Laparoscopic drainage versus interventional radiology for management of appendicular abscess: a randomized controlled trial

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Background
Laparoscopic drainage of appendicular abscess has become a novel technique due to its advantages over interventional radiology like a complete exploration of the abdomen, exclusion of other pathologies, excision of the appendix at the same session, better cosmesis, decreased incidence of wound infection, better visualization of surgical field, fine handling of edematous tissue and drainage of multiple collections.

Patients and methods
This randomized controlled clinical trial included all patients who developed the manifestations of appendicular abscess and were referred to the Zagazig University Hospital Emergency Department between January 2020 and February 2022. The study was prospectively approved by the Zagazig University Faculty of Medicine Institutional Review Board (Approval Number: 9871/26-9-2022), and was retrospectively submitted to clinicaltrials.gov in June 2022 (ClinicalTrials.gov ID: NCT05419440). The sample size was 172 patients divided into two equal groups, a laparoscopic group involved 86 patients (group 1) and an interventional radiology group involved 86 patients (group 2).

Results
Group 1 (laparoscopic drainage group) included 86 patients: 55.8% were males, with a mean age of 41.2 SD 12.2 years-old, while group 2 (interventional radiology group) included 86 patients: 51.2% were males, with a mean age of 36.8 SD 10.9 years-old. The incidence of reported complications in group (1) was 1 (1.2%) for bowel injury, 3 (3.5%) for fecal fistula, 0 (0%) for recurrence, 0 (0%) for pelvic collection and 0 (0%) for mortality while in group (2) were 5 (5.8%) for bowel injury, 0 (0%) for fecal fistula, 3 (3.5%) for recurrence, 8 (9.3%) for pelvic collection and 1 (1.2%). The incidence rates of quality of life in group (1) were 48 (55.8%) for excellent quality of life, 38 (44.2%) for good quality of life and 0 (0%) for poor quality of life, unlike group (2), the incidence rates of quality of life were 12 (14%) for excellent quality of life, 59 (68.6%) for good quality of life and 15 (17.4%) for poor quality of life.

Conclusion
Laparoscopic management of appendicular abscess was safely applied in a good experienced hand without the need for interval appendectomy.

Keywords:
appendicular abscess, interventional radiology, laparoscopy, surgical emergency

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Introduction

Abscess formation is one of the most serious complications of acute perforated appendicitis with an incidence of 2–10% [1]. In cases of acute appendicitis, the gold standard management is appendectomy, while in the setting of appendicular abscess; the standard treatment is still controversial [2]. The surgical management of appendicular abscesses may be complicated by bowel injury, wound infection, and paralytic ileus [3]. With the recent advances in interventional radiology, nonoperative management of appendicular abscesses has become the trend [4]. Appendicular abscess can be managed by computed tomography-guided drainage trans-abdominal, trans-rectal, or trans-vaginal then patients may be later managed with interval appendectomy [5]. Moreover, laparoscopic concurrent appendicular abscess drainage with appendectomy has been established in many centers with the advantages of shorter hospital stay, rapid recovery, better cosmesis, and better access and good visualization of the operative field [6]. In the setting of appendicular abscess, the advantages of laparoscopy over interventional radiology are complete exploration of the abdomen, exclusion of other pathologies, and excision of the appendix at

the same session, while patients, managed with interventional radiology may still need interval appendectomy [7].

Objectives

To compare laparoscopic versus interventional radiology management of appendicular abscess regarding advantages, efficacy, and safety.

Patients and methods

This randomized controlled clinical trial included all patients (172 patients) who developed the manifestations of appendicular abscess and referred to the Zagazig University Hospital Emergency Department between January 2020 and February 2022. The study was prospectively approved by Zagazig University Faculty of Medicine Institutional Review Board (Approval Number: 9871/26-9-2022), and was retrospectively submitted in clinicaltrials.gov in June 2022 (ClinicalTrials.gov ID: NCT05419440). The study was performed in accordance with the code of ethics of the World Medical Association (Declaration of Helsinki) for studies involving human subjects. Written informed consent was obtained from all participants after explaining to them all the study procedures with its benefits and hazards. Patients with ages ranged from 16 to 60 years old, with appendicular abscess (gangrenous, obstructive appendicitis and perforated appendix stage), with early sepsis, no septic shock, American Society of Anesthesia I and II, no other pathology and those fit for laparoscopy were deemed eligible for randomization. We excluded patients with age below 16 and more than 60 years-old, septic shock, appendicular mass, suppurated and catarrhal appendicitis, American Society of Anesthesia III and IV classification, previous abdominal operations, intraoperative presence of other pathologies, immune compromised patients, patients with immune suppressive therapy, pregnant patients and those unfit for laparoscopy.

