopic sutureless repair. (A) A piece of gelatin sponge rolled into a cone is about to be inserted into perforation. (B) Through a twin channel catheter, prewarmed fibrin glue is injected onto the gelatin sponge plug, which has been inserted into the perforation. (C) Fibrin sets and forms on the gelatin sponge plug to seal off the perforation.

Table 1. DEMOGRAPHIC DATA OF PATIENTS

	Group 1 Laparoscopic Suture	Group 2 Laparoscopic Sutureless	Group 3 Open Suture	Group 4 Open Sutureless
No. of patients randomized	26	26	25	26
Postrandomization exclusion	2	2	4	2
No. of evaluable patients	24	24	21	24
Sex (M/F)	20/4	22/2	17/4	20/4
Age (mean ± SD) (yr)	52.3 ± 13.8	47.8 ± 17.5	51.1 ± 19.7	44.9 ± 18.8
Risk factors				
APACHE II range (median)*	0–12 (6)	2–15 (6)	3–17 (5)	3–12 (6)
Shock on admission† (n)	2	1	3	2
Delayed presentation† (n)	2	0	0	1
Underlying medical illness† (n)	3	3	2	1
Site of ulcer				
Duodenum	20	19	16	21
Juxtapyloric	3	4	2	2
Stomach‡	1	1	3	1
Size of perforation of ulcer (mm) range (median)	1–20 (6)	2–15 (5)	2–25 (5)	2–20 (5)

* Acute Physiology and Chronic Health Evaluation (APACHE).
† See reference 4.
‡ All underwent gastrectomy in laparoscopic group conversion and gastrectomy.

had retired, the assessment by the patient of his/her ability to return to work was taken as return to work. The wound was examined for signs of infection. A wound complication was recorded if the patient reported a history of or had signs of redness around any wound or a discharge. A routine gastroscopy was scheduled for all patients 6 to 8 weeks after surgery. Patients who failed to attend the follow-up clinics or the gastroscopy sessions were contacted by a research nurse to return for the gastroscopy.

This study was approved by the Ethical Committee on Human Experimentation of our hospital, and all study subjects gave written informed consent.

Statistical Methods

Sample Size

Our previous nonrandomized study has shown that laparoscopic repair of perforated peptic ulcer required significantly less analgesic than open repair (a median of 2 *vs.* 4 doses, $p = 0.048$ by Mann-Whitney U test).[14] As advised by our statistician that there is no well-established method to estimate sample size for nonparametric data, we decided to analyze the results after the inclusion of a sample size similar to the previous study.

Statistical Analysis

The Mann-Whitney U test was used on the analysis of the main endpoint variables (analgesic doses, days off drip, days off nasogastric tube, days resume diet, and hospital stay). Student's t test was used to compare operating time, size of ulcers, and VAS. A p value of < 0.05 was considered significant.

RESULTS

One hundred three patients were randomly allocated to the four groups of surgical treatment. During the study period, 31 patients who had perforated peptic ulcers were excluded before randomization from this study. The reasons for exclusion were chronic or complicated ulcer requiring definitive ulcer surgery (13), inability to make a correct preoperative diagnosis (10), refusal by patients to give consent for randomization (4), and very poor premorbid state, making a longer laparoscopic surgery hazardous (4). Ten patients were excluded after randomization. The reasons for the postrandomization exclusion were sealed-off perforated peptic ulcer in five patients who did not require further repair, and the following incorrect diagnoses: perforated carcinoma of colon (2), acute pancreatitis (1), intussusception caused by an ileal polyp (1), and ruptured hepatocellular carcinoma (1). The demographic data of the 93 evaluable patients are listed in Table 1, and there is no significant difference between the individual groups of patients.

