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LAPAROSCOPIC VERSUS OPEN APPENDECTOMY: A PROSPECTIVE RANDOMIZED TRIAL OF **81** PATIENTS

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OBJECTIVE: To compare the efficacy of laparoscopic appendectomy (LA) and open appendectomy (OA) in the treatment of acute appendicitis.

DESIGN: A prospective randomized trial.

SETTING: A university teaching hospital.

PATIENTS: Eighty-one patients with a diagnosis of acute appendicitis were prospectively randomized to undergo either LA or OA. The two groups were matched for age and sex.

INTERVENTIONS: LA or OA.

MAIN OUTCOME MEASURES: Number of days in hospital and time to full recovery.

RESULTS: The mean hospital stay for LA was 3.23 days compared with 3.03 days for OA (p < 0.001). The mean number of narcotic injections required for patients in the LA group was 4.05 compared with 5.58 for patients in the OA group (p < 0.001). The mean time to complete recovery for patients in the LA group was 9.0 days compared with 16.2 days for patients in the OA group (p < 0.001). The mean operative time for LA was 73.8 minutes compared with 45.0 minutes for OA (p < 0.001). Three patients in the LA group had intra-abdominal abscesses (p > 0.25). No significant difference in wound infection rates was demonstrated (p > 0.05). Similarly, pain scores at 7 and 28 days showed no significant difference (p > 0.05).

CONCLUSIONS: With LA significantly fewer narcotic injections are required and there is a more rapid return to normal activities. LA takes longer to perform and was associated with three intra-abdominal abscesses. In cases of simple acute appendicitis the hospital stay for LA is significantly shorter.

OBJECTIF : Comparer l'efficacité de l'appendicectomie par laparoscopie (AL) à celle de l'appendicectomie sanglante (AS) comme traitement de l'appendicite aiguë.

CONCEPTION : Étude randomisée prospective.

CONTEXTE : Hôpital d'enseignement universitaire.

PATIENTS : Quatre-vingt-un patients chez qui l'on a diagnostiqué une appendicite aiguë ont été répartis au hasard de façon prospective et ont subi une AL ou une AS. Les deux groupes ont été jumelés en fonction de l'âge et du sexe.

INTERVENTION : AL ou AS.

PRINCIPALES MESURES DES RÉSULTATS : Nombre de jours d'hospitalisation et temps nécessaire au rétablissement complet.

RÉSULTATS : La durée moyenne de l'hospitalisation s'est établie à 3,23 jours dans le cas de l'AL, comparativement à 3,03 jours dans celui de l'AS (p < 0,001). Les sujets du groupe AL ont eu besoin en moyenne de 4,05 injections de narcotiques comparativement à 5,58 dans le cas des sujets qui ont subi une AS (p < 0,001). Les patients qui ont subi une AL ont eu besoin en moyenne de 9,0 jours pour se rétablir complètement, comparativement à 16,2 jours chez les patients qui ont subi une AS (p < 0,001). L'AL a

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duré en moyenne 73,8 minutes, comparativement à 45,0 minutes dans le cas de l'AS (p < 0,001). Trois patients du groupe AL avaient des abcès intra-abdominaux (p > 0,25). On n'a démontré aucune différence significative quant au taux d'infection de la plaie (p > 0,05). De même, la cotation des douleurs à 7 et 28 jours n'a présenté aucune différence significative (p > 0,05).

CONCLUSIONS : L'AL réduit considérablement le nombre des injections de narcotiques et la reprise des activités normales est beaucoup plus rapide. L'AL est plus longue à exécuter et l'on a établi un lien avec trois abcès intra-abdominaux. Dans les cas d'appendicite aiguë simple, la durée de l'hospitalisation est beaucoup plus courte à la suite d'une AL.

