

Comparison of the sonographic findings in laparoscopic cholecystostomy with and without hemostatic agent on 45-day follow-up of patients attending hospital

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ABSTRACT

Introduction: Cholelithiasis is one of the most prevalent pathological conditions, and elective laparoscopic cholecystostomy with and without hemostatic agent (HA) is the therapeutic approach to its treatment. This research study aimed to compare the sonographic findings of patients who underwent cholecystostomy with and without HA use. **Materials and Methods:** This cross-sectional, descriptive-analysis study was conducted by available nonprobability sampling technique, and according to Cochran Formula, 144 patients, who underwent laparoscopic cholecystostomy, were recruited and divided into two groups including a group of 85 patients with HA use and a group of 59 patients without HA use. Patients in each group had sonography on discharge date and 15, 30, and 45 days after the surgery. Data were collected and entered in SPSS-24 software; meanwhile, descriptive statistics was used to analyze Chi-square test, Fisher's exact test, and Friedman and Wilcoxon nonparametric test. **Findings:** The results of the study showed that the presence of echogenic mass with reverberation artifact (abscess mucosa) on 15- and 30-day follow-up sonography of patients, who underwent laparoscopic cholecystostomy, were significantly higher in patients with HA than in the group without HA ($P < 0.05$), and on 45-day follow-up sonography, there was no significant correlation regarding the presence of echogenic mass with reverberation artifact (abscess mucosa) and fluid in the two groups ($P > 0.05$). Besides, HA density significantly decreases in individuals over time ($P < 0.05$); however, there was no significant differences between HA reduction rate and gender ($P > 0.05$). **Conclusion:** These findings might be the indication of HA agents' effect on surgical operations and their resemblance to abscess. Due to the possibility of temporary immune responses to HA, as an external object, it is necessary, in vital pathologies, to pay close attention to what differentiates the normal imaging appearance in follow-up sonography.

Keywords: Cholecystostomy, hemostatic agent, sonography

Introduction

Cholelithiasis is one the most prevalent pathological conditions that affects the biliary tract. Autopsies show that prevalence of gallstones is 11%–36%. Prevalence depends on factors such as age, gender, and racial statues. Obesity, pregnancy, nutritional

factors, Crohn's disease, terminal ileum withdrawal, stomach surgery, heredity spherocytosis, sickle cell disease, and thalassemia cause the expansion of gallstones. Prevalence is thrice as high in women and twice as high in first-degree relatives.^[1] Patients with gallstones are asymptomatic throughout their life. Some of them enter the symptomatic phase of the disease that is characterized by colic pains due to cystic duct obstruction by the

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stone. Sympathetic disease may go on to develop complications including cholecystitis, cholelithiasis with or without cholangitis, pancreatitis, cholecystoduodenal fistula, cholecystoduodenal ulcer, and gallstone ileus. Almost 3% of asymptomatic patients become symptomatic within a year and mostly in the form of biliary colic. In 3%–5% of patients, complications appear within a year. Two-thirds of the patients will still remain asymptomatic after 20 years; therefore, laparoscopic cholecystostomy is rarely indicated in asymptomatic patients. Laparoscopic cholecystostomy is performed on old diabetic patients, those who have not had access to medical services for a long time, and those at gallbladder cancer risk.^[2]

Elective laparoscopic cholecystostomy is a therapeutic approach for acute cholecystitis. The possibility of open cholecystostomy in acute cholecystitis is greater than in chronic cholecystitis (10%–15%). This method is more tedious and longer than elective surgery. However, when compared with a late surgery, the rate of complications equals early ones.^[3] When patients come late, and if they are not ready for surgery after 3–4 days of illness, they will be treated with antibiotics, and they undergo laparoscopic cholecystostomy 2 months later.^[4] Nearly 20% of patients fail to respond to initial treatment and need more serious intervention; thus, laparoscopic cholecystostomy should be attempted, but it highly raises the possibility of turning to open type. For those who are not ready for surgery, percutaneous cholecystostomy or open cholecystostomy with local anesthesia is performed.^[5] Failure of recovery in patients after cholecystostomy is usually due to gangrenous or perforated cholecystitis. Surgery is inevitable in these patients. Cholangiography through the tubes is performed on patients who respond to cholecystostomy, and if the cystic duct is open, the tube can be removed. Laparoscopic cholecystostomy may be scheduled as an immediate surgery. For patients who cannot tolerate surgical procedures, the stones are removed through the cholecystostomy tube, and then the tube can be removed.^[6] Hemostatic agent (HA) used for homeostasis at surgical site is of the following subtypes: physical, synthetic, absorbent, and biological materials.^[7]

