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ORIGINAL ARTICLE

수술 고위험 중증 환자에게서 발생한 급성 담낭염의 경피적 담낭배액술 단독 치료와 담낭절제술 비교: 단일 기관, 단면 연구

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Percutaneous Cholecystostomy Is Appropriate as Definitive Treatment for Acute Cholecystitis in Critically Ill Patients: A Single Center, Cross-sectional Study

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Background/Aims: Percutaneous cholecystostomy (PC) is an effective treatment for cholecystitis in high-risk surgical patients. However, there is no definitive agreement on the need for additional cholecystectomy in these patients.
Methods: All patients who were admitted to Cheju Halla General Hospital (Jeju, Korea) for acute cholecystitis and who underwent ultrasonography-guided PC between 2007 and 2012 were consecutively enrolled in this study. Among 82 total patients enrolled, 35 underwent laparoscopic cholecystectomy after recovery and 47 received the best supportive care (BSC) without additional surgery.
Results: The technical and clinical success rates for PC were 100% and 97.5%, respectively. The overall mean survival was 12.8 months. In the BSC group, mean survival was 5.4 months, and in the cholecystectomy group, mean survival was 22.4 months ($p < 0.01$). However, there was no significant difference between these groups in multivariate analysis (relative risk [RR]=1.92; 95% CI, 0.77-4.77; p=0.16). However, advanced age (RR=1.05; 95% CI, 1.02-1.08; p=0.001) and higher class in the American Society of Anesthesiologists' physical status (RR=3.06; 95% CI, 1.37-6.83, p=0.006) were significantly associated with survival in the multivariate analysis. Among the 47 patients in the BSC group, the cholecystostomy tube was removed in 31 patients per protocol. Recurrent cholecystitis was not observed in either group of patients during the follow-up period.
Conclusions: In high-risk surgical patients, PC without additional cholecystectomy might be the best definitive management. Furthermore, the cholecystostomy drainage catheter can be safely removed in certain patients. (**Korean J Gastroenterol 2014;63:32-38**)

Key Words: Acute cholecystitis; Cholecystectomy; Comorbidity; Cholecystostomy; Elderly

INTRODUCTION

Acute cholecystitis is a disease commonly treated in secondary health care institutions.[1,2] Cholecystectomy is the standard treatment for acute cholecystitis, and emergency laparoscopic cholecystectomy is acceptable as an effective

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and safe treatment modality.[3-6]

However, patients with poor physical status often cannot undergo surgery on admission because of problems such as severe sepsis, extreme old age, and comorbidities. Although cholecystectomy is generally safe, the mortality rate of cholecystectomy in patients with high surgical risk, especially the elderly or critically ill, has been reported between 14% and 30%.[7-9]

Ultrasonography-guided transhepatic percutaneous cholecystostomy (PC) is a minimally invasive, image-guided intervention performed under local anesthesia. Therefore, it has become a useful therapeutic intervention in elderly or critically ill patients.[10,11] However, it has been considered as a bridging modality for high-risk surgical patients until surgical treatment, cholecystectomy.[12,13] It remains controversial whether this procedure should only be used as a temporary measure to delay definitive cholecystectomy or if this procedure can be a definitive treatment.

The aim of this study was to determine if PC is appropriate as definitive treatment for acute cholecystitis in patients with high surgical risks, using a well-designed management protocol.

SUBJECTS AND METHODS

1. Study population

All patients who were admitted to Cheju Halla General Hospital (Jeju, Korea) via the emergency center or outpatient clinic with acute cholecystitis and who underwent ultrasonography-guided PC between November 2007 and November 2012 were consecutively enrolled in this study (Fig. 1). The diagnosis of acute cholecystitis was established at admission based on clinical findings, laboratory data, and radiologic tests, including abdominal ultrasonography (US) and/or CT. Positive clinical findings were defined as right upper quadrant or epigastric pain, tenderness, and fever. Positive laboratory findings were defined as leukocytosis or positive C-reactive protein. Positive diagnostic through US or CT findings included gallbladder wall thickening, gallbladder distension, and presence of inflammatory material.[14]