inimally invasive surgical procedures have expanded to include laparoscopic appendectomy (LA), which has emerged as an alternative to standard open appendectomy (OA). Only a few studies1-7 have compared these two techniques in a prospective randomized fashion. Some authors^{1,2} advocate LA as the procedure of choice for acute appendicitis. The proposed advantages of LA are a shortened hospital stay,^{1,3,8-10} less postoperative pain,^{1,8,10} decreased requirement for narcotic drugs,^{2,3} an earlier return to normal activity1,2,4,10 and fewer wound infections.^{3,4,8,9,11} Others feel that the procedure may be contraindicated if the appendix is perforated, with an abscess or peritonitis.12 Whether LA will lead to a shorter hospital stay is uncertain because recovery from OA is relatively brief.² This question becomes particularly relevant in terms of medical economics. Our hypothesis was that LA would decrease hospital stay and shorten recovery time. The purpose of this study was to compare LA with OA in a prospective randomized fashion.

Methods

From May 1993 to December 1994, patients with a clinical diagnosis of acute appendicitis were randomized to either LA or OA. The study protocol was approved by the hospital ethics committee. Four surgeons trained in the techniques of LA and general surgery residents in their final 2 years of training were participants. Exclusion criteria were generalized peritonitis, multiple previous abdominal operations or pregnancy longer than 24 weeks' gestation. Informed consent was obtained from all patients. Preoperatively, all patients received intravenous antibiotic prophylaxis (ceftizoxime 1 g). Patients were randomized in the operating room by opening computer-generated randomized sealed envelopes. Intraoperatively, appendectomy was performed even if the appendix appeared grossly normal or another diagnosis was made.

OA was performed through a standard right lower-quadrant muscle-splitting incision. Ligatures were applied to the base of the appendix. The appendiceal stump was not invaginated. The abdomen was lavaged with saline, and 0.5% Marcaine with epinephrine (Sterling–Winthrop, Markham, Ont.) was infiltrated into the incision. In contaminated cases delayed primary wound closure was used in both groups.

LA was performed after preoperative bladder catheterization. The patient was placed in the supine position. Four operating ports were used. A 10-mm infraumbilical port was inserted, using the Hasson technique.¹³ Under direct vision, a 10-mm port was inserted in the left lower quadrant, and 5-mm operating ports were inserted in the right upper quadrant and midline suprapubically. Two endoloops (0 Vicryl, Ethicon Corp., Markham, Ont.) were applied to the base of the appendix. The resected appendix was placed in a lapsack (Cook Corp., Stouville, Ont.) before removal from the abdominal cavity. The appendiceal stump was not invaginated. The abdomen was lavaged with saline, and skin incisions were infiltrated with 0.5% Marcaine with epinephrine.

Postoperatively, patients in both groups were initially given fluids orally, beginning on the day of surgery, progressing to a normal diet as tolerated. Early mobilization was encouraged. If they were afebrile, patients were discharged once they were ambulatory and tolerating fluids. Patients were reviewed in the clinic at 7 and 28 days after discharge. Primary end points analysed were days in hospital, defined as the number of nights spent there. Patients admitted in the evening and discharged the following day were recorded as spending 1 day in hospital. Other primary end points were time to full recovery, defined as a return to the patient's premorbid level of activity. This was assessed by each patient. Secondary end points were operative time, postoperative pain as assessed by each patient on a visual analogue pain scale¹⁴ at 7 and 28 days, wound infection rates, conversions to open procedures and postoperative complications.

Statistical analysis

The Wilcoxon two-sample test was used for continuous outcomes and χ^2 tests for dichotomous outcomes. Analyses were then repeated in which adjustments were made for significant covariates using analysis of covariance for continuous outcomes and logistic

regression for dichotomous outcomes. Statistical significance was defined as p < 0.05. Covariates considered in the analysis were age, sex, leukocytosis, fever and pathology as defined by normal, acute, perforated or gangrenous appendicitis.

RESULTS

Eighty-one patients were entered into the trial from May 1993 to December 1994. Groups were equally matched for age and sex (Table I).

Table I

LA was attempted in 44 patients and successfully completed in 40 (91%). In four patients LA was converted to OA for technical reasons. These four patients have been removed from the data calculations. Results are expressed as mean values, with the standard deviation in parentheses (Table II).

