Endobag extraction versus direct extraction of gall bladder specimen during laparoscopic cholecystectomy: is routine usage of endobag mandatory? A prospective cohort study

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Background
During laparoscopic cholecystectomy (LC), the optimal method of retrieval of gall bladder (GB) specimen has not been agreed yet. This study aims to determine how mandatory it is to routinely use endobag for GB extraction in comparison with direct extraction (DE).
Settings
The study was conducted at the General Surgery Department of Ain Shams University Hospital.
Patients and methods
This prospective cohort study recruited patients who underwent LC between March 2017 and March 2019. This cohort was divided into two groups: group A had endobag extraction and group B had DE. Both arms were compared regarding procedure-related and postoperative variants.
Findings
This study included 100 patients who presented to Ain Shams University Hospital with different presentations of GB stones. Mean age of participants was 41.34 ±11.73 years in group A and 42.96±10.53 in group B. Spillage of bile and/or stones took place in the epigastric port-site in eight (16%) individuals of group B, and only one (2%) patient in group A (P=0.031). Cases that had endobag extraction stayed in the hospital for only a mean of 23.68±6.26 h in comparison with 27.08±3.23 h of DE cases (P=0.001). Port-site infection was discovered in 12% (six patients) of the DE arm and none of the opposing group (P=0.027). At 24 h postoperatively, eight (16%) cases of group A and 11 (22%) cases of group B experienced pain (P=0.611), and mean visual analog scale score was 1.84±0.91 and 3.14±0.61 in groups A and B, respectively (P=0.001).
Interpretation
The use of endobag in LC is not routinely mandatory in uncomplicated GB stones. However, it is highly recommended in complicated GB stones like mucocele and empyema, as it minimizes port-site spillage, port-site infection, visual analog scale scores, and hospital stay.

Keywords:
endobag, gall bladder extraction, laparoscopic cholecystectomy

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Introduction

Laparoscopic cholecystectomy (LC) is considered the operation of choice and the standard treatment for symptomatic gall stones and cholecystitis [1]. Worldwide, it is the most frequent laparoscopic procedure performed [2]. Generally, it has the benefits of less postoperative pain, rapid return to daily activity, short duration of hospital stays, and tiny cosmetic marks [3].

One of the most common complications of LC is perforation of the gall bladder (GB) while dissecting it from the liver bed that leads to intraperitoneal spillage of bile and stones which may lead to serious complications such as intraperitoneal abscess or port site infection, and this can be avoided by the use of endobag [4].

Endobag is of great value also if used in suspected cases of GB cancer to minimize the incidence of tumor cell seedling [5] and in cases of acute cholecystitis and empyema of the GB to avoid contamination of the wound with infected bile or stones during retrieval of the GB [6].

As working in a low-resource hospital in a developing country, we still do not routinely use endobag for retrieval of GB. The main objective of this work is to analyze its potential benefits and to determine

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whether or not the routine use of endobag for GB extraction is mandatory. If it is proven mandatory, we will work toward changing our local institutional policy in this regard.

Patients and methods

Study eligibility criteria

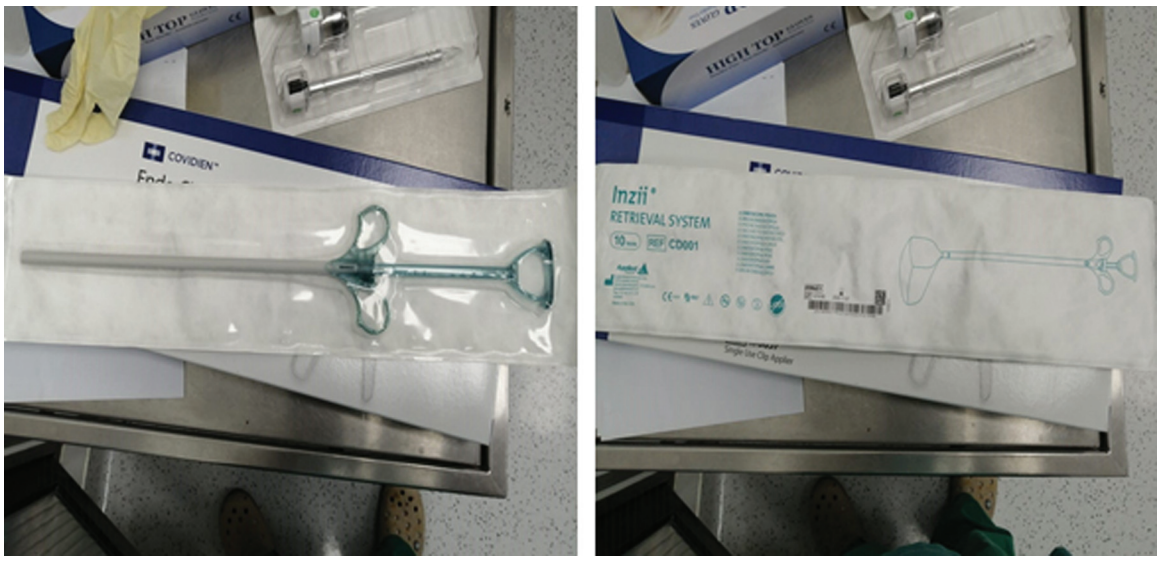
Following are characteristics of this study depicted into the PICOS format:

(1) Participants: this study involved 100 adult patients who presented to the General Surgery Department of Ain Shams University Hospital with diagnosis of GB stones, either complicated or uncomplicated, in the period between March 2017 and March 2019. All patients underwent LC and divided equally based on the mode of specimen extraction into two groups. Group A had endobag extraction (EE) and group B had direct extraction (DE). Patients were followed up at 1, 3, 6, and 12 months at the outpatient clinics. This study excluded patients older than 65 years old and those having concomitant CBD stones, or having severe uncontrolled comorbidities with American Society of Anesthesiology (ASA) score beyond III. Preoperative workup included, besides prompt history taking and thorough physical examination, laboratory investigations like bilirubin, ALP, and LFTs plus pelvi-abdominal ultrasound scan.
(2) Intervention: LC was done for all patients. GB specimen was retrieved using endobag. This group A was referred to as EE.
(3) Control: group B had DE.
(4) Outcomes: both groups were compared against each other regarding the following variants:
    (a) Procedure-related variants: operative time, port-site spillage, intra-abdominal spillage, and extension of fascial defect.
    (b) Postoperative variants: length of hospital stay, postoperative pain, visual analog scale (VAS), port-site hernia, port-site infection, operative bed collection, and pulmonary complications.
(5) Study design: this was a prospective cohort study
(6) Ethical commitment: all patients were well informed with procedure details and its potential risks, and they signed an informed consent before surgery. This study was approved by the Institutional Review Board (IRB) of General Surgery Department at Ain Shams Faculty of Medicine, which is accredited by the Egyptian Ministry of Health.