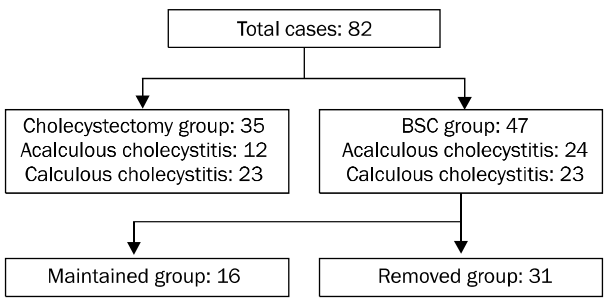

Fig. 1. Clinical outcomes of 82 patients that underwent percutaneous cholecystostomy in Cheju Halla General Hospital (Jeju, Korea) between 2007 to 2012.
BSC, best supportive care.

This study protocol was approved by the Institutional Review Board of Cheju Halla General Hospital. And this study protocol also was registered to www.clinicaltrials.gov. and was approved (No. NCT01894321).

2. Procedure techniques

Percutaneous transhepatic cholecystostomy was performed by an expert interventional radiologist with US and fluoroscopic guidance in the interventional unit. After local anesthesia was injected, an 18-gauge needle was inserted at the sterile puncture site, and a 7F to 10F locking pigtail cholecystostomy catheter was placed into the gallbladder fundus through the guidance of wire. Bile samples were obtained for culture, and the catheter was kept in place for gallbladder drainage. The catheter lumen was then flushed every 8 to 12 hours to prevent obstruction.

Technical success was defined as the proper positioning of the cholecystostomy tube into the gallbladder lumen and proper bile juice drainage without any complications. Clinical success was defined as the resolution of clinical symptoms and abnormal laboratory results after successful technical drainage. All patients recovering from acute treatment were re-assessed for elective cholecystectomy after successful cholecystostomy.

3. Post-cholecystostomy management

The physician, surgeon, anesthesiologist, and interventional radiologist discussed each case to determine further strategies, including elective cholecystectomy. The American Society of Anesthesiologists' (ASA) physical status classification,[15] Eastern Cooperative Oncology Group (ECOG) performance scores,[16] clinical condition, and comorbidities that might affect surgical outcomes were considered for each patient. Then, cholecystectomy was recommended for low-risk surgical patients, and best supportive care (BSC) for high-risk patients.

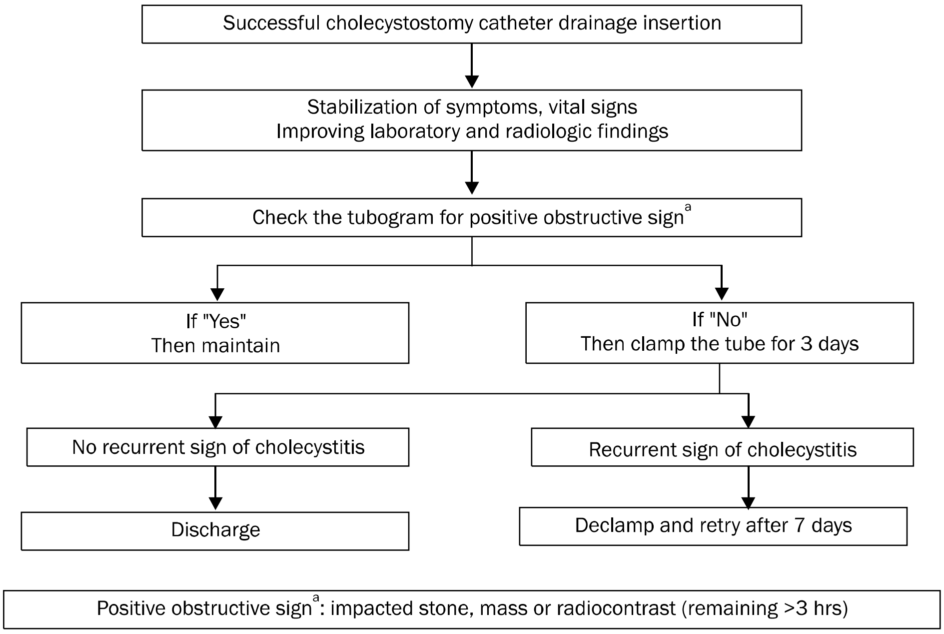

Fig. 2. Flow chart of the post-cholecystostomy management protocol devised by Digestive Disease Center in Cheju Halla General Hospital (Jeju, Korea).
[a]Impacted stone, obstructive mass, or sustained radiocontrast media (remaining >3 hours).