Patients in the OA group had a significantly (p < 0.001) shorter hospital stay (3.03 [1.24] days) than those undergoing LA (3.23 [5.55] days). Age and gangrenous appendicitis were

Data for Patients Who Underwent Laparoscopic Appendectomy (LA) and Open Appendectomy (OA)

	Proce	Total no. of				
Data	LA	OA	patients			
No. of patients	44	37	81			
Sex						
Male	29	21	50			
Female	15	16	31			
Mean (and standard deviation) age, yr	29.4 (12.2)	(16.7) 32.6				
Status of appendix						
Normal	13	7	20			
Acute appendicitis	27	26	53			
Gangrenous or perforated	4	4	8			
Four cases of LA were converted to OA. These patients were excluded from data calculations.						

found to be significant covariates. If patients presented with a gangrenous appendix the difference in hospital stay was not significant when open and laparoscopic procedures were compared. These results are significantly influenced by three patients in the LA group who had an intra-abdominal abscess. If they are excluded from the calculations, patients in the LA group have a significantly (p < 0.026) shorter hospital stay (2.15 [1.89] days).

Patients in the LA group had a more rapid return to premorbid activity levels (p < 0.001). These patients had resumed full activity by 9 (8.4) days after discharge compared with 16.2 (9.9) days for patients in the OA group. Age was found to be a significant covariate, with older patients requiring longer recovery times. Statistical significance was still demonstrated for all age groups (p < 0.002).

Our patients required significantly (p < 0.001) fewer postoperative narcotic injections after LA than after OA, 4.05 (6.39) injections versus 5.58 (3.36) injections respectively. Age of the patient was found to be a significant covariate, with older patients requiring more narcotic injections (p < 0.009).

Postoperative pain was assessed

Table II

Comparison of Course of Laparoscopic Appendectomy (LA) and Open Appendectomy (OA)

	Procedure					Significant	
Course	LA		OA		p value	covariates	p value
Hospitalization, d	3.23	(5.55)	3.03	(1.24)	< 0.001	Age/gangrene	> 0.09
Narcotic injections, no.	4.05	(6.39)	5.58	(3.36)	< 0.001	Age	< 0.009
Pain score at							
7 d	2.53	(2.59)	2.59	(2.07)	> 0.55		_
28 d	0.48	(1.175)	0.38	(0.90)	> 0.23		_
Time to full recovery, d	9.0	(8.4)	16.2	(9.9)	< 0.001	Age/sex	< 0.002
Operative time, min	73.8	(23.2)	45	(12.9)	< 0.001		_
Figures are means (and standar	rd deviations).						

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subjectively by patients in both groups by means of a visual analogue scale marked from 0 to $10.^{14}$ Patients in both groups classified their pain as 2.59 (2.07) and 2.53 (2.59) at 7 days (p > 0.55), and as 0.38 (0.89) for LA and 0.475 (1.76) for OA at 28 days (p > 0.23).

Operative time was significantly (p < 0.001) longer in the LA group (73.8 [23.2] minutes) than the OA group (45 [12.9] minutes).

Three patients subsequently had an intra-abdominal abscess diagnosed by elevated temperature, leukocytosis, ultrasonography and computed tomography (CT). All had undergone LA. This difference, however, was not significant according to Fisher's exact test (p > 0.25). All three patients who had an intra-abdominal abscess had a perforated appendix at the time of LA. Eight patients in our series had a perforated appendix; four in the LA group and four in the OA group.

Infectious wound complications, defined as the presence of cellulitis and excessive incisional pain, were similar in both groups (three in the LA group and three in the OA group [p > 0.92]), for an overall wound infection rate of 8%.

On histologic examination 61 (75%) patients were found to have evidence of acute appendicitis, 31 in the LA group and 30 in the OA group.