Operative technique

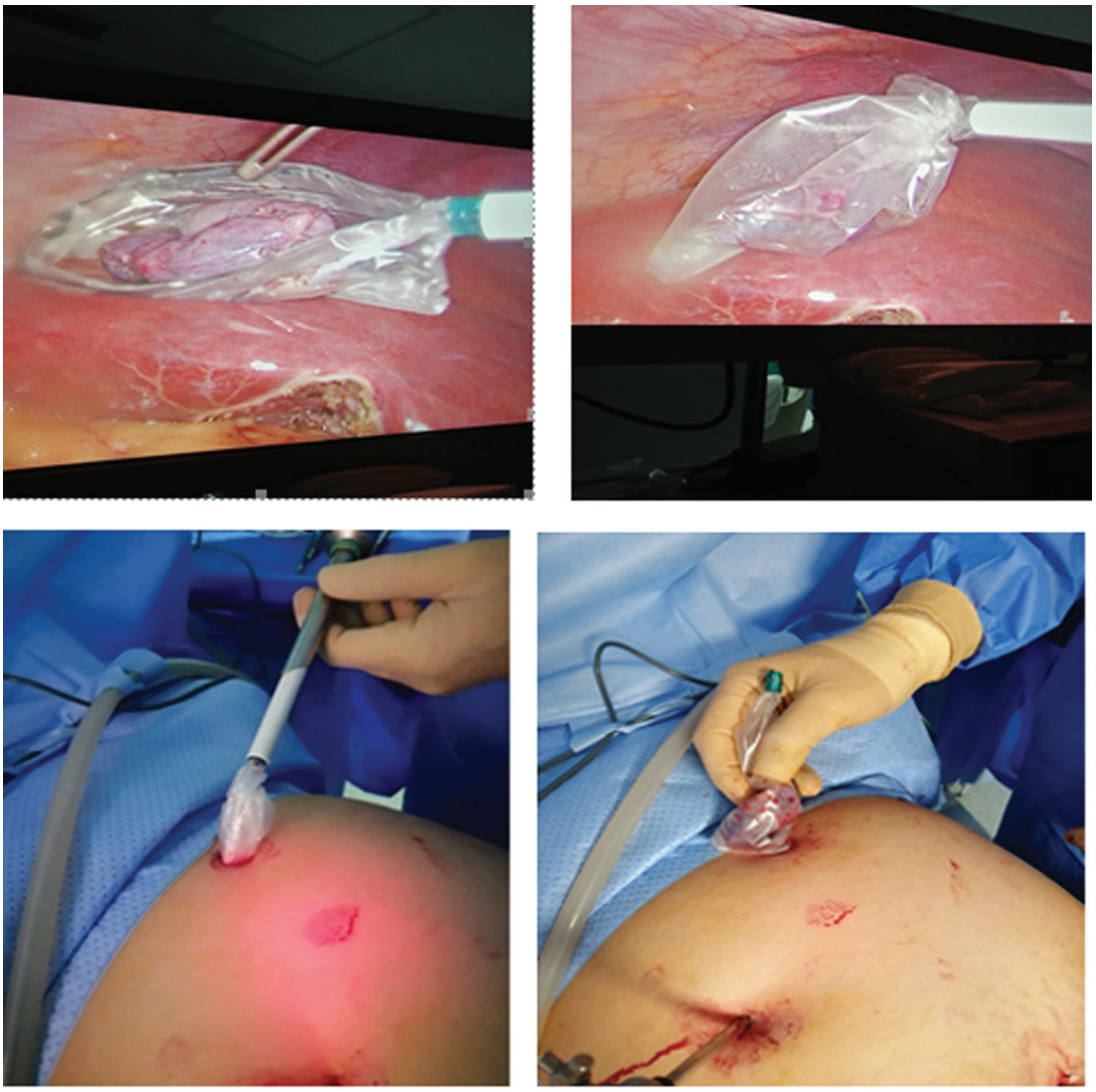
All patients were operated using four ports: 10-mm epigastric, 10-mm umbilical, 5-mm midclavicular, and 5-mm anterior axillary line (below costal margin). Monopolar diathermy was the main source of energy and was used over hook for all dissection and achieving critical view of safety. The GB was retrieved through 10-mm port in epigastric port in all patients, using a sterilized endobag in group A (EE) and without endobag in group B (DE). The endobag, which is used in this study, is commercially designed by Applied Medical (Southern California, USA), 10 mm in size and called Inzii retrieval system (Figs 1 and 2).

Figure 1



Endobag 10-mm, Inzii retrieval system.

Figure 2



Steps of GB retrieval using endobag. GB, gall bladder.

Postoperative care and hospital discharge

Early mobilization and restoration of oral intake was carried out a few hours after surgery as patient tolerates. Pain was assessed using VAS shown in Fig. 3. Postoperative analgesia was introduced in stepladder fashion starting with intravenous paracetamol, then NSAIDs, and escalating to opioids whenever needed. Veno-thrombo-embolic prophylaxis was maintained for all patients unless contraindicated. Drain was removed when it produced less than 50 ml of nonbilious discharge. Hospital discharge was decided when patient is hemodynamically stable, symptom free, nonsignificant drain output (if any), and absent blood investigation abnormalities.