The included patients were simply randomized at a 1 : 1 ratio to 'laparoscopic group (LG)' or 'interventional radiology group (IG)' via the drawing of sealed envelopes containing computer-generated random numbers prepared by a third party before the start of the procedure. The sample size was calculated by using open Epi program depending on the following data; confidence interval 95%, power of the test 80%, ratio of unexposed/exposed 1, percent of patients with complications after management of appendicular abscess by interventional radiology 15%, and those managed by laparoscopy 2%, odds ratio 8.7, and risk ratio 7.5, So the calculated sample size was 172 patients divided into two equal group. This study included 200 patients, 28 patients of them did not met inclusion criteria (10 patients had appendicular mass not abscess after laparoscopic exploration, four patients were pregnant, four patients with intestinal obstruction due to ileus not candidate for laparoscopy or interventional radiology due to distended bowel with risk of injury, six patients were diabetic mellitus, four patient were on immunosuppressive medications). So the final number of the patients included in our study was 172 patients divided into equal groups (86 patients in the Laparoscopic group and 86 patients in the interventional radiology group).

Primary outcome was postoperative incidence of fecal fistula and secondary outcomes were recurrent collection and quality of life in each group during the 3-months follow-up period, respectively.

Diagnosis

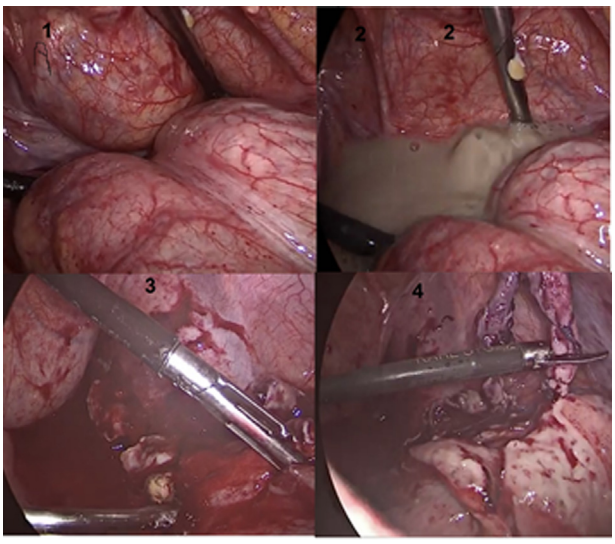
After full history taking and complete physical examination (fluctuant high grade fever especially at evening, severe pain and tenderness at right iliac fossa, toxic manifestations), appendicular abscess was clinically suspected and then confirmed by laboratory investigations, liver and kidney functions, coagulation profile, radiological imaging [abdominal ultrasound (US) or computed tomography (CT) with oral and I.V contrast confirmed the appendicular abscess]. There were criteria for preoperative diagnosis of appendicular abscess and used in diagnosis in cases with negative CT and US findings constant throbbing pain at right iliac fossa, high grade hectic fever, mass at right iliac fossa felt/abdomen, diarrhea with nausea and vomiting, increased micturition and tenesmus, high white bold cell count more than 16 000 [8].

Intervention

Laparoscopic group patients were subjected to the following steps after the diagnosis was confirmed as appendicular abscess. Under general anesthesia, in supine position, ports were inserted, one 10 mm port supra-umbilical (open method or Veress needle), one 5 mm port at left iliac fossa, one 5 mm port at right iliac fossa. First step was exploration of the abdomen to exclude other pathologies and confirm the diagnosis (we excluded patients with other pathologies after laparoscopic exploration). First step was irrigation and suction of the whole the abdominal cavity with warm saline 0.9%, irrigation with warm saline help in separating the adhesions between the bowels [9], better visualization of the tissue. Second step was removal of

any adhesions. We then gained access to the caecum by tilting the table head down and to left to keep all the small intestine away from caecum, removal of any adhesions with the surroundings by sharp and blunt dissection to gain access to appendicular abscess, drain all the pus by suction and irrigation with warm saline. After complete separation of the appendix from surrounding and complete drainage of pus and removal of all necrotic tissue, removal of the remnant appendix was performed as shown in Fig. 1. In cases with healthy base of appendix, we closed the stump with endo-loop. In cases with unhealthy base, we closed the stump by suturing by ethibond 2/0 in two layers in case with little edema and inflammation of caecum (sutures not cut through) but if there was marked edema and inflammation of caecum and due to severe inflammation and adhesions in the right iliac fistula we closed the site of base by omental patch that was fixed in place by full thickness sutures in wall of caecum and pass through omental patch. We examined any leak by pressing on caecum and observed any fecal matter leak and air leak test. Finally, irrigation and suction with 2000cc warm saline were performed and a large caliber drain was left in the pelvis to be removed later according to its output. Then patients stayed in hospital under observation till drain removal. For interventional radiology group, patients were subjected for tube drain or pigtail catheter insertion at right iliac fossa by an interventional radiologist either by US or CT guided, then drain was removed according the amount of discharge and US confirmed that there is no residual according to the interventional radiologist advice [10]. In the failed cases of percutaneous (PC), there was no clear ultrasonic window to the right iliac fossa. We routinely performed interval appendectomy. In failed PC drainage, the patients were subjected for laparoscopic or open drainage.