Six of 24 patients randomized to laparoscopic suture repair had conversion to open surgery because of large ulcer (4) or technical problems of laparoscopic repair (2),

Table 2. RESULTS OF TREATMENT OF FOUR GROUPS OF PATIENTS

	Group 1 Laparoscopic Suture	Group 2 Laparoscopic Sutureless	Group 3 Open Suture	Group 4 Open Sutureless
No. of evaluable patients	24	24	21	24
Conversion to open surgery	7	4	—	—
Operation time (min) (mean ± SD)	112.9 ± 44.1	74.8 ± 24.3	56.9 ± 47.6	50.8 ± 38.6
Nasogastric tube* (days) (range [median])	1–4 (2)	2–10 (3)	1–13 (2)	1–17 (3)
Intravenous drip* (days) (range [median])	2–8 (4)	2–11 (4)	2–17 (4)	2–19 (4)
Days to resume diet* (range [median])	3–7 (4)	2–11 (4)	3–16 (4)	3–19 (4)
Analgesic (doses)* (range [median])	0–12 (1)	0–17 (2)	0–10 (3)	1–9 (4)
Hospital stay (days)* (range [median])	3–20 (5)	3–11 (6)	3–19 (5)	2–21 (5)
VAS† score for pain in first 24 hr* (range [median])	2–8 (4)	1–9 (4)	2–9 (5)	2–9 (5)

* Including all cases of conversion to open surgery, excluding mortality.
† Visual analogue scale from 1 to 10.

whereas 3 patients randomized to laparoscopic sutureless repair had conversion because of large ulcers (2) or hemodynamic instability at the start of the procedure (1). All nine patients had open suture repair after conversion. Laparotomy and emergency definitive ulcer operation was performed in seven patients, all with formal laparotomy. Partial gastrectomy for gastric ulcers was performed in one patient each randomized to laparoscopic suture, laparoscopic sutureless, and open sutureless groups. Three patients in the open suture group had gastrectomy for gastric ulcers. Repair and highly selective vagotomy were performed in one patient with chronic duodenal ulcer randomized to the open sutureless group.

The results of treatment are shown in Table 2. Laparoscopic repair of perforated peptic ulcer (groups 1 and 2) took significantly longer than open repair (groups 3 and 4; 94.3 ± 40.3 *vs.* 53.7 ± 42.6 minutes; Student's t test, $p < 0.001$). Laparoscopic sutureless repair (group 2) took significantly less operation time than laparoscopic suture repair (group 1; 74.8 ± 24.3 *vs.* 112.9 ± 44.1 minutes; $p < 0.001$), but it took significantly longer than open sutureless repair (group 4; 74.8 ± 24.3 *vs.* 50.8 ± 38.6 minutes; Student's t test, $p = 0.015$). There was no significant difference in the operation time between laparoscopic sutureless repair (group 2) and open suture repair (group 3; 74.8 ± 24.3 *vs.* 56.9 ± 47.6 minutes; Student's t test, $p > 0.05$). Patients who had laparoscopic repair (groups 1 and 2) required significantly fewer doses of analgesic than those who had open surgery (groups 3 and 4; median 1 dose *vs.* 3 doses; Mann-Whitney *U* test, $p = 0.03$). The difference also was significant when patients who required conversion to open surgery were excluded for analysis ($p = 0.01$). There was no significant difference between the laparoscopic and the open groups in the durations of nasogastric aspiration, intravenous drips, hospital stay, the time to resume normal diet, and the VAS for pain in the first 24 hours after surgery. At the end of 6 to 8 weeks after surgery, gastroscopy showed that the ulcers had healed for all patients.

The morbidity and mortality of the patients are shown in Table 3. There was no significant difference in morbidity, reoperation rate, and mortality rate between patients who underwent laparoscopic repair (groups 1 and 2) and open repair (groups 3 and 4). Similarly, there was no significant difference between patients who had suture repair (groups 1 and 3) and sutureless repair (groups 2 and 4). Three patients underwent reoperation. In two patients, leakage was demonstrated on water-soluble contrast meal. In the presence of abdominal signs, both underwent reoperation, repair, and highly selective vagotomy. The third patient underwent reoperation because histopathology revealed adenocarcinoma of stomach with involved histologic margin after a partial gastrectomy performed for a perforated gastric ulcer. Three patients died in this study. An 80-year-old woman (group 2) who developed fast atrial fibrillation after operation died of heart failure 1 day after surgery. Postmortem examination revealed intact repair perforation site, pulmonary congestion, and edema. A 51-year-old man with psychiatric illness (group 2) became hemodynami-