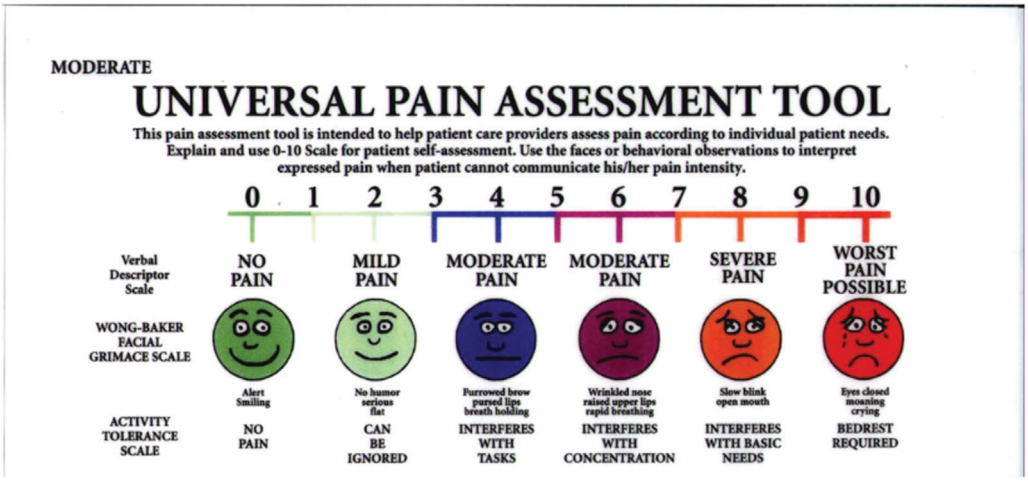
Specifications

Operative time refers to the time consumed to only perform LC from skin to skin. Hospital stay was defined as the number of hours from time of procedure till hospital discharge. Spillage refers to accidental escape of bile or stones from the GB during its retrieval.

Statistical analysis of data

Data were revised, coded, and entered on a computer and analyzed using SPSS package (SPSS Inc., Chicago, IL, USA), version number 20. Quantitative data were tested for normality with Shapiro–Wilk test and appropriate analysis was done according to data distribution. Student t test was used for comparing quantitative variables between two study groups. Paired t test was used to compare quantitative variables measured twice among the same group. χ^2 and Fisher exact tests were used to test the association between qualitative variables. P value less than or equal to 0.05 was considered significant.

Figure 3



Universal pain assessment tool.

Results

This study included 100 patients who presented to General Surgery Department at Ain Shams University Hospital with different presentations of GB stones. Mean age of participants was 41.34±11.73 years in group A and 42.96±10.53 years in group B. Female patients formed the majority of this study, with 76% in group A and 78% in group B. Mean BMI was 29.32 ±6.29 and 31.18±5.23 in groups A and B, respectively. Of the whole study population, 13 (13%) patients had diabetes mellitus, 14 (14%) patients had hypertension, 19 (19%) patients were smokers, and 72 patients were categorized as ASA I. Only five (5%) patients reported history of jaundice before surgery. Preoperative pelvi-abdominal ultrasound scan revealed that eight (16%) cases and 10 (20%) cases had single stones in groups A and B, respectively, with *P* value of 0.603 (Table 1).

In the cohort of EE, uncomplicated GB stones prevailed in 36 patients, whereas two (4%) candidates had empyema, four (8%) had mucocele, and eight (16%) had acute cholecystitis. On the contrary, empyema and mucocele occurred in 6%, whereas acute cholecystitis occurred in 8% of the DE cohort (*P*=1.00) (Table 2).

This study did not record any mortality, iatrogenic bile duct injury, or conversion to open in both arms. During DE of GB, spillage of bile and/or stones took place in the epigastric port-site in eight (16%) individuals of group B, and only one patient in group B (*P*=0.031). Surgical procedure duration was slightly shorter in group A (38.22±9.31 min) versus 39.74±7.63 in the other group (*P*=0.374). Adhesions between GB and surrounding tissues, like greater omentum, were found in 9% of the whole participants (group A 4% and group B 5%, *P*=1.00). During GB retrieval, spillage into abdominal cavity was reported in only a single patient (2%) of the EE arm and in five (5%) patients of the DE arm; however, *P* value did not reach the significance threshold (*P*=0.204). Intra-abdominal drain was left in a minority of patients upon completion of the procedure (group A 8% and group B 10%, *P*=1.00). It was mandatory to extend the epigastric fascial defect in three (6%) patients of group A, and in only one (2%) patient of group B (*P*=0.617) (Table 3).