Oxidized cellulose is one of the absorbable materials with a long history in surgical applications. Surgicel is made of oxidized regenerated cellulose that is sterile and is like a flexible woven fabric that can easily attach to the surgical site and cause homeostasis. Surgicel, in addition to homeostasis, has bactericidal properties against *Staphylococcus aureus*, methicillin-resistant streptococcus pneumonia, *Staphylococcus epidermidis*, and pseudomonas. Although surgicel is safe, due to its possible pressure, it is necessary to take it off the surgical site in some specific circumstances such as when in close proximity to a foramen, the spinal cord, and the optic nerve and to kiasma.^[8]

Now the question is whether HA causes diagnostic pitfalls. HA, at surgical site, needs a differential diagnosis from an abscess, a mass recurrence removed, or a new mass. Given that abscess mortality rate is 100%, if unidentified, timely diagnosis and initiation of treatment are considered clinically important. According to what is mentioned above, this study aimed to

compare sonographic findings in a 45-day follow-up of patients who underwent laparoscopic cholecystostomy with and without an HA; they attended Imam Reza Hospital from August to March in 2017–2018.

Materials and Methods

This study is a cross-sectional descriptive analysis, and the statistical population included all the patients who underwent laparoscopic cholecystostomy at Imam Reza Hospital in Birjand during August 2017 to March 2018.

Inclusion criteria

In this study, the inclusion criterion for all patients was they should have undergone laparoscopic cholecystostomy at Imam Reza Hospital in Birjand within the specific time period.

Exclusion criteria

Patients' dissent to participate in the study or specific patient condition such as intensive care unit cases and so on caused patients being excluded from the study.

Cochran's formula was used to calculate sample size. The sample size of the study was calculated by Cochran's formula as follows:

$$n = \frac{\frac{z^2 pq}{d^2}}{1 + \frac{1}{N} \left(\frac{z^2 pq}{d^2} - 1 \right)}$$

Let us assume P and q to be 0.5. The z value is usually 1.96. We assume d to be 0.05. Then,

$$n = \frac{\frac{(1.96)^2 * 0.5 * 0.5}{(0.05)^2}}{1 + \frac{1}{70} \left(\frac{(1.96)^2 * 0.5 * 0.5}{(0.05)^2} - 1 \right)}$$

$n = 59.$

In this research, available nonprobability sampling technique was used. Patients who satisfied inclusion criteria were included in the study and placed into two groups: one group included patients with no HA at the surgical site and the other were patients with HA at the surgical site. In this study, ultimately, there were 144 subjects, of which 85 patients were with HA and 59 were without HA.

Demographic findings, medical history, and clinical symptoms on the basis of clinical manifestation of patients were made available in the form of a questionnaire. Patients in each group underwent sonography on discharge date and 15, 30, and 45 days after surgery. The sonographic results of groups were compared at each stage. Besides, in the group with HA, the density of HA was assessed at a 45-day follow-up.

Therefore, according to previous studies, we expected that HA at surgical site show a similar image to abscess, and to conclude that clinical symptoms as well as type and technique of the

surgery for sonographic scan are helpful to prevent diagnostic pitfalls. And finally we may come to the conclusion of how long it would take for HA to be absorbed in patients who underwent laparoscopic cholecystostomy.

Data were collected and entered in SPSS-24; meanwhile, descriptive statistics was used to analyze Chi-square test, Fisher's exact test, and Friedman and Wilcoxon nonparametric test, and the significant level of alpha was assumed to be 0.05.

Ethical considerations

The findings of the study were presented in general terms and no name was mentioned. Before implementation, the study protocol was approved by the ethics committee (ir.bums.REC.1396.171). All patients received written informed consent. They were removed from the study in case they were dissent.