Table 3. MORBIDITY AND MORTALITY

	Group 1 Laparoscopic Suture	Group 2 Laparoscopic Sutureless	Group 3 Open Suture	Group 4 Open Sutureless
No. of evaluable patients	24	24	21	24
Radiologic leaks*	0	1	1	0
Wound infection	1	0	0	1
Intraperitoneal collection†	2	0	0	0
Prolonged ileus‡	1	2	2	2
Incisional hernia	0	0	1	0
Pulmonary infection	1	2	0	1
Urinary tract infection	0	0	1	0
Cardiac arrhythmia	0	1	0	1
Morbidity	5	6	5	5
Reoperation	0	1	1	1
Mortality	0	2	1	0

* Patients reoperated.
† Managed with ultrasound-guided aspiration of collection. Culture revealed no growth in both patients.
‡ Defined as postoperative ileus of more than 7 days.

cally unstable 15 minutes into laparoscopic surgery. The deterioration was thought to be related to septicemia as a result of very delayed clinical presentation, but not related to carbon dioxide insufflation required for the laparoscopy. He had conversion to open surgery and died 14 hours after operation. Postmortem examination revealed severe peritonitis, pulmonary congestion, and heart failure. A 72-year-old man (group 3) had shock on admission. He died 17 days later of sepsis and multiorgan failure.

Table 4 shows the results of the first follow-up visit approximately 4 weeks after surgery. Similar proportions of patients with laparoscopic repair (group 1 and 2) and open repair (groups 3 and 4) were available at follow-up (73% *vs.* 69%), respectively. Among these patients, the sex and age distribution did not differ significantly between the laparoscopic and open groups. Similar proportions of patients attending this follow-up had returned to normal activity (80% for laparoscopic *vs.* 77% for open repair) and had returned to work (57% for laparoscopic *vs.* 52% for open repair). The data for patients who did not attend this first follow-up visit but who were called back for a check-up gastroscopy were not included in this analysis because there was a delay of at least 1 month in the recording of these data, which made it less reliable. The subgroups of patients having different categories of occupation were too small for analysis.

Table 4. RESULTS AT FIRST FOLLOW-UP VISIT

	Laparoscopic Repair (Suture or Sutureless)	Open Repair (Suture or Sutureless)
No. (%)	35 (73)	31 (69)
Mean time of follow-up consultation*	28 (26–38)	30 (24–35)
No. (%) of patients		
Returned to normal activity	28 (80)	24 (77)
Returned to work	20 (57)	16 (52)

* Days from operation to follow-up.

DISCUSSION

Improvements in video cameras and instrument technology have been central to the development of laparoscopic surgery. Perforated peptic ulcer is a condition for which laparoscopic approach has attractions. Not only is the site and pathology of perforation identified, the procedure also allows closure of the perforation and adequate peritoneal toilet without a large incision. However, whether such theoretical advantages can be reflected in better patient outcome in clinical practice can be determined only by a randomized study. As far as we know, there is no randomized study that has been reported that compares laparoscopic with open surgery in perforated peptic ulcer, although a wish to conduct such a trial has been expressed by us[12] and by another group.[17]

In a previously reported nonrandomized study of 100 consecutive patients who underwent open suture, laparoscopic suture, or laparoscopic sutureless repair, we have shown that the postoperative analgesic requirement was less with laparoscopic than with open repair, and laparoscopic sutureless repair had the additional advantage over laparoscopic suture repair in being technically easier so that the operation time was significantly shorter.[12] Such a study can be criticized easily because it is difficult to ensure the absence of selection bias in determining the type of procedure performed.