Cases that had EE stayed in the hospital for only a mean of 23.68±6.26 h in comparison with 27.08±3.23 h of DE cases (*P*=0.001). Port-site infection was discovered in 12% (six patients) of the DE arm and none of the opposing group (*P*=0.027). Port-site hernia occurred in a single patient (2%) of group A and two (4%) patients of group B (*P*=1.00). Operative bed collection and postoperative basal lung atelectasis were recorded only in the DE group by 4 and 2%, respectively (Table 4, Figs 4 and 5).

Among the DE group B, 36 (72%) patients had uncomplicated GB stones at time of presentation and did not record any cases of port-site infection (*P*=0.001). The remaining 14 (28%) patients presented with pictures of complicated GB stones: three (6%) cases of empyema, three (6%) cases of mucocele, and eight (16%) cases of acute cholecystitis. Port-site infection was recognized in two patients with empyema (*P*=0.035), two patients with mucocele (*P*=0.035), and in two patients with acute cholecystitis (*P*=0.24) (Table 5).

Table 1 Basic demographic characteristics of study population

	Groups			
	Group B (DE) Mean±SD	Group A (EE) Mean±SD	*P*	Significance
Age	42.96±10.53	41.34±11.73	0.469‡	NS
BMI	31.18±5.23	29.32±6.29	0.112‡	NS
Sex (%)				
Male	11±22.0	12±24.0	0.812*	NS
Female	39±78.0	38±76.0		
DM (%)				
No	41±82.0	46±92.0	0.137*	NS
Yes	9±18.0	4±8.0		
HTN (%)				
No	41±82.0	45±90.0	0.249*	NS
Yes	9±18.0	5±10.0		
Smoking (%)				
No	37±74.0	44±88.0	0.074*	NS
Yes	13±26.0	6±12.0		
ASA score				
I	31±62.0	41±82.0	0.085**	NS
II	15±30.0	7±14.0		
III	4±8.0	2±4.0		
History of jaundice (%)				
No	47±94.0	48±96.0	1.0**	NS
Yes	3±6.0	2±4.0		
Number of stones (%)				
Single	10±20.0	8±16.0	0.603	NS
Multiple	40±80.0	42±84.0		

ASA, American Society of Anesthesiology; DE, direct extraction; DM, diabetes mellitus; EE, endobag extraction; HTN, hypertension.
‡Student *t* test. *χ^2 tests. **Fisher exact test.

Table 2 Various pathology of gall bladder during presentation

	Groups			
	Group B (DE) Mean±SD (%)	Group A (EE) Mean±SD (%)	*P*	Significance
Empyema				
No	47±94.0	48±96.0	1.0**	NS
Yes	3±6.0	2±4.0		
Mucocele				
No	47±94.0	46±92.0	1.0**	NS
Yes	3±6.0	4±8.0		
Acute cholecystitis				
No	42±84.0	42±84.0	1.0*	NS
Yes	8±16.0	8±16.0		
Uncomplicated GB stones				
No	14±28.0	14±28.0	1.0*	NS
Yes	36±72.0	36±72.0		

DE, direct extraction; EE, endobag extraction; GB, gall bladder.
*χ^2 tests. **Fisher exact test.

At 12 h after the procedure, 15 (30%) cases of group A and 19 (38%) cases of group B experienced pain (*P*=0.39), and mean VAS score was 2.48±1.07 and 3.24±0.89 in groups A and B, respectively (*P*=0.001). At 24 h postoperatively, eight (16%) cases of group A and 11 (22%) cases of group B experienced pain (*P*=0.611), and mean VAS score was 1.84±0.91 and 3.14±0.61 in groups A and B, respectively (*P*=0.001) (Table 6 and Fig. 6).

Discussion

LC is the most common elective general surgical procedure performed worldwide and remains the gold standard for symptomatic gallstones. The most common drawbacks observed during this procedure are GB tears, resulting in spillage of stones and bile into peritoneal cavity and wound. To avoid such complications, GB is commonly extracted in an endobag [7]. However, using endobag increases the final expense of the procedure. We aim to detect how worth it is to routinely utilize endobag, and whether DE is enough.

Demographic characteristics like age, sex, comorbidities, ASA score, history of jaundice, and number of stones were not statistically significant among both arms of the study.