Results

Overall 144 individuals were included in this study. The mean age of the subjects under study was 15.40 ± 44.40 years, with a minimum age of 15 years and a maximum age of 81 years. About 31 were males (21.5%) and 113 were females (78.5%). Based on the results obtained, none of the patients reported the following symptoms: unexplained fever, increased inflammation, inflammation over time, or pus coming from the surgical site.

In all, 59 participants (41.0%) had operations without HA and 85 patients (59.0%) had operations with HA.

The result of the Chi-square test showed that the comparison of frequency distribution in sonographic findings, immediately after surgery, indicated a significant correlation in patients who underwent cholecystostomy concerning the use of HA, and that it was higher in patients who underwent the surgery with HA [Table 1].

The result of Chi-square test showed that the comparison of frequency distribution in sonographic findings indicated a significant correlation in patients with and without HA concerning echogenic mass 15 days after surgery; in patients with HA, it was higher, but there was no significant difference concerning the presence of fluid in patients [Table 2].

The result of Chi-square test showed that the comparison of frequency distribution in sonographic findings indicated a significant correlation concerning echogenic mass in patients with and without HA 30 days after surgery, and the correlation was higher with those who underwent surgery with HA, but there was no significant difference in the level of fluid in the patients, and no fluid was reported in any patients [Table 3].

The result of Chi-square test showed that there was no significant relationship between the results in sonographic findings (echogenic mass and fluid presence) of patients underwent cholecystostomy with and without HA 45 days after surgery [Table 4].

It is necessary to state that according to the studies, hemostatic materials showed the shape of abscess at the surgical site

Table 1: Comparison of frequency distribution in sonographic findings of patients who underwent cholecystostomy with and without hemostatic agent, immediately after surgery

		Surgery operation type		Total (%)	Chi-square test result
		Without HA (%)	With HA (%)		
Echogenic mass with reverberation artifact (abscess mucosa)	Negative	0 (0.0)	75 (52.1)	75 (52.1)	$\chi^2=108.64$ df=1 P=0.001
	Positive	59 (41.0)	10 (6.9)	69 (47.9)	
Fluid	Positive	2 (1.4)	85 (59.0)	87 (60.4)	$\chi^2=135.92$ df=1 P=0.001
	Negative	57 (39.6)	0 (0.0)	57 (39.6)	

HA: Hemostatic agent

Table 2: Comparison of frequency distribution of sonographic findings in patients with and without hemostatic agent, 15 days after surgery

		Surgery operation type		Total (%)	Chi-square test result
		Without HA (%)	With HA (%)		
Echogenic mass with reverberation artifact (abscess mucosa)	Negative	0 (0.0)	73 (50.7)	73 (50.7)	$\chi^2=102.77$ df=1 P=0.001
	Positive	59 (41.0)	12 (8.3)	7 (49.3)	
Fluid	Positive	0 (0.0)	6 (4.2)	6 (4.2)	$\chi^2=4.34$ df=1 P=0.008
	negative	51 (41.0)	79 (54.9)	138 (95.8)	

HA: Hemostatic agent

sonography; in fact, they suggest abscess. In other words, the echogenic mass, reported in patients' sonography, was related to sonographic features of the abscess. According to the results depicted in the above tables, most patients undergoing cholecystostomy with HA had an echogenic mass in their post-sonography that was significantly different from the other group; therefore, it can be concluded that the reported mass is not related to cholecystostomy, and in fact the hemostatic materials had sonographic features similar to abscess. Figure 1 shows the distributions of the echogenic mass in patients with HA and Figure 2 shows the distributions of fluid in patients with HA.

The result of Kolmogorov–Smirnov test for the mean density of HA immediately and 15, 30, and 45 days after surgery showed that the distribution of this variable in the sample size was abnormal.

Comparison of the mean volume of HA in the group treated with HA immediately and 15, 30, and 45 days after surgery with

Friedman test showed that there was a significant difference concerning the volume of HA in subjects under study. The volume of HA decreases over time since the surgical operation day [Tables 4-6], and the results of the Wilcoxon test showed that the difference observed in all the different occasions was statistically significant with $P < 0.001$ [Table 6 and Figure 3].