This randomized study was undertaken within our normal hospital practice. We sought to avoid a comparison of one or two experienced and enthusiastic laparoscopic surgeons, with the everyday results of open repair achieved by the on-call surgeons. The study started after we had sufficient experience of the laparoscopic procedures[12] and adequate numbers of trained staff, and does not represent our initial experience in laparoscopic suture or sutureless repair. Even with a randomized study like this one, bias still could happen because the study cannot be conducted as double-blind. If a surgeon believes that laparoscopic surgery is advantageous, his/her attitude to patients and their management still may be influenced. In an attempt to cut down on the bias, postoperative management was decided by several different surgeons, excluding the surgeon who did the individual operation. However, the types of operation each patient had had was known.

This randomized study showed that the requirement for postoperative analgesic dose was significantly less with laparoscopic than with open repair. However, the VAS score for pain in the first 24 hours of operation cannot confirm that there was less postoperative pain with laparoscopic repair. There are three possibilities for these apparently inconsistent results. First, laparoscopic surgery was as painful as open surgery, and the less demand in the postoperative analgesic was due to the influence of the psychological impact of minimally invasive surgery and the medical and nursing staffs' positive attitudes toward the procedure. This explanation is difficult to prove or disprove because it is difficult to perform a double-blind study to eliminate these biases. Second, laparoscopic repair actually was less painful than open repair, but it was difficult for the patients to differentiate between pain due to the peritonitis and postoperative pain within 24 hours of surgery. Third, there was an actual difference in the postoperative VAS pain score between laparoscopic and open repair, but the difference was too small to be detected by the small number of patients studied (type II statistical error). The actual difference in the VAS pain score in this study was so small and the number of patients required to show a possible significant difference is so enormous that we decided that it is impossible to include the required number of patients into the study. No matter what the explanation is, the impact of laparoscopic repair in inducing less postoperative pain when compared with open surgery was small. Although there was a trend toward a lower score on the VAS in the immediate postoperative period, and there were slightly higher proportions of patients who returned to normal activity and to work at the time of the first follow-up visit in the laparoscopic repair group when compared with the open repair group, the difference was marginal.

The findings of absence of significant difference between laparoscopic and open repair of perforated peptic ulcer in terms of duration of nasogastric aspiration, intravenous drip, hospital stay, and time to resume diet are not surprising because we were dealing with patients with peritonitis and the gastrointestinal motility needed almost the same duration of time to recover, irrespective of the ways in which the perforations were repaired. Furthermore, decisions as to how long to keep nasogastric tubes and intravenous drips and when to allow the patients to resume diet are arbitrary and were decided by the managing surgical team without strict criteria.

The main disadvantage of laparoscopic repair of perforated peptic ulcer was the significant longer operation time, which means higher costs—especially when laparoscopic equipment costs also have to be added. This study showed the operation time of laparoscopic repair could be reduced with laparoscopic sutureless repair with gelatin sponge plug and fibrin glue. The study also showed that the sutureless repair is as safe as the suture repair with both techniques having the same operative morbidity and mortality rates. Peptic ulcers with perforations larger than 1 cm cannot be satisfactorily repaired using the laparoscopic route with either the suture or the sutureless method. For technical reasons, it is difficult to seal off the perforations adequately using the laparoscope. Such ulcers need open surgery. We were biased toward a simple repair for perforated ulcer mainly because of the recent findings that eradication of *Helicobacter pylori* can heal and can prevent recurrence of duodenal ulcer,[18,19] and perforated duodenal ulcers are associated with a high incidence of *H. pylori* infection.[20]

Thus, laparoscopic repair of perforated peptic ulcer is a viable option in the treatment of perforated duodenal and juxtapyloric ulcer. Although it has the advantages of the minimally invasive surgery and our data suggest that it causes less postoperative pain, its overall advantages over open repair are minor. Furthermore, it has the main disadvantage of long operation time. Improvements in technology and increase in laparoscopic experience may eventually change the findings of this study in future. Based on our experience, laparoscopic sutureless repair has the advantage over laparoscopic suture repair because it is technically much less demanding. The technique can be learned easily by those who have some experience with laparoscopic surgery.

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