Procedure-related variants

The duration of the surgical procedure was slightly shorter with the usage of endobag. However, this difference did not reach the threshold for statistical significance. Operative time could be confounded by

Table 3 Procedure-related variants in both groups

	Groups			
	Group B (DE) Mean±SD (%)	Group A (EE) Mean±SD (%)	*P*	Significance
Operative time (min)	39.74±7.63	38.22±9.31	0.374‡	NS
Intraoperative adhesions				
No	45±90.0	46±92.0	1.0**	NS
Yes	5±10.0	4±8.0		
Intra-abdominal spillage				
No	45±90.0	49±98.0	0.204**	NS
Yes	5±10.0	1±2.0		
Drain				
No	45±90.0	46±92.0	1.0**	NS
Yes	5±10.0	4±8.0		
Port-site spillage				
No	42±84.0	49±98.0	0.031**	S
Yes	8±16.0	1±2.0		
Extension of fascial defect				
No	49±98.0	47±94.0	0.617**	NS
Yes	1±2.0	3±6.0		

DE, direct extraction; EE, endobag extraction. ‡Student t test. **Fisher exact test.

Table 4 Postoperative variants in both groups

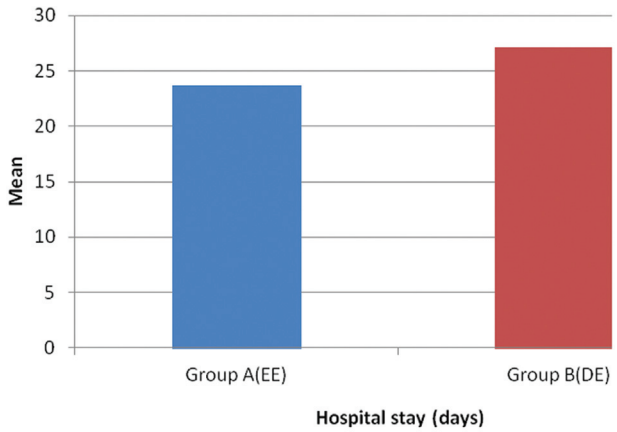
	Groups			
	Group B (DE) Mean±SD (%)	Group A (EE) Mean±SD (%)	*P*	Significance
Hospital stay (h)	27.08±3.23	23.68±6.26	0.001‡	HS
Port-site infection				
No	44±88.0	50±100.0	0.027**	S
Yes	6±12.0	0±0.0		
Port-site hernia				
No	48±96.0	49±98.0	1.0**	NS
Yes	2±4.0	1±2.0		
Operative bed collection				
No	48±96.0	50±100	0.495	NS
Yes	2±4.0	0±0		
Pulmonary complications				
No	49±98.0	50±100.0	1.0**	NS
Yes	1±2.0	0±0.0		

DE, direct extraction; EE, endobag extraction. ‡Student *t* test.
**Fisher exact test.

many factors like intraoperative adhesions, intraabdominal spillage, drain use, and extension of fascial defect. Therefore, those factors were included in our study, and they demonstrated no statistical significance (Table 7).

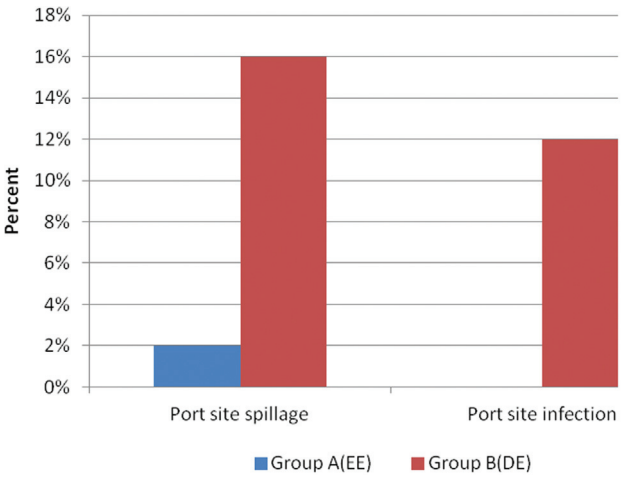
DE of GB proved to significantly exaggerate the possibility of spillage at port sites. This results from the resistance of abdominal wall which squeezes the potentially edematous and friable GB leading to its tear while impacted at the exit or escape of bile and stones from minor apertures. On the contrary, it

Figure 4



Hospital stay in both groups.