Figure 1



1- sharp& blunt dissection for appendix access.
2- irrigation & suction of the pus.
3- separation of the appendix from surrounding structures.
4- ligation of the base of the appendix.

Steps of laparoscopic drainage.

Statistical analysis

Analysis of data was done by IBM computer using SPSS (statistical program for social science version 23) as follows: description of quantitative variables as Mean, SD, median, and interquartile range. Shapiro test of normality used to check the data distribution. Description of qualitative variables was number and percentage. Chi-square test was used to compare qualitative variables between groups. Fisher exact test was used when one expected cell or more are less than 5. Independent *T* test was used to compare quantitative between two groups .Mann Whitney test was used instead of unpaired *t*-test in nonparametric data (SD>30% mean). Multiple linear regression models were conducted to find predictors to hospital stay. Multiple Binary logistic regressions were conducted to find predictors to quality of life. *P* value was considered significant when it was less than 0.05 [11].

Results

In our study there was no significant difference regarding sex in both groups as shown in Table 1. But there was significant difference regarding age in both group as shown in Table 2. Patients in Laparoscopic groups presented with nausea, vomiting, fever, pain at right iliac fossa, tenderness and rebound tenderness at right iliac fossa and a mass felt at right iliac fossa with incidence of 43 (50%) for nausea, 39 (45.3%) for vomiting, 38 (44.2%) for fever, 19 (22.1%) for pain at right iliac fossa, 22 (25.6%) for tenderness and rebound tenderness at right iliac fossa and 18 (20.9%) for a mass felt at right iliac fossa. In Interventional radiology group, patients presented with nausea, vomiting, fever, pain at right iliac fossa, tenderness and rebound tenderness at right iliac fossa and a mass felt at right iliac fossa with incidence of 36 (41.9%) for nausea, 35 (40.7%) for vomiting, 42 (48.8%) for fever, 24 (27.9%) for pain and tenderness at right iliac fossa, 14 (16.3%) for rebound tenderness at right iliac fossa, and 15 (17.4%) for a mass felt at right iliac fossa as in Table 1. US and CT findings of suggestive of appendicular abscess were with no clinical significant in both groups as shown in Table 1. Size of appendicular abscess ranged from

Table 1 Demographic criteria, clinical presentation, ultrasound and computed tomography finding, size of appendicular abscess in both group, conversion to open, need for further operation, complications, mortality, quality of life in both groups

	Laparoscopic Drainage	Interventional Radiology	*P* value
Sex	***N* (%)**	***N* (%)**	
Male	48 (55.8)	44 (51.2)	0.541
Female	38 (44.2)	42 (48.8)	
Clinical presentation	***N* (%)**	***N* (%)**	
Nausea	43 (50)	36 (41.9)	0.284
Vomiting	39 (45.3)	35 (40.7)	0.538
Fever	38 (44.2)	42 (48.8)	0.541
Right iliac fossa pain	19 (22.1)	24 (27.9)	0.379
Tender at RIF	22 (25.6)	24 (27.9)	0.73
Rebound tenderness	22 (25.6)	14 (16.3)	0.134
Mass felt	18 (20.9)	15 (17.4)	0.561
US finding positive	***N* (%)**	***N* (%)**	
Negative	62 (72.1)	61 (70.9)	0.866
Positive	24 (27.9)	25 (29.1)	
CT finding	***N* (%)**	***N* (%)**	
Negative	24 (27.9)	25 (29.1)	0.866
Positive	62 (72.1)	61 (70.9)	
Size of appendicular abscess	***N* (%)**	***N* (%)**	
Small (1–2 cm)	22 (25.6)	18 (20.9)	0.723
Moderate (2–4 cm)	30 (34.9)	34 (39.5)	
Large (4–7 cm)	34 (39.5)	34 (39.5)	
Conversion to open	***N* (%)**	***N* (%)**	
Yes	0	13 (15.1)	<0.001
No	86 (100)	73 (84.9)	
Needs further operation	***N* (%)**	***N* (%)**	
Yes	0	86 (100)	<0.001
No	86 (100)	0	
Mortality	***N* (%)**	***N* (%)**	
Yes	0	1 (1.2)	1*
No	86 (100)	85 (98.8)	
Complications	***N* (%)**	***N* (%)**	
No	82 (95.3)	70 (81.4)	0.004
Bowel injury	1 (1.2)	5 (5.8)	*0.21
Faecal fistula	3 (3.5)	0	*0.246
Recurrence	0	3 (3.5)	*0.246
Pelvic collection	0	8 (9.3)	*0.007
Quality of life	***N* (%)**	***N* (%)**	
Excellent	48 (55.8)	12 (14)	0.002
Good	38 (44.2)	59 (68.6)	<0.001
Poor	0	15 (17.4)	0.012