The result of Mann–Whitney test showed that the mean volume of HA in the group treated with HA immediately after surgery and during periodic follow-ups did not show any significant difference with regard to gender of the subjects. In other words, the gender variable had no effect on the volume of HA [Table 7 and Figure 4].

Discussion

Cholelithiasis disease is one of the major problems affecting the digestive system.^[9,10] Although the mortality rate is low, concerning

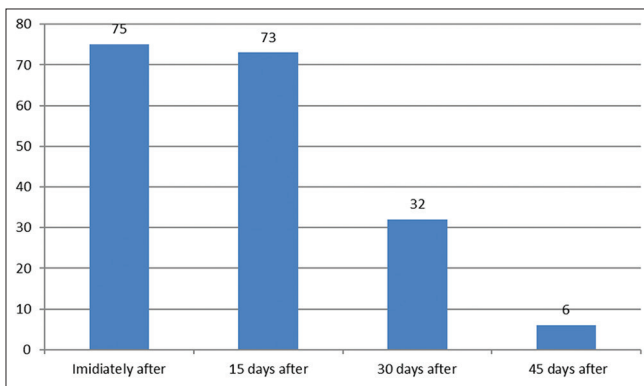


Figure 1: Distribution of echogenic mass with hemostatic agent use

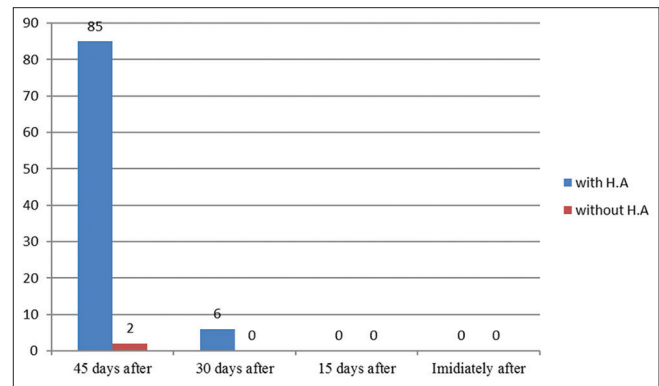


Figure 2: Frequency distribution of fluid with hemostatic agent use

Table 3: Comparison of frequency distribution of sonographic findings in patients with and without hemostatic agent, 30 days after surgery

		Surgery operation type		Total (%)	Chi-square test result
		Without HA (%)	With HA (%)		
Echogenic mass with reverberation artifact (abscess mucosa)	Negative	0 (0.0)	32 (22.2)	32 (22.2)	$\chi^2=28.56$ df=1 P=0.001
	Positive	59 (41.0)	53 (36.8)	112 (77.8)	
Fluid	Positive	-	-	-	-
	negative	59 (41.0)	85 (59.0)	144 (100)	

HA: Hemostatic agent

Table 4: Comparison of frequency distribution in sonographic findings of patients with and without with and without hemostatic agent, 45 days after operation

		Surgery operation type		Total (%)	Chi-square test result
		Without HA (%)	With HA (%)		
Echogenic mass with reverberation artifact (abscess mucosa)	Negative	0 (0.0)	6 (4.2)	6 (4.2)	$\chi^2=4.35$ df=1 P=0.08
	Positive	59 (41.0)	79 (54.9)	138 (95.8)	
Fluid	Positive	-	-	-	-
	Negative	59 (41.0)	85 (59.0)	144 (100)	

HA: Hemostatic agent

economic and health factors, the disease has a big effect on morbidity.^[9] Besides, it is considered to be a common cause of hospital admission in the United States and other Western countries.^[11] Today, laparoscopic cholecystostomy is widely used and is the golden standard method to treat gallstones.^[12,13]

The use of HAs to improve the quality of surgical procedures has long been considered by surgeons. Hemostatic factors are of different types including the old methods such as sutures, clips, electrocautery, argon lasers, harmonic/ultrasonic scalpel, and radiofrequency and newer methods such as biomaterials, surgical, and tachosil.^[14-16] The hemostatic factors used in the operating rooms are classified according to the source (herbal, animal, synthetic, and human) and the function (hemostatic, sticky, etc.).^[17] All the HAs, used in the operating rooms, are directly used at the surgical site, and they improve the function of the coagulation cascades and reduce the fluid leakage.^[18]