Figure 5



Port-site spillage and infection in both groups.

has been confirmed, in this study, that the use of endobag is directly associated with reduced incidence of port-site infection and port-site spillage, because endobag is supposed to contain the whole GB with its bile and stone contents, and act as a barrier against spillage. This undoubtedly aids in protecting the skin surface and subcutaneous tissues from unwanted contact with the potentially infected GB and its contents.

The occurrence of port-site infection has proven to be closely correlated with direct retrieval of GB. However, this could be confounded with the existence of stone complications like empyema, mucocele, and acute cholecystitis at presentation. That is why we plotted various presentations against the incidence of port site infection. We found out that DE of complicated GB with empyema or mucocele is intimately associated with development of port-site infection, in contrast to EE, which seems to be protective particularly against those complications. In cases of acute cholecystitis or uncomplicated GB stones, there is no significant difference between EE and DE.

Similar results were obtained in a study that recommends extraction of the GB in a retrieval bag in cases of complicated cholecystitis [6].

Moreover, our results are consistent with a meta-analysis that is conducted in 2018 and included 279 published articles. It showed no significant benefit of retrieval bags in reducing the infection rate after elective LC unless the GB is complicated [11].

It is worth mentioning that several studies confirmed that postoperative wound infections were owing to skin commensals not typical gram negative organisms, concluding that port-site infections do not necessarily depend on direct contact of the GB with the wound [12,13].

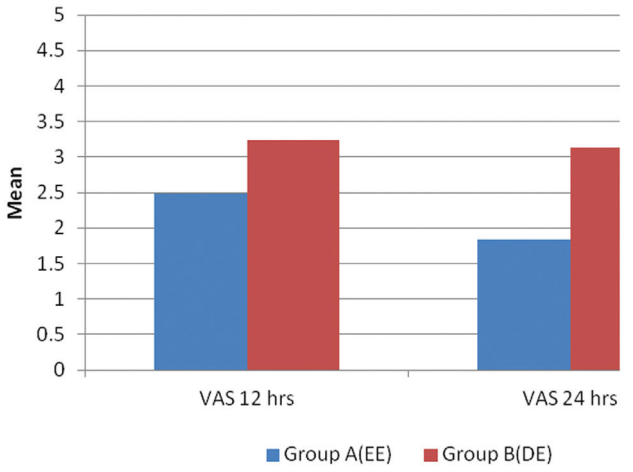
Narayanswamy *et al.* [14] concluded that case of acute cases and those with risk factors for wound infections require an endobag retrieval. Otherwise in uncomplicated LC for radiologically confirmed benign disease, there was no benefit in using a

Table 5 Correlation between gall bladder pathology and incidence of port-site infection in group B (direct extraction)

	Port-site infection [*n* (%]			
	No *N* (row)	Yes N (row)	*P*	Significance
Empyema				
No	43 (91.5)	4 (8.5)	0.035**	S
Yes	1 (33.3)	2 (66.7)		
Mucocele				
No	43 (91.5)	4 (8.5)	0.035**	S
Yes	1 (33.3)	2 (66.7)		
Acute cholecystitis				
No	38 (90.5)	4 (9.5)	0.24**	NS
Yes	6 (75.0)	2 (25.0)		
Uncomplicated GB stones				
No	8 (57.1)	6 (42.9)	0.001**	HS
Yes	36 (100.0)	0		

GB, gall bladder. **Fisher exact test.

Figure 6



VAS score at 12 and 24 h postoperatively in both groups. VAS, visual analog scale.

Table 6 Postoperative pain and visual analog scale score at 12 and 24 h after surgery

	Groups [*n* (%)]			
	Group B (DE)	Group A (EE)	*P*	Significance
Pain 12 h				
No	31 (62.0)	35 (70.0)	0.39*	NS
Yes	19 (38.0)	15 (30.0)		
Pain 24 h				
No	39 (78.0)	42 (84.0)	0.611*	NS
Yes	11 (22.0)	8 (16.0)		
VAS 12 h (mean±SD)	3.24±0.89)	2.48±1.07)	0.001**	HS
VAS 24 h (mean±SD)	3.14±0.61)	1.84±0.91)	0.001**	HS

DE, direct extraction; EE, endobag extraction; VAS, visual analog scale. *χ^2 test. **Student *t* test.