small, moderate and large size in both groups, small size abscess (1–2 cm) occurred in 22 (25.6%) patients, moderate size (2–4 cm) according to radiological classification [12] occurred in 30 (34.9%) patients, large size (more than 4 cm) occurred in 34 (39.5%) patients this in group (1). Small size abscess (1–2 cm) occurred in 18 (20.9%) patients, moderate size occurred in 34 (39.5%) patients, large size 34 (39.5%), in group (2) as in Table 1. The incidence of reported complications in group (1) were 1 (1.2%) for bowel injury, 3 (3.5%) for fecal fistula, 0 (0%) for recurrence, 0 (0%) for pelvic collection and 0 (0%) for

Table 2 Hospital stay and age in both groups

	Laparoscopic Drainage *N* (%)	Interventional Radiology *N* (%)	*P* value
Age in years			
Mean±SD	41.2±12.2	36.8±10.9	0.013
hospital stay in days			
Mean±SD	6.01±2.34	13.86±3.70	<0.001

Table 3 Quality of life in both groups

Quality of life	*N* (%)	*N* (%)	Relative risk	95% CI	*P* value
Excellent	48 (55.8)	12 (14)	2.25	1.5–3.4	0.002
Good	38 (44.2)	59 (68.6)	1.25	1.1–1.4	<0.001
Poor	0	15 (17.4)			0.012

mortality while in group (2) were 5 (5.8%) for bowel injury, 0 (0%) for fecal fistula, 3 (3.5%) for recurrence, 8 (9.3%) for pelvic collection and 1 (1.2%) as in Table 1. The mean length of hospital stay in group (1) was 6.01 ±2.34 days, while in group (2), it was 13.86±3.70 days. No patients needed conversion to open surgery or needed further operation to remove appendix in group (1), while in group (2), there were 13 (15.1%) patients needed a completion surgery (either open in three patients or laparoscopic in 10 patients), and all patients needed to be subjected for further surgery to remove appendix as in Table 1. In multiple backward linear regression models, the predictors of prolonged postoperative hospital stay group were being in the intervention radiology group (adjusted B coefficients −0.873) and being female. The incidence rates of quality of life in group (1) were 48 (55.8%) for excellent quality of life, 38 (44.2%) for good quality of life and 0 (0%) for poor quality of life, unlike group (2), The incidence rates of quality of life were 12 (14%) for excellent quality of life, 59 (68.6%) for good quality of life and 15 (17.4%) for poor quality of life as in Table 3. In multiple backward linear regression models, the significant predictors of excellent quality of life were patients who underwent perform laparoscopic intervention (OR 7.897).