No published guidelines regarding tube removal were available to follow when this study began. Therefore, we created a protocol for the management of cholecystostomy tubes based on our experiences from previous cholecystostomy cases. All patients in this study were evaluated for removal of their cholecystostomy tube according to the devised protocol, for which we obtained consent from the Digestive Disease Center of Cheju Halla General Hospital (Fig. 2).

We checked the patency of the biliary tract in all patients who had been stabilized clinically (except medically deteriorating cases), and performed follow-up cholecystogram under fluoroscopy. If contrast media injected through the cholecystostomy tube drained into the duodenal lumen without any obstruction, then the catheter was clamped from that day forward. All clamped patients were assessed through their clinical conditions and laboratory results 3 days later. Then, the decision was made whether or not to remove the catheter and discharge the patient.

If the patient complained of symptoms that suggested recurrence of cholecystitis, or showed worsening laboratory results, then the tube was de-clamped, the drainage kept open for 7 days, and the tube was re-locked. If the patient's cholecystogram showed any obstruction in the biliary tract, including the cystic and common bile ducts, or stasis of the contrast media for more than 3 hours, then we maintained the drainage and recommended the patient discharged with the catheter in place.

4. Data analysis

Through retrospective analysis of hospital records, all patients in the study who underwent PC were assessed for clinical measures including underlying morbidities; past history; laboratory and imaging findings; complication rate after cholecystostomy or cholecystectomy; recurrence of biliary complications including cholecystitis; cholangitis and biliary pancreatitis; and cause of death. Preoperative surgical risks were assessed using the ASA physical status classification and ECOG performance scale. For some patients who were discharged to their home, their date and cause of death were obtained by telephone interview with family members. In the cases of patients transferred to local nursing homes, information related to their death, such as causes and dates of death, were obtained through medical teams working in their respective institutes.

5. Statistics

Descriptive statistics, including continuous and categorical variables, were given as mean±SD, frequencies, and percents. To compare the variables between groups, Student's t-test was used for continuous variables and chi-square test for categoricals. Values of $p<0.05$ were accepted as significant. The overall survival of each treatment group was analyzed using Kaplan-Meier methods, and study groups were compared with the use of the log rank test. The hazard ratio was estimated using a stratified Cox proportional hazard model. All the statistical analyses were carried out using SPSS software version 15.0 (SPSS Inc., Chicago, IL, USA).

RESULTS

A total 82 subjects that underwent ultrasound-guided PC were enrolled in this study. Listed comorbidities are shown in Table 1. Baseline characteristics of the enrolled patients and the two groups are described in Table 2.

The technical success rate for PC was 100%, and the clinical success rate was 97.5% (80 of 82 patients). A 76-year-old male patient underwent emergent cholecystectomy because of ongoing severe pain with fever and insufficient drainage despite appropriate medical treatment with antibiotics and analgesics. A 71-year-old male patient, who was admitted with multiple organ failure (septic shock, renal failure, respiratory distress syndrome, and loss of consciousness), died of organ failure in the intensive care unit (ICU), despite successful drainage and aggressive medical therapy, including infusion of inotropic agents, mechanical ventilation, and administration of antibiotics. Caregivers of the patient refused urgent operative management. Procedure-related complications occurred in 2 cases (2.4%) with bile leakage peritonitis, and the condition of these patients improved with medical treatment alone.

Among the 82 PC patients, 35 patients underwent laparoscopic cholecystectomy and 47 were managed by BSC. In the cholecystectomy group, the mean bridging period (defined as the time between cholecystostomy and elective cholecystectomy) was 7.43±4.99 days. Operation related mortality occurred in 2 cases (5.71%), 1 with bile peritonitis and 1 with wound infection. In the BSC group, 16 patients treated with cholecystostomy had their tube left in place, while 31 patients were extubated following cholecystostomy management protocols.