DISCUSSION

Standard OA was first described by Fitz in 1886.¹⁵ The procedure is considered to be safe, carries low morbidity and can be performed by every general surgeon. LA was described first by Semm in 1983¹⁶ as an incidental procedure. Recently, many studies have been published comparing LA and OA but only a few have been prospective randomized trials. Two of these^{1,2} concluded that LA should be the procedure of choice for suspected appendicitis. Proponents of LA have emphasized a shorter hospital stay,^{1,3,8-10} decreased need for narcotic drugs postoperatively,^{2,3,8} less postoperative pain^{1,8,10} and an earlier return to normal activities.^{1,2,4,10} In addition, LA allows a more complete visualization of the abdominal cavity in the event that acute appendicitis is not the correct diagnosis, thus enhancing diagnostic capability.

Data from the published prospective randomized trials dealing with days in hospital is conflicting. In this series, we demonstrated a significant decrease in mean hospital stay in favour of OA. These results differ from those of previously reported British studies.^{1,3} Other trials also were unable to show a significant decrease in hospital stay in favour of LA.^{2,4} In one retrospective review there was no difference in hospital stay between open and laparoscopic groups.12 However, a difference was found between simple and complicated appendicitis regardless of the type of procedure performed.12 Complicated appendicitis was defined as the presence of a gangrenous or perforated appendix in association with an abscess or peritonitis. In our series, hospital stay was not prolonged in patients with a gangrenous appendix, but the number of patients with perforated appendices being compared was small (8 of 81). Three patients in the LA group had an intra-abdominal abscess, and they stayed in hospital much longer. If these three patients are excluded the mean hospital stay for LA was significantly shorter at 2.15 (1.89) days (p <0.026). All three had a perforated appendix at their initial procedure. They had ultrasonographic confirmation of their abscess and subsequently underwent CT-guided drainage in conjunction with a 2-week course of antibiotics. This treatment regimen was

adequate for two of the patients, one who had a pelvic abscess and one who had a periappendiceal abscess. The third patient required laparotomy 2 weeks after the original procedure for an unresolved small-bowel obstruction. Multiple adhesions were found and there was a periappendiceal abscess caused by a fecolith that had not been identified at the initial laparoscopic procedure. Subsequently, a ventral hernia developed. Complicated appendicitis, as already defined, occurred in 22% of OA cases and 16.7% of LA cases in one retrospective review.12

The incidence of infectious complications requiring readmission for that series was 45.5% in the laparoscopic complicated group and 3% in the open complicated group. The authors concluded that LA is contraindicated in these cases. In a recently published multicentre, prospective, randomized trial,⁵ six patients in the LA group had an intra-abdominal abscess whereas no patients in the OA group had such an abscess. This finding was not significant, consistent with our reported data. During LA, a localized purulent collection may be spread throughout the peritoneal cavity.17 Several mechanisms that may contribute to this are patient positioning, creation of a pneumoperitoneum and laparoscopic manipulation of a perforated appendix. During LA, dissemination of bacteria through the peritoneal cavity may occur more frequently due to intraperitoneal manipulation of a localized infectious process compared with the situation in OA in which the appendix is mobilized into the wound early. This, however, is a theoretical consideration, and there is no objective supporting evidence. A potential benefit of laparoscopic surgery, however, is that thorough irrigation of the abdomen can be performed under direct vision. Although only three patients in our series and six patients in a large multicentre US study⁵ had intraabdominal abscesses (neither result being statistically significant), this issue is one that must be examined in trials with larger numbers of patients to determine its true incidence.

In our study, patients returned to full activity by 9 days after LA, and 16.2 days after OA, a result that is in agreement with those of many studies, demonstrating a more rapid return to normal activity in favour of LA.^{1,2,4,10}

Using a visual analogue scale, we were unable to demonstrate a significant difference in postoperative pain experienced between our groups at 7 and 28 days after discharge. Objective assessment of postoperative pain is difficult. Our data conflict with those of several other series,^{1,8,10} which have shown less pain after LA than after OA. In reviewing our data, it is interesting that although patients in the LA group reported postoperative pain scores equal to those undergoing OA, the LA patients were still discharged from hospital earlier and had a more rapid return to normal activity. Pain for a procedure such as OA is considered minimal; therefore, to detect small differences between OA and LA. assessment should be performed in the immediate postoperative period. We attempted to assess pain on the 1st postoperative day; however, poor patient reporting precluded the use of this information.