Table 5: Normality test for statistical distribution on the density of HA variable in the subjects

	K-S test		Kurtosis	Skewness	
	df				
HA density immediately after surgery	0.32	144	0.001	-1.61	0.17
HA density 15 days after surgery	0.30	144	0.001	-0.13	0.77
HA density 30 days after surgery	0.47	144	0.001	6.93	2.70
HA density 45 days after surgery	0.53	144	0.001	39.87	6.09

HA: Hemostatic agent; K-S: Kolmogorov-Smirnov

Table 6: Comparison of the mean volume of hemostatic agent in the group treated with hemostatic agent immediately and 15, 30, and 45 days after surgery

	Mean±SD	Friedman test results
Immediately after surgery	12.77±12.82	df=3,
15 days after surgery	7.78±8.80	P=0.001
30 days after surgery	1.61±3.92	
45 days after surgery	0.29±1.59	

SD: Standard deviation

Table 7: Comparison of the mean density of HA in the group treated with hemostatic agent immediately and 15, 30, and 45 days after surgery with regard to gender

	Gender		Total (mean±SD)	Mann-Whitney test
	Male (mean±SD)	Female (mean±SD)		
Immediately after surgery	20.25±11.10	21.96±8.84	21.63±9.25	MW=516.00 P=0.68
15 days after surgery	11.50±9.01	13.58±7.43	13.18±7.73	MW=445.00 P=0.23
30 days after surgery	3.81±5.28	2.48±4.70	2.72±4.80	MW=469.00 P=0.27
45 days after surgery	0.63±2.50	0.48±1.95	0.50±2.05	MW=548.00 P=0.93

HA: Hemostatic agent; SD: Standard deviation; MW: Mann-Whitney

This study aimed to compare sonographic findings in a 45-day follow-up of patients who underwent laparoscopic cholecystostomy with and without HA; they attended Imam Reza Hospital from August to March in 2017–2018; a total of 144 subjects, 59 subjects (41.0%) from the first group (without HA) and 85 subjects (59.0%) from the second group (with HA), were included in the study. Based on the results obtained, none of the patients underwent postsurgical complications including unexplained fever, increased inflammation and inflammation over time, and pus coming from the surgical site.

Many scholars confirmed in their studies that HA use in surgery, particularly in liver, lung, and gynecological and urology surgeries, can be very useful and has short- and long-term beneficial effects; besides, they shorten the duration of surgery.^[19]

The study by Tamaro *et al.* showed that the use of hemostatic biomaterials in kidney transplant can reduce the amount of bleeding and effusion of fluid after surgery.^[18]

The study by Giday *et al.* showed that the use of HAs can reduce the chance of recurrent hemorrhage of the surgical site by 20%.^[20] According to a study by Chandra *et al.*, individuals who had undergone endoscopic sinus surgery with floseal hemostatic matrix, in a 4- to 21-month follow-up, obviated the need for recurrent

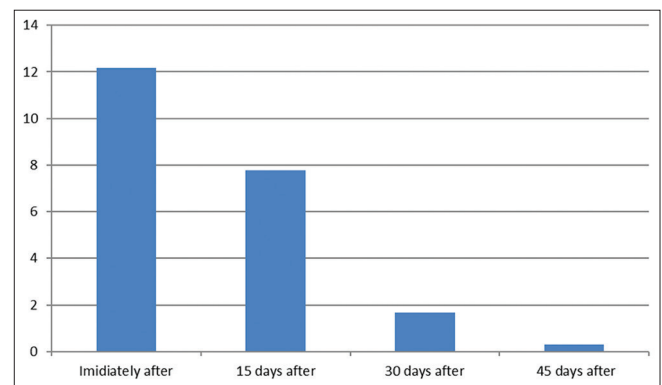


Figure 3: Comparison of the mean volume of hemostatic agent in the group treated with hemostatic agent immediately and 15, 30, and 45 days after surgery