1. Baseline characteristics and clinical outcomes between cholecystectomy and BSC groups

Baseline characteristics of the 2 treatment groups are

Table 1. Comorbidities of the Subjects[a]

Disease category	Value
Advanced malignant disease	23 (16.5)
Renal failure	20 (14.4)
Severe cardiovascular disease	19 (13.7)
Septic shock	18 (12.9)
Severe cerebrovascular disease	15 (10.8)
Severe neuropsychiatric disease	13 (9.4)
Severe bone and spinal disease	9 (6.5)
COPD	7 (5.0)
Miscellaneous	6 (4.3)
Heart failure	4 (2.9)
Chronic repiratory disease	3 (2.2)
Decompesated liver cirrhosis	2 (1.4)
Total response	139 (100.0)

Values are presented as n (%).
[a]Eighty-seven patients who underwent percutaneous cholecystostomy in Cheju Halla General Hospital, Jeju, Korea, between 2007 and 2012.
COPD, chronic obstructive pulmonary disease.

Table 2. Baseline Characteristics of the Subjects[a]

	Cholecystectomy group (n=35)	Best supportive care group (n=47)	Total (n=82)	p-value
Age (yr)	71.0±12.2	73.0±14.7	72.1±13.7	0.519
Sex				0.460
Male	20 (57.1)	23 (48.9)	43 (52.4)	
Female	15 (42.9)	24 (51.1)	39 (47.6)	
ASA class				<0.001
≤3	31 (88.6)	18 (38.3)	49 (59.8)	
≥4	4 (11.4)	29 (61.7)	33 (40.2)	
ECOG class				<0.001
≤2	26 (74.3)	6 (12.8)	32 (39.0)	
≥3	9 (25.7)	41 (87.2)	50 (61.0)	
Gallstone				0.130
Acalculous	12 (34.3)	24 (51.1)	36 (44.0)	
Calculous	23 (65.7)	23 (48.9)	46 (56.0)	
Hypotension				0.210
Yes	5 (14.3)	12 (25.5)	17 (20.7)	
No	30 (85.7)	35 (74.5)	65 (79.3)	
Renal failure				0.340
Yes	6 (17.1)	12 (26.1)	18 (22.2)	
No	29 (82.9)	34 (73.9)	63 (77.8)	
ICU admission				<0.01
Yes	1 (2.9)	20 (43.5)	21 (25.9)	
No	34 (97.1)	26 (56.5)	60 (74.1)	
Follow-up duration (mo)	9.5 (0.8-87.7)	4.0 (4.0-51.5)	5.2 (5.4-87.7)	0.623
Survival time (mo)	15.3 (0.8-92.0)	2.4 (0.1-24.8)	4.4 (0.1-92.0)	0.001

Values are presented as mean±SD, n (%), or median (range).
[a]Eighty-two enrolled acute cholecystitis patients who underwent ultrasound-guided percutaneous cholecystostomy.
ASA class, American Society of Anesthesiologists' physical status classification; ECOG, Eastern Cooperative Oncology Group; ICU, intensive care unit.

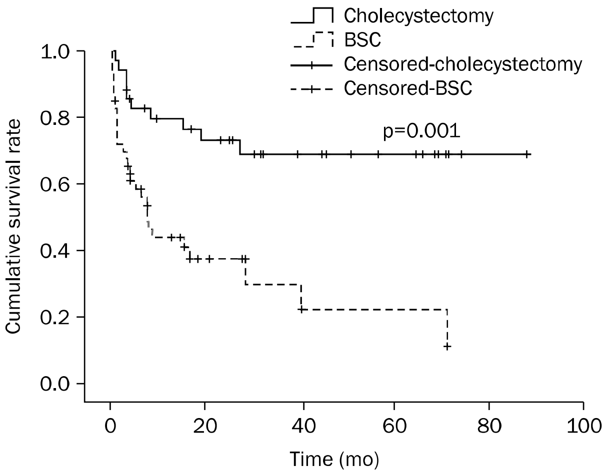

Fig. 3. Cumulative survival rates of 2 treatment groups (cholecystectomy *vs.* the best supportive care [BSC]) after percutaneous cholecystostomy.