Table 7 Comparison of operative time among other studies

Studies	Operative time (mean)
Our study	DE: 39.74
	EE: 38.22
Kirshtein *et al.* [8]	In drain group 42.5 min
	In undrain group 37 min
Makama and Ameh [9]	37 min
Singh *et al.* [10]	In group A-53.40 min
	In group B-57.90 min

DE, direct extraction; EE, endobag extraction.

retrieval bag. In a study done by Memon *et al.* [15], port-site spillage was 0.88%, and in the study by Memon *et al.* [16], port-site infection was 5.11%. In a study by Singh *et al.* [10], port-site infection in group A was 2%. In group B, it was 8, as 10% of the patients in group B had port-site spillage. Although intraabdominal spillage was reported in 10% of DE group and in only 2% of EE, yet there was no statistical significance between using endobag or not. Singh *et al.* [10] demonstrated close results to ours: 6% for DE and 0% for EE.

Postoperative variants

Along the whole study, no cases of death, post-operative bleeding, or bile leakage were reported.

Endobag utilization did not produce significant influence on the occurrence of postoperative complications like port-site hernia, operative bed collection, and pulmonary complications, as those complications were rare in both groups. In the study by Singh *et al.* [10], port-site hernia took place in 0% of EE arm and 2% of DE arm.

Although the number of patients in EE cohort who experienced pain at 12 and 24 h postoperatively was lower than that of DE cohort, with no statistical significance in this regard, VAS scores were still statistically significant in favor for the EE group. This could be explained by the ease of specimen extraction the endobag provides, in contrast to the difficulties encountered using DE mandating harsh maneuvers such as forceful dilatation of port opening by artery forceps. Extension of fascial defect could be a confounder for pain, but it is statistically neutralized. In the study by Singh *et al.* [10], 4% patients in group A had port-site pain, whereas in group B, 8% patients had port-site pain. The statistical analysis showed that difference between the two groups was insignificant. The results in these studies are comparable.

In our series, we needed to extend the fascial defect only in one case of DE group and three cases of EE without statistical significance. In a large study, an enlargement of the port-site incision was required in 9.7% (36/373) of patients [2]. In both studies, port-site hernia rates were low. The study by Narayanswamy and Prajwal [17] showed opposing results. It claimed that using endobag for retrieval is associated with difficulty in extracting the specimen and need for extension of the fascial incision, hence resulting in longer operating time and increased postoperative pain.

Hospital stay was significantly shorter in the EE group. It is presumed that reduced rates of port-site infection, port-site spillage, and favorable VAS scores, which were associated with Endobag usage, have contributed to minimizing the duration of hospital admission. Drain placement seemed not to affect the length of hospital stay. These results were consistent with the results from a research conducted by Singh *et al.* [10], in which EE group had a mean hospital stay of 2.52 days as compared with 2.94 in DE group.

Total cost

Retrieval bags are not cheap, ranging from &z.euro; 25 to &z.euro; 120, and their use must be questioned in a time of rising economic pressure on the health care providers [11]. Using endobag has piled up the final cost of the whole procedure by $60, which is approximately equivalent to 900 Egyptian pounds. There is evidence in the literature about cost-effectiveness of alternative retrieval bags, such as male condoms, recloseable zipper bags, Nadiad bags, and surgical gloves [18]. Nevertheless, we decided to use the commercially manufactured endobag because we believe that endobags are designed in high quality in comparison with alternatives.

Limitations of the study

Few limitations of this study include the relatively low number of patients and absence of randomization.

Conclusion

Using endobag for GB retrieval has proven to be superior to DE in terms of reduced incidence rates of port-site spillage and port-site infection, less VAS scores, and shorter hospital stay. Nevertheless, EE has similar results to DE in operative time, intra-abdominal spillage, the need for fascial extension, port-site hernia, operative bed collection, and postoperative complications. In spite of increased financial burden, endobag usage can be cost-effective, and therefore strongly recommended, in cases of complicated GB stones, especially empyema and mucocele. In uncomplicated GB stones, DE can be used, especially in low-resource hospitals, without major sequelae.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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