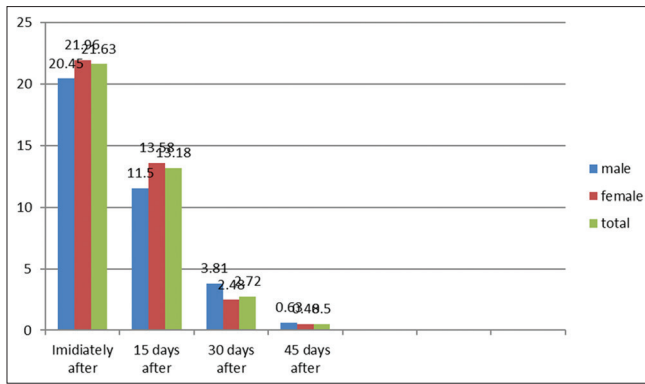


Figure 4: Comparison of the mean density of hemostatic agent in the group treated with hemostatic agent immediately and 15, 30, and 45 days after surgery with regard to gender

surgeries; besides, postoperative complications of surgical patients with HA were significantly lower than the other group.^[21]

In the study by Melamed *et al.*, sonographic findings of hemostatic materials in the surgical site resemble abscess,^[22] and in a study by Young *et al.*, a computed tomography scan of hemostatic materials in the surgical site resembles abscess.^[23]

The difference between the results of our study and other studies can be a result of different surgical sites, different surgical techniques, different HAs, and different follow-up schedules after the surgery; however, studies with similar variables were not found.

Based on the study results, in sonographic findings (echogenic mass and fluid), immediately after surgery, there was a significant correlation between surgical patients with and without HA and it was higher in patients with HA.

According to previous studies,^[24,25] hemostatic materials at the surgical site showed abscess or tumor recurrence in sonography, and in fact they suggest abscesses and pathological lesions. In other words, the echogenic mass reported in patients' sonography was related to abscess sonographic features. According to our findings, the majority of patients who underwent cholecystostomy with hemostatic materials, in their follow-up sonography, had an echogenic mass; This finding was significantly different with regard to the other group; therefore, it can be concluded that the reported mass was not related to cholecystostomy, and in fact, the appearance of hemostatic materials in sonography is similar to abscess; this finding is in line with other studies.

According to our study, the comparison of frequency distribution in sonographic findings of patients, with and without HA 15 and 30 days after surgery, indicated a significant difference concerning echogenic mass, and it was higher in patients with HA, but there was no significant difference concerning fluid in patients. However, these findings were not statistically significant in patients who underwent chemotherapy with and without the use of HA 45 days after surgery.

Observation of the echogenic mass in patient's follow-up sonography can be attributed to patient's immune response to HA as a foreign substance. Sabino *et al.*, in their study, stated that after 21 days of oxidized cellulose use as HA, the immune system reaction to HA as a foreign substance was evident in echogenic mass and granuloma formation.^[26] Although the clinical nature of this immune response is still unclear, the studies have shown that follow-up sonographic findings in surgical patients with HA were similar to tumor recurrence^[27] and abscess formation.^[28]

In another study by Ibrahim *et al.*, in which surgical was used as HA, it was reported that 1 week after surgery, multinucleated giant cells were formed in the surgical site that resembled abscess in imaging but gradually disappeared after 4–8 weeks.^[24] Other studies reported similar complications of HA use in abdominal and neurological surgeries.^[24]

Conclusion

According to our study, it became clear that an echogenic mass with reverberation artifact was observed in surgical site of almost all patients; this indicated a significant difference between the groups at different follow-ups that cannot be attributed to laparoscopic cholecystostomy. No clinical finding, to confirm abscesses in patients, was reported by the surgeon in the successive visits. In fact, observation of echogenic mass with reverberation artifact in the surgical site, in the absence of any clinical symptoms associated with this issue in any of the patients, suggested the presence of surgical in surgical site. In other words, surgical showed sonographic features of abscess in all patients. Therefore, close attention should be paid to differentiate the normal imaging appearance in follow-up sonographies of patients with HA with vital pathologies like abscess.

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Conflicts of interest

There are no conflicts of interest.

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