Table 3. Multivariate Analysis of Overall Survival Rates of Total Cholecystitis Subjects with Percutaneous Cholecystostomy[a]

Variable	p-value	Exp (B)	95% CI Lower	95% CI Upper
Age	0.001	1.05	1.02	1.08
Sex (male *vs.* female)	0.300	1.42	0.73	2.75
Cholecystectomy *vs.* BSC group	0.160	1.92	0.77	4.77
ASA class (≤3 *vs.* ≥4)	0.006	3.06	1.37	6.83
Comorbidity (≤2 *vs.* ≥3)	0.092	0.54	0.26	1.11
ICU admission (yes *vs.* no)	0.420	1.37	0.64	2.93

[a]By the Cox proportional hazard model using the log-rank test. BSC, best supportive care; ASA class, American Society of Anesthesiologists' physical status classification; ICU, intensive care unit.

Table 4. Baseline Characteristics and Clinical Outcomes of 2 Subgroups among 47 Best Supportive Care (BSC) Patients

Content	Remained group (n=16)	Removed group (n=31)	Total BSC group (n=47)	p-value
Age (yr)	77.2±12.2	70.8±15.6	73.0±14.7	0.121
Sex				0.365
Male	6 (37.5)	17 (54.8)	23 (48.9)	
Female	10 (62.5)	14 (45.2)	24 (51.1)	
Duration of PC (day)	43.8±50.7	29.6±41.2	34.6±44.6	0.363
Comorbidity (n)	1.8±1.1	2.3±1.3	2.1±1.2	0.171
ASA class				0.161
≤3	8 (50.0)	10 (32.3)	18 (38.3)	
≥4	8 (50.0)	21 (67.7)	29 (61.7)	
ECOG class				0.031
≤2	4 (25.0)	2 (6.5)	6 (12.8)	
≥3	12 (75.0)	29 (93.5)	41 (87.2)	
Gallbladder polyp				0.763
Acalculous	8 (50.0)	16 (51.6)	24 (51.1)	
Calculous	8 (50.0)	15 (48.4)	23 (48.9)	
Hypotension				0.223
Yes	6 (37.5)	6 (19.4)	12 (25.5)	
No	10 (62.5)	25 (80.6)	35 (74.5)	
Renal failure				0.040
Yes	7 (43.8)	5 (16.1)	12 (25.5)	
No	9 (56.3)	26 (83.9)	35 (74.5)	
ICU admission				0.172
Yes	9 (60.0)	11 (35.5)	20 (43.5)	
No	6 (40.0)	20 (64.5)	26 (56.5)	
Follow up (mo)	2.6 (0.1-24.8)	7.1 (0.4-51.5)	4.1 (0.1-51.5)	0.049
Survival time (mo)	3.2 (0.1-20.7)	7.9 (0.5-71.3)	6.9 (0.1-71.3)	0.012

Values are presented as mean±SD, n (%), or median (range). PC, percutaneous cholecystostomy; ASA class, American Society of Anesthesiologists' physical status classification; ECOG, Eastern Cooperative Oncology Group; ICU, intensive care unit.

shown in Table 2. There were no statistical differences between the 2 groups in age, sex, proportion of gallstone disease, organ dysfunction, initial laboratory results, or mean follow-up duration. Higher classes of ASA physical status and ECOG scores were observed for patients in the BSC group than for patients in the cholecystectomy group ($p<0.001$). Additionally, the BSC group had more patients who needed ICU care ($p<0.001$).

During the median 5.2 months of observation, median survival times were recorded to be 2.4 months for the BSC group, 15.3 for the cholecystectomy group, and 4.4 overall (p=0.001, Fig. 3).

We separated all patients' based on ASA class and ECOG scores into 2 groups (higher group and lower group). When we did this, we found no significant difference in survival rates between the cholecystectomy group and BSC group in the Kaplan-Meier survival analysis. In the multivariate analysis of survival based on the Cox proportional hazard model using log-rank test, age and ASA class were significantly correlated with survival (Table 3). However, the survival difference between the cholecystectomy and BSC groups did not reach statistical significance (Table 4).