We defined operative time as the time from skin incision to wound dressing. In our study, LA took significantly longer to perform. The operative times in several studies were shorter than ours.^{1,4,11,18} In one reported prospective study⁴ no difference in mean operative time was demonstrated; however, perforated appendices were excluded from this analysis, and experienced laparoscopists were operating in one group,

whereas for OA the operator was only required to have 6 months' training. In our series, all patients who were randomized to LA had an initial attempt at laparoscopic removal, including those with perforated and gangrenous appendices.

The conversion rate in this study is comparable to those of previous prospective randomized trials. Of the 44 attempted laparoscopic appendectomies, 40 (91%) were completed and 4 (9%) were converted for technical reasons. In three cases a phlegmonous mass precluded a safe dissection, and in the fourth case control of hemorrhage was required. Recent prospective studies reported conversion rates of 6.7%1 and 5.2%.2 However, conversion rates as high as 20% have been reported in cases of acute appendicitis.7 In a review of 625 laparoscopic appendectomies a 2% conversion rate was reported.11

In our series the overall diagnostic accuracy for acute appendicitis was 75% — 68% in the LA group and 81% in the OA group. The rate of positive pathologic findings increased to 89% (72 cases) when all conditions found at the time of surgery were accounted for. Eleven patients not found to have acute appendicitis had a variety of other conditions (Table III). No significant difference was demonstrated between the two groups with regard to nonappendiceal disease. Nine patients (five LA and four OA) had no pathologic diagnosis that would account for their pain. The diagnostic accuracy rate in this study is consistent with previously reported data. Two prospective studies^{1,2} reported a true positive rate of appendiceal disease in more than 80% of their patients. In a review of 1000 patients with a clinical diagnosis of acute appendicitis, a negative appendectomy rate of 20% was reported.¹⁹ This is an accepted true negative rate, since it has been established that as diagnostic accuracy increases so does rate of perforation.^{2,18,20}

In our study, all appendices were removed regardless of gross appearance. Several studies have left normalappearing appendices in situ.^{1,7} Removal of a normal appendix at the time of surgery is supported by data that demonstrate a false-negative rate ranging from 3%¹⁷ to 19%.⁶ None of our patients who had a grossly normal appendix removed suffered any postoperative morbidity. Current practice is to perform appendectomy when the appendix appears normal in OA cases, and our data indicate that this practice should be employed for LA.

Cellulitis developed around trocar sites in three patients and around open incision sites in three patients. All were treated with antibiotics and none required drainage. All patients who had

Table III

Conditions Identified in Patients Without Acute Appendicitis at the Time of Operation

Condition	LA	OA		
Ruptured ovarian cyst	6	0		
Closed loop small-bowel obstruction	0	1		
Infarcted hydatid of Morgagni	1	0		
Mesenteric adenitis	0	1		
Terminal ileitis	1	0		
Infarcted appendix epiploicae	0	1		
No morbid condition was identified in 5 LA patients and 4 OA patients.				

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procedures that were classified as contaminated had delayed primary wound closure. This may be the reason why no abscesses developed in contaminated wounds. Our data did not demonstrate any difference in wound infection rates between the two groups. Most studies report a very low incidence of wound infection after LA in contrast to a rate of up to 11% after OA.^{1,3,17}

CONCLUSIONS

Patients who undergo LA for acute appendicitis have a significantly earlier return to normal activity and require fewer postoperative narcotic injections. LA, however, takes significantly longer to perform. LA is safe and was successfully completed in 91% of patients in this study. There was a trend (though not significant) toward a greater number of intra-abdominal abscesses in patients who underwent LA for acute perforated appendicitis. Studies with larger groups of patients may clarify the issue of intra-abdominal abscess formation after LA. The development of an intra-abdominal abscess in patients who undergo LA affects the mean length of hospital stay. Patients with simple appendicitis who undergo LA, however, are discharged from hospital more rapidly than those who undergo OA.

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