Discussion

At first it should be referred that both laparoscopy and interventional radiology could be complementary methods for management of appendicular abscess. Laparoscopic drainage of appendicular abscess in a good experienced hand has proven its efficacy and safety without increased incidence of mortality and morbidity [13]. In this study, the complications that were occurred in laparoscopic group included bowel injury in one patient during sharp and blunt dissection of adhesions between the edematous bowel loops by laparoscopic instruments; fecal fistulae were occurred in three patients due to slipped ligature at the base of either nonhealthy or friable appendix. The fecal fistulae were managed successfully using conservative treatment. All the fistulae were closed within 1 week without any mortality or morbidity. We used the omental patch in our center in attempt to seal perforation and actually, it might help to prevent leakage or fistula and it was unlikely to cause fistula or leak as we used it to cover the site of base of appendix and fixed it in healthy tissue. If fistula occurred it was not related to omental patch fixation, even if fistula was occurred, it was low output fistula and close spontaneous within 1 week provided drainage [14,15]. While in interventional radiology group the complications included bowel injury was occurred in five patients, four of them with small size abscess, one with moderate size abscess. The bowel injury was probably occurred due to improper visualization of bowel by US or CT due to edema and adhesions. Different anatomical variations of the appendix added a challenge for interventional radiologist to easily gain access to the abscess cavity, for example pelvic position of the tip of appendix or sub-hepatic position were associated with high incidence of bowel injury as the adhesions between the bowel made it was difficult to access easily to the abscess cavity. The adhesions between the bowel loops mainly the ileum and caecum made it were difficult for radiologists to easily gain access to the abscess cavity. Obesity was another challenge for interventional radiologist to easily gain access to the abscess cavity. Recurrence of appendicular abscess occurred in three patient in interventional radiology group due to inadequate drainage, blockage of drain tube or pigtail by debris and multi-loculated abscess. These three patients were successfully managed using laparoscopy. Pelvic collections occurred in eight patients in interventional radiology group and were successfully managed using laparoscopy, as well. Mortality occurred in one patient in interventional radiology group due to bowel injury that resulted in sepsis, septic shock with multi-organ failure and death. 15.1% of PC drainage patients needed surgery either laparoscopic (10 patients) or open (three patients as there were not candidate for laparoscopy as they developed ileus) surgery, they needed surgery as there was no improvement in their conditions regarding fever, abdominal pain, vomiting, no decrease in leucocyte count, patients were still toxic, surgery was done immediately. Failure of interventional radiology drainage did not mean radiologists were not experienced, as there were many causes of failure like multiloculated abscess, cases associated with pelvic abscess also thick pus that could not be come

out through the drain, tip of drain was blocked by necrotic tissue or omentum and distended surrounding bowel [16].

The length of hospital stay in laparoscopic group was shorter than interventional radiology because in laparoscopic group the source of sepsis was managed and peritoneal wash helping the patients to recover rapidly. However, in interventional radiology group, we placed US or CT guided drain and waited several days for the pus to come out, so this prolonged the time needed for the patients to recover and all over length of hospital stay. In our study, in interventional radiology group, 13 patients needed surgery immediately as they were not improved, the remaining patients during period of follow-up, some of them still complain with recurrent attack of pain at right iliac fossa which improved by analgesics (chronic appendicitis) but without toxic manifestations, US or CT finding reported remnant appendicular stump, they were subjected to elective laparoscopic appendectomy. In good experienced hands in laparoscopy, the conversion to open was extremely rare and we did not experience any conversions, while in interventional radiology group, there were 13 patients converted to surgery either laparoscopic or open surgery as the abscess was in accessible or small in size. According to World Journal of Emergency Surgery guidelines: regarding nonoperative treatment of acute appendicitis, antibiotic therapy can be successful in selected patients with uncomplicated appendicitis who wish to avoid surgery and accept the risk up to 38% recurrence. PC drainage of a periappendiceal abscess, if accessible, is an appropriate treatment in addition to antibiotics for complicated appendicitis. Nonoperative management (PC drainage plus antibiotics is a reasonable first line treatment for appendicitis with phlegmon or abscess. Operative management of acute appendicitis with phlegmon or abscess can be a safe alternative to nonoperative management but only in experienced hands [17].

The quality of life was better in laparoscopic group; criteria that were used to assess the quality of life were absence of recurrent pain at right iliac fossa, patients without any discomfort and the need for further management [18].

In comparison to study that was done by Mentula and colleagues, there was no difference in hospital stay: 4 days (interquartile range: 3–5 days) in the laparoscopy group versus 5 days (3–8) in the conservative group, P=0.105. Patients in the laparoscopy group had 10% risk for bowel resection and 13% risk for incomplete appendectomy. There were significantly fewer patients with unplanned readmissions in the laparoscopy group: one (3%) versus eight (27%), P=0.026. Additional interventions were required in two (7%) patients in the laparoscopy group (PC drainage) and in nine (30%) patients in the conservative group (surgery), P=0.042. Recurrent abscesses and failure to respond to conservative treatment were the main reasons for additional interventions. Open surgery was required in three (10%) patients in the laparoscopy group and in 4 (13%) patients in the conservative group. Postoperative complications occurred in three patients in laparoscopic group versus two patients in the conservative group. The rate of uneventful recovery was 90% in the laparoscopy group versus 50% in the conservative group, P=0.002, so laparoscopic surgery in experienced hands is safe and feasible first-line treatment for appendiceal abscess. It is associated with fewer readmissions and fewer additional interventions than conservative treatment with comparable hospital stay [19].

Conclusion

Laparoscopic management of appendicular abscess was safely applied in a good experienced hand without the need for interval appendectomy.

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no

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Conflicts of interest

There are no conflicts of interest.

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