2. Clinical outcomes of the 2 BSC subgroup: removed and maintained

Among the 47 patients in the BSC group, the drainage tube was removed in 31 (75.6%) and maintained in 16 (34.0%), according to the protocol described above. The baseline characteristics and clinical outcomes of the 2 subgroups

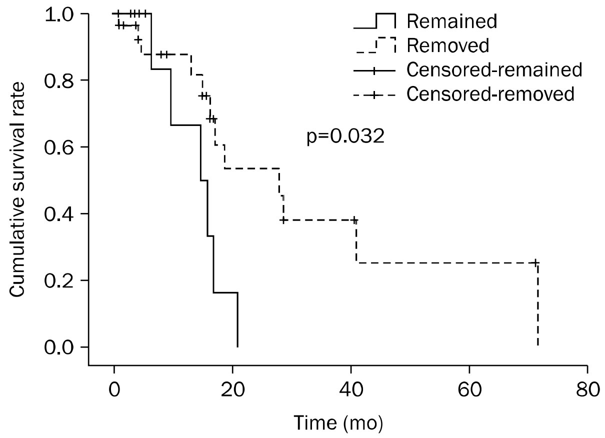

Fig. 4. Cumulative survival rates of remained *vs.* removed groups after percutaneous cholecystostomy.

within the BSC group are described in Table 4.

Between the 2 BSA subgroups, ASA class, ECOG performance score, proportion of the gallstones, and incidence of organ failure (such as shock or renal failure) did not differ. Median survival times were 6.9 months in the BSC group, 3.2 in the maintained group, and 7.9 in the removed group (p=0.012, Fig. 4). One patient died 12 days after cholecystostomy because of cholecystitis-related sepsis.

None of the patients in the removed group died from cholecystitis. They expired for their underlying diseases or other causes unrelated to cholecystitis. None of them experienced recurrent biliary complications (such as cholecystitis, cholangitis, or pancreatitis) requiring re-intubation during a median follow-up period of 7.1 months. One patient, a 74-year-old male, was readmitted for newly developed abdominal pain owing to intrahepatic biloma 2 weeks after removal of the cholecystostomy tube, but his condition improved with medical treatment.

DISCUSSION

Elective cholecystectomy after cholecystostomy is the optimal treatment for acute calculous or acalculous cholecystitis. However, in patients with considerable surgical risks, cholecystectomy under general anesthesia can cause serious morbidity and mortality.[17,18]

Therefore, this study assessed if PC is appropriate as a definitive treatment for acute cholecystitis in patients with surgical risks.

Recent reports have demonstrated that PC is effective as a definitive procedure without further cholecystectomy in certain populations. Some reports insisted that these patients should receive elective cholecystectomy because of the high rates of recurrent biliary complications after removal of cholecystostomy tubes (as high as 40%).[19-22]

In contrast, other studies have shown lower recurrence rates of biliary complications after removal of cholecystostomy tubes. These studies concluded, therefore, that PC could be a definite therapy without additive cholecystectomy.[23-26] They reported the recurrence rates of biliary complications as 0-15%. Additionally, a randomized controlled trial showed that only 1 of 19 cases reported recurrent biliary complications,[17] and most recurrent cases improved with conservative medical treatment.[17,24,27]

We demonstrate similar success and complication rates to previous studies using these procedures. We found no significant difference in survival rate between the 2 treatment groups (cholecystectomy *vs.* BSC) in surgical high-risk cases (ASA class ≥4, ECOG score ≥3). Rather, we found that old age and comorbidity state (ASA class) were more important predictors of better clinical outcomes via multivariate analysis.

Another important finding of this study is the non-recurrence of biliary complications, including cholecystitis, observed in 25 cases where cholecystostomy tubes were removed. In our study, no recurrent biliary complications occurred during an overall median follow-up of 7.1 months. This lower incidence of recurrence may be due to the tailored management of the cholecystostomy tubes according to our well-designed protocols. We performed cholecystograms to check the patency of the biliary trees in each of the 31 cholecystostomy cases, and then decided whether or not to remove their tubes. In previous studies, no detailed strategy for the management of cholecystostomy tubes was employed--they did not conduct cholangiograms before deciding to remove patients' cholecystostomy tubes, except in one case.

Our study has several limitations. First, this was a retrospective study and it contained a relatively small group size. Second, the observation period of the BSC subgroups (maintained group and removed group) was relatively short. In addition, the definition of biliary patency was not obvious on cholangiogram images. Therefore, validation of this management protocol in a well-designed, randomized, prospective study is warranted.

In summary, we concluded that BSC with PC rather than cholecystectomy may be considered in cholecystitis patients with extreme old age and higher morbidity (ASA ≥4). It can be considered to recommend BSC rather than cholecystectomy.

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